



**PM Group**  
Killakee House  
Belgard Square  
Dublin 24  
Ireland

Our Reference: IE0311237.22.040

T +353 1 404 0700  
F +353 1 459 9785  
E dublin@pmgroun-global.com  
W www.pmgroun-global.com

9<sup>th</sup> September 2015

Environmental Protection Agency  
P.O. Box 3000  
Johnstown Castle Estate  
Co. Wexford

*International Office Network*

Belgium	Saudi Arabia
China	Singapore
Czech Republic	Slovakia
India	Turkey
Ireland	UK
Poland	USA
Russia	

**Re: Application for Review of Industrial Emissions Licence  
P0643-02**

**The project delivery specialists**

Dear Sir/Madam,

Please find enclosed the Industrial Emissions Activity (IEA) Licence review application for AbbVie Ireland NL B.V., Manorhamilton Road, Co. Sligo.

The following documents (hard copy and electronic copy) are enclosed in this application:

- 1 No. original IEA licence application (hard copy)
- 1 No. copy IEA licence application (hard copy)
- 2 No. Environmental Impact Statement & Environmental Report (hard copy)
- 2 No. full IEA licence application (soft copy, CD-Rom)
- 2 No. Environmental Impact Statement & Environmental Report (soft copy, CD Rom)

Also included in the application is the detail of the purchase order (PO) from AbbVie Ireland NL B.V., with regard to payment made to the EPA for the amount of €16,506.

We declare that the content of the electronic files submitted with this application is a true copy of the original application form.

If you have any questions please do not hesitate to contact me.

Yours sincerely,

**Ciarán Reay**  
EHS Consultant  
PM Group on behalf of AbbVie Ireland NL B.V.

**Project Management Limited**  
t/a PM Group, is a private company limited by shares, registered in Ireland.  
Company Registration No. 043789.  
Registered Office: Killakee House, Belgard Square, Dublin 24, Ireland.

**Directors** D Flinter (Chairman), D Murphy (CEO), B Gallagher, H Keelan, S Kelly, M Lynam, P McGrath, L O Mahony, A Schouten (British), M Shelly, L Westman

**Secretary** J Sheehan



Office of Climate, Licensing & Resource Use  
PO Box 3000  
Johnstown Castle Estate  
County Wexford

Licence Reg. No: P0643-02  
Company Name: AbbVie Ireland NL B.V.

31st August 2015

**Re: Industrial Emissions Licence Review**

To Whom It May Concern,

AbbVie Ireland NL B.V. wishes to take this opportunity to formally request a review of its Industrial Emissions Licence. This review is required to allow for the addition of chlorinated solvents to the schedule of solvents permitted under the current licence. This licence update will facilitate the abatement of chlorinated solvents to a new thermal oxidiser at AbbVie Sligo, which is currently being qualified under an approved test programme.

The Sligo facility has been selected to be the sole manufacturer of a breakthrough oncology treatment, Venetoclax (ABT-199) which is currently due for approval in early Quarter 1 2016. This is based on a breakthrough designation from the FDA and will allow for a swifter supply of this therapy for patients. Dichloromethane (DCM) is used in the manufacture of venetoclax. Current abatement solutions for the process are suitable only for R&D and development work. Inclusion of dichloromethane on the schedule of solvent will mean that the site remains a key strategic location for the manufacture of launch volumes of this product as well as other breakthrough therapies in the AbbVie pipeline.

If you require any additional information or clarification please do not hesitate to contact me at 071 9136671.

abbvie

Yours Sincerely,



Marc O'Donoghue,  
Site Director

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# Industrial Emissions Activities Licence

## Application Form

<p>EPA Reg. N<sup>o</sup>: (Office use only)</p>	<input type="text"/>
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ELECTRONIC COPIES OF THE APPLICATION **MUST** BE SUBMITTED IN ACCORDANCE WITH THE "INSTRUCTIONS FOR LICENCE APPLICANTS" DOCUMENT AT THE LINK BELOW.

**FAILURE TO DO SO MAY RESULT IN A DELAY IN PROCESSING YOUR APPLICATION.**

<http://www.epa.ie/pubs/forms/lic/industrial%20emissions/instructionsforapplicantsreapplicationform.html>

### Environmental Protection Agency

P.O. Box 3000, Johnstown Castle Estate, Co. Wexford

Lo Call: 1890 335599 Telephone: 053-9160600 Fax: 053-9160699

Web: [www.epa.ie](http://www.epa.ie) Email: [Industrial\\_Emissions\\_Licensing\\_Queries@epa.ie](mailto:Industrial_Emissions_Licensing_Queries@epa.ie)

### Tracking Amendments to Application Form

<b>Version No.</b>	<b>Date</b>	<b>Amendment since previous version</b>	<b>Reason</b>
V.1.0	June 2013	N/A	Introduction of IE (Licensing) Regulations 2013
V.2.0	March 2014	Amendments to Section A, B and I.	Further clarification of IE (Licensing) Regulations 2013
V.3.0	January 2015	Amendments to Section G.1 Amendments to Section I.8	REACH Environmental Considerations, Main Alternatives and BAT
V.4.0	June 2015	Amendments to Section A  Amendment to Section B.1  New Section B.3B Amendments to Section B.6  Amendment of Section B.10  New Section D.2.2  Amendments to Section L	To require summary table of impacts in Non-Technical summary  Change from "Owner/Operator" to "Applicant"  In relation to Fees  Additional requirements in relation to planning history and the submission of EISs.  Addition of Yes/No tick box  Additional information required in relation to waste storage and closure costs.  To reflect BAT & IED requirements

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## ABOUT THIS APPLICATION FORM

This form is for the purpose of making an application for an Industrial Emissions Activity Licence under the Environmental Protection Agency Act, 1992, as amended. There is a separate application form for applicants who wish to apply for Classes 6.1 or 6.2 Intensive Agriculture.

The Application Form **must** be completed in accordance with the instructions included in this form and available on the EPA website. A valid application for an Industrial Emissions Activity (IEA) licence must contain the information prescribed in the Environmental Protection Agency (Industrial Emissions)(Licensing) Regulations, 2013. Regulation 9 of the Regulations sets out the statutory requirements for information to accompany a licence application. The application form is designed in such a way as to set out these questions in a structured manner and not necessarily in the order presented in Regulation 9. In order to ensure a legally valid application in respect of Regulation 9 requirements, please complete the Regulation 9 Checklist provided in Annex 2.

This Application Form does not purport to be and should not be considered a legal interpretation of the provisions and requirements of the Environmental Protection Agency Act, 1992, as amended, and the Environmental Protection Agency (Industrial Emissions)(Licensing) Regulations 2013. While every effort has been made to ensure the accuracy of the material contained in the Application Form, the EPA assumes no responsibility and gives no guarantees, undertakings and warranties concerning the accuracy, completeness or up-to-date nature of the information provided herein and does not accept any liability whatsoever arising from any errors or omissions.

Should there be any contradiction between the information requirements set out in the Application Form and any clarifying explanation on the EPA website then the requirements in this Application Form shall take precedence. The requirements of the 2013 Regulations, referenced above, shall take precedence over any considerations mentioned in this Application Form or on the website.

## SECTION A: NON-TECHNICAL SUMMARY

A non-technical summary of the application is to be included here. The summary should identify all environmental impacts of significance associated with the carrying on of the activity/activities and describe mitigation measures proposed or existing to address these impacts. This description should also indicate the normal operating hours and days per week of the activity.

The following information must be included in the non-technical summary:

- The relevant class or classes of activity in the First Schedule of the EPA Act 1992 as amended,
- Indication of whether EIS and planning permission documents are included,
- Indicate relevant BAT guidance documents or BAT Conclusions decisions,
- The title of the relevant BREF document
- Information on how the emission levels have been determined,
- Indication if EC (Control of Major Accident Hazards involving Dangerous Substances) Regulations 2006 apply,
- If a derogation under Section 86A(6) is being sought and the specific reasons for such derogation,
- A description of:
  - the installation (plant, methods, processes, abatement, recovery and treatment systems and operating procedures for the activity), with emphasis on the main measures to avoid, reduce and, if possible offset the major adverse effects on the environment
  - the raw and auxiliary materials, substances, preparations, fuels and energy which will be produced by or utilized in the activity,
  - the sources of emissions from the installation,
  - the environmental conditions of the site of the installation (e.g. soil and groundwater, air, noise, surface water) including reference to a Baseline Report where applicable,
  - the nature and quantities of existing and proposed emissions from the installation into each medium as well as a summary of the assessment of the effects of the emissions on the environment as a whole,
  - the proposed technology and other techniques to prevent or eliminate, or where this is not practicable, limit, reduce or abate emissions from the installation,
  - summary of the quantity and nature of wastes which may be produced or accepted at the installation,
  - measures to ensure that waste production is avoided in accordance with the waste hierarchy in Council Directive 98/2008/EC on waste and section 21A of the Waste Management Act 1996, as amended; where waste is generated, it is prepared for re-use, recycled or recovered or, where that is technically and economically impossible, it is disposed of while avoiding or reducing any impact on the environment (applicants should provide this information in the context of the Waste Management Act 1996, as amended);
  - all the appropriate preventive measures are taken against pollution, in particular through application of the Best Available Techniques (BAT) or BAT Conclusions Decision;



- the necessary measures are to be taken under abnormal operating conditions, including start up, shutdown, leaks, malfunctions, breakdowns and momentary stoppages;
- the necessary measures to be taken on and following permanent cessation of activities to avoid any risk of environmental pollution and return the site of the activity to a satisfactory state or the state established in the baseline report if required;
- measures planned to monitor emissions into the environment,
- measures to comply with an environmental quality standard,
- measures to comply with Council Directive 80/68/EEC and 2006/118/EC in relation to the protection of groundwater,
- measures to be taken for minimizing pollution over long distances or outside the territory of Ireland,
- the main alternatives to the proposed technology, techniques and measures studied by the applicant.

The non-technical summary has been included as Attachment A.1

Where an EIS is submitted as part of the licence application, summarise the likely significant effects of the activity in the following format:

The existing EIS has been submitted as part of the licence review application. It is concluded that the installation of the new thermal oxidiser will have no impact on any of the environmental parameters below.

Environmental Factor	Likely identified effects	Brief description of effect	Mitigation measures proposed to control effect
Human Beings			
Flora and fauna			
Soil			
Water			
Air			
Climate			
Landscape			
Material Assets			
Cultural Heritage			

Supporting information should form **Attachment N<sup>o</sup> A.1**

<b>SECTION B: GENERAL</b>
---------------------------

**B.1. Applicant**

<b>Name*:</b>	AbbVie Ireland NL B.V.
<b>Address:</b>	Manorhamilton Road
	Sligo
	Co. Sligo
<b>Tel:</b>	+353 71 9136600
<b>Fax:</b>	-
<b>e-mail:</b>	michaelo.gallagher@abbvie.com

\* This should be the name of the applicant which is current on the date this Licence Application is lodged with the Agency. It should be the name of the legal entity (which can be a limited company or a sole trader). A trading/business name is **not acceptable**.

**Name and Address for Correspondence**

Only application documentation submitted by the applicant and by the nominated person will be deemed to have come from the applicant.

<b>Name:</b>	Mr Michael Gallagher
<b>Address:</b>	AbbVie Ireland NL B.V.
	Manorhamilton Road,
	Sligo
	Co. Sligo
<b>Tel:</b>	+353 71 9136641
<b>Fax:</b>	-
<b>e-mail:</b>	michaelo.gallagher@abbvie.com

**CRO No. and address of registered or principal office of Body Corporate**

<b>CRO No.</b>	906838
<b>Address:</b>	AbbVie Ireland NL B.V
	Manorhamilton Road
	Sligo
	Co. Sligo
<b>Tel:</b>	+353 71 9136600
<b>Fax:</b>	-
<b>e-mail:</b>	michaelo.gallagher@abbvie.com

If the applicant is a body corporate, the following information must be attached as **Attachment B1**:

- a) a Certified Copy of the Certificate of Incorporation under the Companies Act.
- b) the Company's Registration Number from the Companies Registration Office.
- c) Particulars of Registered Office of the Company.

Details on the body corporate including Certificate of Incorporation are included in Attachment B.

**Name and address of the proprietor(s) of the land on which the activity is situated (if different from applicant named above):**

<b>Proprietor's Name:</b>
<b>Address:</b>
<b>Tel:</b>
<b>Fax:</b>
<b>e-mail:</b>

**Name and address of the owner(s) of the building and ancillary plant in which the activity is situated (if different from applicant named above):**

<b>Name:</b>
<b>Address:</b>
<b>Tel:</b>
<b>Fax:</b>
<b>e-mail:</b>

**Primary Contact details for enforcement purposes where licence is granted. PLEASE NOTE THIS CONTACT CANNOT BE A CONSULTANT. ALSO IT MUST NOT BE A PERSON WHO IS ALREADY A REGISTERED EDEN CONTACT FOR ANY OTHER LICENCE ISSUED BY THE AGENCY.**

**\*mandatory fields**

<b>*Name:</b>	Mr Michael Gallagher
<b>Position in organisation:</b>	Site Services & EHS&E Manager
<b>Tel:</b>	Office +353 71 9136641 Mobile +353 86 8094288
<b>*e-mail:</b>	michaelo.gallagher@abbvie.com

**B.2. Location of Activity**

<b>Name:</b>	AbbVie NL B.V.
<b>Address*:</b>	Manorhamilton Road Ballytivnan Sligo Co. Sligo
<b>Tel:</b>	Office +353 71 9136641
<b>Fax:</b>	-
<b>Contact Name:</b>	Mr Michael Gallagher
<b>Position:</b>	Site Services & EHS&E Manager
<b>e-mail:</b>	michaelo.gallagher@abbvie.com

\* Include any townland.

<b>National Grid Reference (12 digit 6E,6N)</b>	170576E, 337383N Irish Grid
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Location maps ( $\leq A3$ ), appropriately scaled, with legible grid references should be enclosed in **Attachment B.2**. The site boundary must be outlined on the map in colour.

Geo-referenced digital drawing files (e.g. AutoCAD files) in Irish Grid projection of the site boundary and overall site plan, including labelled emission, monitoring and sampling points, are also required. This data should be provided to the Agency on a separate CD-Rom containing sections B.2, E.6 and F.3.

<b>Name of geo-referenced digital drawing files</b>	IE0311237-22-DR-0001 IE0311237-22-DR-0002
<b>Name of CD-Rom with digital drawing files</b>	CD-ROM labelled: AbbVie Ireland NL B.V, Manorhamilton Road Co. Sligo IED Licence Review Application P0643-02

### B.3. Class of Activity

Identify the relevant activities in the First Schedule of the EPA Act 1992, as amended, to which the activity relates:

Class	Description	Identify Main IED Activity
5.16	The production of pharmaceutical products including intermediates.	4. Chemicals Industry

### B.3A Industrial Emissions Directive

Specify which category/categories of industrial activity referred to in Annex I of the Industrial Emissions Directive (2010/75/EU) is/are to be carried out at the installation.

Category	Description	Identify Main IED Activity
4.5	Production of pharmaceutical products including intermediates	4. Chemicals Industry

State whether the installation falls under the scope of Chapters III, IV, V and/or VI of the Industrial Emissions Directive (2010/75/EU) and if yes specify the relevant sections and Annex.-

<b>IED Chapter(s) and relevant Annex(es)</b>
Chapter IV – Annex VI, Parts 3, 6 ,8
Chapter V – Annex VII, Part 1(8), 2

Supporting information should be included in **Attachment N° B.3A**.

### **B.3B Application Fee**

State each class of activity (per the First Schedule of the EPA Act) for which a fee is being submitted. Application fees are set out in the following regulations:

- EPA (Licensing Fees) Regulations 1994, for all First Schedule activities except classes 11.2 to 11.7; and
- EPA (Licensing Fees) Regulations 2013, for First Schedule activity classes 11.2 to 11.7.

First Schedule Activity	Fee (in €)
5.16 The production of pharmaceutical products including intermediates.	€16,506
Total fee paid	€16,506*

\*Purchase Order 4200390362 has been issued to the EPA in respect of this fee.

### **B.4 Classes of Waste Activity**

Not Applicable

If a waste activity is proposed, i.e. if any First Schedule of the EPA Act 1992, as amended class 11 activity is specified in section B.3 above, identify below the relevant activities as listed in Annex I and Annex II of the Waste Framework Directive (2008/98/EC).

**TABLE B.4 Classes of Waste Activity**

#### **Waste Framework Directive 2008/98/EC**

<b>Annex I Disposal Operations</b>		<b>Y/N</b>
D 1	Deposit into or on to land (e.g. including landfill, etc.).	
D 2	Land treatment (e.g. biodegradation of liquid or sludgy discards in soils, etc.).	

<b>Annex I Disposal Operations</b>		<b>Y/N</b>
D 3	Deep injection (e.g. injection of pumpable discards into wells, salt domes or naturally occurring repositories, etc.).	
D 4	Surface impoundment (e.g. placement of liquid or sludgy discards into pits, ponds or lagoons, etc.).	
D 5	Specially engineered landfill (e.g. placement into lined discrete cells which are capped and isolated from one another and the environment, etc.).	
D 6	Release into a water body except seas/oceans.	
D 7	Release to seas/oceans including sea-bed insertion.	
D 8	Biological treatment not specified elsewhere in this Annex which results in final compounds or mixtures which are discarded by means of any of the operations numbered D 1 to D 12.	
D 9	Physico-chemical treatment not specified elsewhere in this Annex which results in final compounds or mixtures which are discarded by means of any of the operations numbered D 1 to D 12 (e.g. evaporation, drying, calcinations, etc.).	
D 10	Incineration on land.	
D 11	Incineration at sea. <sup>1</sup>	
D 12	Permanent storage (e.g. emplacement of containers in a mine, etc).	
D 13	Blending or mixing prior to submission to any of the operations numbered D 1 to D 12. <sup>2</sup>	
D 14	Repackaging prior to submission to any of the operations numbered D 1 to D 13.	
D 15	Storage pending any of the operations numbered D 1 to D 14 (excluding temporary storage, pending collection, on the site where the waste is produced). <sup>7</sup>	

<b>Annex II Recovery Operations</b>		<b>Y/N</b>
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<sup>1</sup> This operation is prohibited by EU legislation and international conventions.

<sup>2</sup> If there is no other D code appropriate, this can include preliminary operations prior to disposal including pre-processing such as, inter alia, sorting, crushing, compacting, pelletising, drying, shredding, conditioning or separating prior to submission to any of the operations numbered D1 to D12.

Annex II Recovery Operations		Y/N
R 1	Use principally as a fuel or other means to generate energy. <sup>3</sup>	
R 2	Solvent reclamation/regeneration.	
R 3	Recycling /reclamation of organic substances which are not used as solvents (including composting and other biological transformation processes). <sup>4</sup>	
R 4	Recycling/reclamation of metals and metal compounds.	
R 5	Recycling/reclamation of other inorganic materials. <sup>5</sup>	
R 6	Regeneration of acids or bases.	
R 7	Recovery of components used for pollution abatement.	
R 8	Recovery of components from catalysts.	
R 9	Oil re-refining or other reuses of oil.	
R 10	Land treatment resulting in benefit to agriculture or ecological improvement.	
R 11	Use of waste obtained from any of the operations numbered R 1 to R 10.	
R 12	Exchange of waste for submission to any of the operations numbered R 1 to R 11. <sup>6</sup>	
R 13	Storage of waste pending any of the operations numbered R 1 to R 12 (excluding temporary storage, pending collection, on the site	

<sup>3</sup> This includes incineration facilities dedicated to the processing of municipal solid waste only where their energy efficiency is equal to or above:

- 0.60 for installations in operation and permitted in accordance with applicable Community legislation before 1 January 2009,

- 0.65 for installations permitted after 31 December 2008,

using the following formula:

$$\text{Energy efficiency} = (E_p - (E_f + E_i)) / (0.97 \times (E_w + E_f))$$

In which:

'E<sub>p</sub>' means annual energy produced as heat or electricity and is calculated with energy in the form of electricity being multiplied by 2.6 and heat produced for commercial use multiplied by 1.1 (GJ/year),

'E<sub>f</sub>' means annual energy input to the system from fuels contributing to the production of steam (GJ/year),

'E<sub>w</sub>' means annual energy contained in the treated waste calculated using the net calorific value of the waste (GJ/year),

'E<sub>i</sub>' means annual energy imported excluding E<sub>w</sub> and E<sub>f</sub> (GJ/year),

'0.97' is a factor accounting for energy losses due to bottom ash and radiation.

This formula shall be applied in accordance with the reference document on Best Available Techniques for waste incineration.

<sup>4</sup> This includes gasification and pyrolysis using the components as chemicals.

<sup>5</sup> This includes soil cleaning resulting in recovery of the soil and recycling of inorganic construction materials.

<sup>6</sup> If there is no other R code appropriate, this can include preliminary operations prior to recovery including pre-processing such as, inter alia, dismantling, sorting, crushing, compacting, pelletising, drying, shredding, conditioning, repackaging, separating, blending or mixing prior to submission to any of the operations numbered R1 to R11.

<b>Annex II Recovery Operations</b>		<b>Y/N</b>
	where the waste is produced). <sup>7</sup>	

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<sup>7</sup> Temporary storage means preliminary storage according to point (1) of Article 3 [of the Waste Framework Directive 2008/98/EC].



**B.5. Employees/ Capital Cost**

Give-

(i) In the case of an established activity, the number of employees and other persons working or engaged in connection with the activity on the date after which a licence is required and during normal levels of operation, or

(ii) In any other case, the gross capital cost of the activity to which the application relates.

<b>Number of Employees (existing facilities):</b>	195 (AbbVie) + 16 (Contractors)
<b>Gross Capital Cost (new proposals) €</b>	The new Thermal Oxidiser represents a €6 Million investment in the site.

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## B.6. Relevant Planning Authority and/or Public Authority

Give the name of the planning authority in whose functional area the activity is or will be carried out.

<b>Name:</b>	Sligo County Council
<b>Address:</b>	County Hall
	Riverside
	Sligo
	Co. Sligo
<b>Tel:</b>	071-9111111
<b>Fax:</b>	071-9141119

Considering the entire site to which the activity relates, has planning permission ever been required for the site? (Tick No or Yes in the table)

<b>No</b>		See Section <b>B.6(a)</b> below  <b>NOTE:</b> For <b>Agency initiated reviews</b> , you can disregard the instructions in B.6(a) and progress to Section B.7.
<b>Yes</b>	✓	See <b>all</b> of Sections <b>B.6(b) to (f)</b> below. Please note that <b>all</b> structures comprising or for the purposes of the activity must be accounted for in the tables in sections below B.6(c) to B.6(f) below.  <b>NOTE:</b> For <b>Agency initiated reviews</b> , you only need to <u>complete the tables</u> in Sections B.6(c), B.6(d) and B.6(e) below. You <b>DO NOT</b> need to submit an EIS or the letters on confirmation referred to below.

If this is a licence review application, was planning permission required for the changes proposed as part of this review application? (Tick No or Yes in the table)

<b>No</b>	✓	Provide confirmation in writing from the planning authority or An Bord Pleanála that this is the case. Confirmation from Sligo County Council of exemption pursuant to Section 5 of the Planning & Development Act 2000 (as amended) included in Attachment B6(i)
<b>Yes</b>		Planning Ref No: N/A

### B.6 (a) Where planning has never been required

Where the activity which is the subject of this licence/review application has never required a grant of planning permission previously, **Attachment N<sup>o</sup> B.6** must include a confirmation in writing from the planning authority or An Bord Pleanála, as the case may be, that the activity does not involve development or that the activity constitutes development but is exempted development. The letter of confirmation from the planning authority and/or An Bord Pleanála, as the case may be, must also confirm whether EIA has been carried out by the planning authority or An Bord Pleanála for any part of the site of the activity.

## B.6 (b) Environmental Impact Statements

In the following table, indicate the option which applies to your application and provide the information requested accordingly.

A supplementary document Attachment B.6 (ii) has been prepared to address the sites planning history and how the environmental impact has been considered at each stage of the sites development in respect of the parent Environmental Impact Statement (EIS).

The EIS for the original planning application along with subsequent environmental assessment reports for significant works have been submitted with the application.

A letter from Sligo county Council concerning EIS exemption for the subsequent planning applications is included as part of Attachment B.6 (iii).

Option	Applicable? (Yes/No)
<p><u>For new licence applications OR review applications where the last licence (excluding reviews initiated by the EPA) was determined <b>before</b> 30<sup>th</sup> September 2012</u></p> <ul style="list-style-type: none"> <li>Where planning permission has been/is required for the site of the activity, <b>you must submit the most recent EIS associated with a planning application or planning permission for the site of the activity.</b></li> <li>Where planning is granted, the planning decision and planners report associated with the EIS should <u>also</u> be submitted.</li> </ul>	Yes
<p><u>For review applications where the last licence (excluding reviews initiated by the EPA) was determined <b>after</b> 30<sup>th</sup> September 2012</u></p> <ul style="list-style-type: none"> <li>If this is an application for a licence review, and the last licence review (not including reviews initiated by the EPA) <b>was determined after 30<sup>th</sup> September 2012</b>, you are only required to submit the most recent EIS which has arisen through the planning process <b>since the last licence review</b>. The planning decision and planners report associated with the EIS should also be submitted.</li> </ul>	
<p><u>Where an EIS has never been required at planning stage</u> Where an EIS has never been required for any planning permission then you must provide confirmation in writing from the planning authority or An Bord Pleanála that an environmental impact assessment was not required by or under the Planning and Development Act 2000, as amended for <b>each</b> of the planning permissions associated with the site of the activity. This information should be included in <b>Attachment N<sup>o</sup> B.6.</b></p>	

### B.6 (c) Planning under Consideration

There are currently no planning permissions under consideration at the time of this application.

Where there is currently a planning application under consideration with a Planning Authority or An Bord Pleanála for any aspect of the site to which this licence application relates:

1. Provide confirmation in writing from a planning authority or An Bord Pleanála, as the case may be, that an application for permission comprising or for the purposes of the activity to which the application for a licence relates is currently under consideration.
2. Complete the Planning under Consideration Table below, indicating whether an Environmental Impact Statement (EIS) is required by the Planning Authority/An Bord Pleanála as part of that application.
3. Where an EIS is not required by the Planning Authority/An Bord Pleanála for a planning application, you must provide confirmation in writing from the planning authority or An Bord Pleanála that an environmental impact assessment is not required by or under the Planning and Development Act 2000 in **each** case. This information should be included in **Attachment N<sup>o</sup> B.6**.

#### Planning under Consideration Table:

Planning or Appeal Reference Number	Planning Authority (PA)/An Bord Pleanála (ABP)	Date of application	Brief description	Letter of confirmation from PA/ABP that application is under consideration?	EIS required with Planning Application? (Yes/No)	If "no", letter of confirmation from PA/ABP that EIA is not required?

**Note:** Please be advised that in accordance with Section 87(1D)(d) of the EPA Act 1992, as amended, a Proposed Determination **cannot** issue on a licence application while a planning application (for a development comprising or for the purposes of an activity to which the licence application relates and for which EIA is required) is under consideration with a planning authority or An Bord Pleanála.

**B.6 (d) Planning Granted**

Where planning permissions have been granted for the site of the activity:

1. List all of the permissions relating to the site in the Planning Granted Table below and indicate whether an EIS was required by the Planning Authority/An Bord Pleanála as part of that permission. Submit the planners report and final decision for each permission granted.

The Planning Granted table is included as part of Attachment B.6 (iii).

2. Where an EIS was not required by the Planning Authority/An Bord Pleanála for a planning permission, you must provide confirmation in writing from the planning authority or An Bord Pleanála that an environmental impact assessment was not required by or under the Planning and Development Act 2000 for **each** planning permission granted. This information should be included in **Attachment N<sup>o</sup> B.6**.

A letter from Sligo county Council concerning the requirements for EIS is included as part of Attachment B.6 (iii).

**Planning Granted Table:**

Planning or Appeal Reference Number	Planning Authority/ An Bord Pleanála	Date of Planning Decision (Final)	Brief description	EIS required with Planning Application? (Yes/No)	If "no", Letter of confirmation from planning authority/An Bord Pleanála that EIA was not required?

**Note:** Please be advised that where planning permission has been granted or a planning application is under consideration, and in accordance with Section 87(1C) of the EPA Act 1992, as amended, the Agency shall **refuse to consider** the licence application if the applicant does not comply with the requirements of Section 87(1B) of the EPA Act.

### B.6 (e) Exempted Developments and structures/modifications not regarded as “development”.

Where any structure or modification on site has been determined by the planning authority or An Bord Pleanála to be “exempted development” or is considered not to be development, provide confirmation in writing from the relevant authority. List all of the structures/modifications considered to be “exempted development” or to not involve development in the table below.

#### Exempted Development/No Development:

Planning Authority/ An Bord Pleanála	Date of letter from PA/ABP confirming their determination	Brief description of structure/modification	Tick if exempted development	Tick if considered not to be development
Sligo County Council	13 <sup>th</sup> December 2013	Installation of new thermal oxidiser plant	✓	

An application was made to Sligo County Council seeking an exemption in accordance with Section 5 of the Planning and Development Act 2000 (as amended) in respect of the installation of the new thermal oxidiser. Sligo County Council granted the exemption and a copy of the Managers Order is included in Attachment B.6 (i).

### B.6 (f) Other Consents Granted

List all consents (**other than planning permissions**) issued by any relevant competent authority (other than the planning authority/An Bord Pleanála) for the development relating to this application which required EIA to be carried out as part of the consent process e.g. a foreshore licence. These EISs are **not** required to be submitted with the licence application at this point.

Consent Reference Number	Competent Authority	Date of Grant of Consent	Brief description	EIS required with Consent Application?

#### Appropriate Assessment

Where applicable, provide a copy of any screening for Appropriate Assessment report and Natura Impact Statement (NIS) that was prepared for consideration by any planning/public authority as defined in Regulation 2(1) of the European Communities (Birds and Natural Habitats) Regulations 2011 (S.I. No. 477 of 2011) in relation to the activity. Where a determination that an Appropriate Assessment is required has been made by any planning/public authority in relation to the activity, a copy of that determination and any screening report and Natura Impact Statement (NIS), and any supplemental information furnished in relation to any such report or statement, which has been provided to the planning/public authority for the purposes of the Appropriate Assessment shall be included in **Attachment N<sup>o</sup> B.6**.

Attachment B.6 (iv) includes an Appropriate Assessment Screening Report (as required under Article 6(3) of the Habitats Directive (Council Directive 92/43/EEC) by PM Group identifying that there will be no impacts on the Natura 2000 Network due to the installation the new thermal oxidiser.

Licences and permits

For existing activities, **Attachment N° B.6** should also contain a table of references to all licences and permits past and present, including those in force at the time of submission of this application. This should include, but is not limited to, any permits/licenses or registration under GHG Emissions Trading Regulations and GMO Regulations.

Licence/Permit reference number	Brief Description	Date granted	Currently in force? (Yes/No)
P-0643-01 / 755	IPC Licence Grant	11 Dec 2002	No
P-0643-02	IPPC Licence Review	21 Nov 2005	Yes
P-0643-02	Technical Amendment A	30 June 2009	Yes
P-0643-02	Technical Amendment B	21 Feb 2013	Yes
P-0643-02	IED Amendment	19 Dec 2013	Yes
P-0643-02	Technical Amendment C	24 April 2014	Yes

**B.7. Relevant Water Services Authority**

In the case of a discharge of any trade effluent or other matter to a sewer of a Water Services Authority, give the name of the Water Services Authority in which the sewer is vested or by which it is controlled.

<b>Name:</b>	Irish Water
<b>Address:</b>	City Old Jail St Anne's Place Sligo
<b>Tel:</b>	071 9111373
<b>Fax:</b>	071 911371

In the case of a discharge of any trade effluent or other matter to a sewer not vested by a Water Services Authority, the applicant must supply as **Attachment N° B.7**;

(a) the name and address of the owner(s) of the sewer and the waste water treatment plant to which the sewer discharges (e.g. IDA, SFADCo or private undertaker) and who are responsible for the quality of the treated effluent discharging to waters and

(b) a copy of the effluent regulations and the agreement between the applicant and the aforementioned.

***Details of owner(s) of a sewer and waste water treatment plant not vested in a Water Services Authority***

<b>Name:</b>	N/A
<b>Address:</b>	
<b>Tel:</b>	
<b>Fax:</b>	

**B.8. Relevant Regional Health Service Executive**

The applicant should indicate the Regional Health Service Executive where the activity is or will be located.

<b>Name:</b>	HSE Sligo/Leitrim/Cavan
<b>Address:</b>	St. Johns Hospital Campus
	Ballytivnan
	Sligo
	Co.Sligo
<b>Tel:</b>	(071) 982 0524
<b>Fax:</b>	-

**B.9 Site Notice, Newspaper Advertisement and Planning Authority Notice.**

**Attachment N<sup>o</sup> B.9** should contain a copy of the text of the site notice, a map (no larger than A3) showing its location on site (in accordance with Article 6 of the Regulations) and a copy of the newspaper advertisement. A copy of the notice given to the Planning Authority should also be included.

A copy of the site notice, map showing its location, and copy of the newspaper advertisement are included in Attachment B.9. Notification to the planning authority is also included as Attachment B.9.

**B.10 Seveso II Regulations**

State whether the activity is an establishment to which the EC (Control of Major Accident Hazards involving Dangerous Substances) Regulations (S.I. No. 74 of 2006) apply.

Yes       No

If yes, outline how the process comes under these regulations.

Supporting information should be included in **Attachment N<sup>o</sup> B.10**.

The AbbVie Facility is below all lower tier thresholds for Seveso II and Seveso III and an assessment has been submitted to the HSA. The Seveso Regulations do not apply to the facility.

**B.11 Mercury Regulation**

State whether the activity is one to which the following apply:

- European Communities Mercury (Export Ban and Safe Storage) Regulations (S.I. No. 27 of 2012),
- Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports or metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury.

Yes       No

If yes, outline in **Attachment N<sup>o</sup> B.11** how the activity comes under these Regulations.



## B.12 Regulations Controlling Fluorinated Greenhouse Gases and Ozone Depleting Substances

State whether the installation is one to which the following apply:

- Operator of equipment and systems containing ozone depleting substances, in accordance with Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer.

Yes       No

- Operator of equipment and systems containing fluorinated greenhouse gases, in accordance with Regulation (EC) No. 842/2006 on certain fluorinated greenhouse gases.

Yes       No

If yes, outline in **Attachment N<sup>o</sup> B.12** how the activity comes under these regulations.

More information and guidance is available on the EPA website:

<http://www.epa.ie/air/airenforcement/ozone/guidanceanddownloads/>

Attachment B.12 includes a full inventory of fluorinated greenhouse gases used in refrigeration systems at the AbbVie facility. The inventory identifies the refrigerant charge and leak detection checking requirements. Only certified maintenance engineers are used for leak detection in accordance with the regulations.

Also attached is the overview of obligations on the operator regarding installation, maintenance, leak prevention and record keeping. AbbVie complies fully with these obligations.

For inspection purposes only. AbbVie complies fully with these obligations.  
Consent of copyright owner required for any other use.

### B.13 Review of a licence

State the grounds on which an application for a review of a licence is being made and give the reference number to the relevant licence in the register.

A review of Licence P0643-02 is requested to support the following:

1. Proposal to install a Direct Fired Thermal Oxidiser (TO) to abate both chlorinated and non-chlorinated solvent waste gas streams from the pharmaceutical manufacturing processes resulting in a new main emission point A2-1(c) with the flows and limits in the licence remaining the same as per the existing TO emission point A2-1(a) with the addition of a HCl limit and Dioxin/Furans limit.

Note that on completion of the commissioning phase of the new TO, the existing TO will be decommissioned.

2. Delete references to actual API's or pharmaceutical product names (e.g. Trandolapril and ABT-510) in the licence introduction. The AbbVie facility was designed to cope with a diverse range of products and future unknown products. It is a multi-purpose plant for multiple products. The process plant and equipment have been designed to be flexible. This will allow the future manufacture of products other than those specified in the introduction to the current licence. Before a new product or process is introduced, hazard and risk assessment studies will be carried out to ensure safe operation and protection of the environment. Requests will continue to be made to the OEE for permission to develop and manufacture new products as per the current licence conditions.
3. Application to cease the annual noise survey as per Condition 6.9. It is proposed to carry out one last noise survey during the operational period of the new Thermal Oxidiser plant being on site. The site has conducted annual noise surveys since it first went operational and has an impeccable record with no noise emission limit exceedances and has received no complaints.
4. General revision of wording and content of licence to take account of transfer of licence from Abbott Ireland Pharmaceutical Operations to AbbVie Ireland NL B.V. and also amend changes as per Technical Amendments A, B and C.
5. Update Condition 6.13 to read PRTR (Pollutant Release Transfer Register).
6. Update/Delete Conditions 6.14, 6.15, 6.16, 6.17 & 6.18 regarding commissioning test programmes /operating conditions to take account for the new Thermal Oxidiser instead of the Cryogenic Condenser. A test programme has been submitted and agreed with the OEE for the commissioning of the new thermal oxidiser.
7. Update Condition 6.21 regarding the restriction of treating chlorinated solvent waste gases in the thermal oxidiser. The new thermal oxidiser can treat both chlorinated and non-chlorinated solvent waste gases.
8. Review the wording of Condition 6.25 regarding the testing of the efficiency of the Thermal Oxidiser and remove requirement for a report on the findings of the assessment to be available for on-site inspection and that this assessment shall be included in the Schedule of Environmental Objectives and Targets.
9. Update Condition 10.2.1 to reference the new EPA 'Guidance on Assessing and Costing Environmental Liabilities -2014'.

10. Update Condition 11.1 regarding the specifics of contacting the Office of Environmental Enforcement (OEE).
11. Delete the requirement associated with Condition 11.13 requiring the licensee to keep a record of the occasions when the cryogenic condenser abatement system is used to simultaneously treat the chlorinated, and the non-chlorinated vapours diverted from the thermal oxidiser.

Conservative air dispersion modelling has shown that even with the two abatement plants (new thermal oxidiser & cryogenic condenser) running simultaneously that the air quality standards is not breached. This condition relates to a historical situation on site when the old Thermal Oxidiser & cryogenic condenser could not operate simultaneously. This condition was removed in Technical Amendment C.

12. Update Condition 12 regarding financial charges as per the agency's requirements.
13. Update Condition 12.3.2 to reference the new EPA '*Guidance on Assessing and Costing Environmental Liabilities -2014*'.
14. Update Schedule B – Include new Emission Point A2-1(c) and associated parameters and limits. Remove emission point A2-1(a).
15. Amend Schedule C – Include new Emission Point A2-1(c) and associated control and monitoring conditions. Remove emission point A2-1(a).
16. Amend Schedule C – Include reference to boiler emission points A1-3, 1-4, A1-5 & A1-6 which have been previously approved under Section 1.4 by the OEE.
17. Amend Schedule C to include update temperature and volume limits granted under Technical Amendment C.
18. Amend Schedule C.4 – Requirement for waste monitoring assigned to very specific waste classes. AbbVie request that this condition be more generic to take account for future waste types. Waste management and analysis at the AbbVie facility is carried out in accordance with the Waste Management Act 1996 and reported in the AER.
19. Amend Schedule C.7 – Groundwater Monitoring – It is proposed to change the monitoring frequency from Bi-annually to annually.
20. Deletion of all references to "*Monitoring shall take place on the thermal oxidiser exhaust immediately prior to the mixing of the cryogenic condenser exhaust and the thermal oxidiser exhaust*" in the notes section in the schedules.

There will be no mixing of the exhausts from the abatement plants. The new thermal oxidiser has its own exhaust stack and there will be no future scenario where mixing of exhausts occurs.

Provide, where appropriate, a copy of the Office of Environmental Enforcement (OEE) correspondence that indicates that the reason for the review cannot be accommodated within the scope of the existing licence.

A copy of the OEE correspondence in this regard has been attached in attachment B.13.

Include results of emission monitoring and other data, that enables a comparison of the operation of the installation with the best available techniques described in the applicable BAT conclusions and with the emission levels associated with the best available techniques in accordance with Section 86A(9) of the Act of 1992 as amended.

A copy of the most recent Annual Environmental Report (AER) has been included in Attachment B.14. The 2014 AER includes details of all emission monitoring carried out to demonstrate compliance with licence conditions. AER for previous years are available on the EPA's website: [www.epa.ie](http://www.epa.ie).

Where the OEE has agreed any variations or adjustments to the conditions or schedules of the existing licence, the licensee must provide details of these agreed variations and adjustments to the existing licence conditions. An updated, scaled drawing of the site layout (no larger than A3) providing visual information on such adjustments or variations where appropriate should be included.

A copy of OEE correspondence in this regard has been attached in attachment B.13. Technical Amendments A, B and C to licence P0643-02 are included in Attachment B.6.

In the case of once-off assessments/ reports required under conditions/ schedules of the existing licence the licensee must provide details of those assessments/ reports that have been completed and agreed with the OEE or as otherwise agreed.

**Attachment N<sup>o</sup> B.13** shall include the schedule of variations and/or adjustments together with the updated drawing.

Condition/ Schedule No.	Existing Condition	OEE Agreement Reference	Description
IPC Licence	-	-	Construction of Pharmaceutical Plant
IPPC Licence Review	-	-	New cryogenic condenser
Technical Amendment A	Condition 6 & Schedule B, C	-	Update emission points/limits. Run TO and Cryogenic Condenser at any time
Equipment Installation	Condition 6	P0643- 02(11)APR11JG	Small steam boiler
New Emission Points	Schedule C	P0643- 02(12)APR14HB	New boiler emission points
Technical Amendment B	Condition 6	-	Compliance with VOC Directive
IED Amendment	Condition 2, 5	-	Compliance with IED Directive
Technical Amendment C	Condition 6 & Schedule B, C	-	New dust extraction emission point
New Product	Condition 1.4	LR001139	Manufacture of new product
Test Programme	Condition 6 & Schedule B, C	LR017838	Test programme for the new thermal oxidiser

Supporting information should be included in **Attachment N<sup>o</sup> B.13**.

## SECTION C: MANAGEMENT OF THE INSTALLATION

### C.1 Site Management & Control

Details should be provided on the management structures for the activity. Organisational charts and all relevant environmental management policy statements, including provisions for on-going assessment of environmental performance, are required.

AbbVie EHS Management system consists of many elements which are set out in the diagram below, figure 1. The system documents and operates on a continual improvement basis from policy to management review. Through a process of continuous improvement, specific programmes are implemented and maintained to achieve the intent of the written policy, objectives and other requirements including the international standards ISO 14001:2004 and OSHAS 18001:2007.



(Figure 1: Management System Diagram)

Management structure flow charts are included in attachment C.1. The AbbVie EHS policy is also included in Attachment C.1.

The site completes EHS management reviews on quarterly basis whereby Senior Management perform a review of the EHS management system. The review is an opportunity to ensure continual improvement.

Inputs to the quarterly annual EHS management review include:

- a) Follow up actions from previous management reviews.
- b) Review of the EHS policy.
- c) Review of EHS performance.
- d) Results of the evaluation of compliance with legal requirements and changes in the legal and other requirements to which the site subscribes.
- e) The extent to which the EHS objectives and targets have been met.
- f) EHS audit results.
- g) The status of open corrective actions and preventive actions.
- h) Projected EHS performance for the following period.
- i) Recommendations for improvement.

Outputs from the EHS management review include an EHS performance statement which details the progress made on achieving the EHS objectives and targets and on any other key aspects of the EHS Management system.

Inclusive are any decisions or actions related to;

- a) Changes in the EHS performance of the organisation.
- b) Changes to the EHS policy.
- c) Changes to the EHS legal compliance.
- d) Changes to objectives, targets or other elements of the EHS Management System, consistent with the sites commitment to continual improvement; and allocation of resources.

## C.2 Environmental Management System (EMS)

Indicate whether an Environmental Management System has been developed for the installation. If yes, specify which standard and include a copy of the accreditation certificate.

AbbVie has an EMS accredited to ISO 14001 in place to enable a systematic and documented approach to environmental performance and improvement. The EMS provides a structured process for the achievement of continual improvement. A copy of the accreditation certificate issued by Certification Europe Ltd. is included as attachment C.2.

## C.3 Hours of Operation

Provide details of the hours of operation for the installation, including:

(a) Proposed hours of operation.

API Building - operates 24 hours a day, 7 days a week.  
Drug Product Building – operates 24 hours a day, 5 days a week.

(b) Proposed hours of construction and development works and timeframes.

The construction works and installation of the new Thermal Oxidiser occurred during normal working hours.

(c) For waste activities, the proposed hours of waste acceptance.

No waste acceptance activities.

(d) Any other relevant hours of operation expected.

N/A

## C.4 Fit and Proper Person

The EPA Act in Section 83(5)(xi) specifies that the Agency shall not grant a licence unless it is satisfied that the applicant or licensee or transferee as the case may be is a fit and proper person. Section 84(4) of the EPA Act specifies the information required to enable a determination to be made by the Agency.

- Indicate whether the applicant or other relevant person has been convicted under the Environmental Protection Agency Act 1992, as amended, the Waste Management Act 1996, as amended, the Local Government (Water Pollution) Acts 1997 and 1990, the Air

Pollution Act 1987 and the Air Pollution Act 1987 (Environmental Specifications for Petrol and Diesel Fuels)(Amendment) Regulations 2004.

Neither AbbVie nor any staff involved with managing the operations at the facility has been convicted of any offence under the Environmental Protection Agency Act 1992 to 2011, the Waste Management Acts 1996 to 2011, the Local Government (Water Pollution) Acts 1997 and 1990, the Air Pollution Act 1987 and the Air Pollution Act 1987 (Environmental Specifications for Petrol and Diesel Fuels) (Amendment) Regulations 2004.

- Provide details of the applicant's technical knowledge and/or qualifications, along with that of other relevant employees.

**Site Director: Marc O' Donoghue, PH.D (Organic Chemistry)**

18 year career in pharmaceutical manufacturing in 3 No. IPPC/IED licence companies, covering roles in technical development, production support and operations management. Experience includes working with IPPC/IED licences in both emissions abatement systems and waste water treatment management.

**EHSS & Engineering Manager: Michael Gallagher**

Degree Qualified Mechanical Engineer with over 17 year's industry experience, the last 3.5 years as Site Services and EHS Manager for the AbbVie Sligo Site managing the IPPC/IED licence.

The EHSS & E Manager is supported by an extensive team of Engineering & EHS specialists. Please see the EHSS & E management structure included as part of **Attachment C.1**.

Independent expertise will be continually engaged for specific tasks related to the sites environmental responsibilities (e.g. environmental monitoring and emissions, maintenance) and certification/auditing requirements (e.g. ISO 9001, ISO 14001, ISO 15001 etc.)

- Provide information to show that the person is likely to be in a position to meet any financial commitments or liabilities that may have been or will be entered into or incurred in carrying on the activity to which the application relates or in consequence of ceasing to carry out that activity.

AbbVie is fully committed to furnish the EPA with any evidence required to satisfy the Agency of the company's ability to meet any financial commitments or liabilities that will be entered into or incurred in carrying on the activities to which this review application relates or in consequence of ceasing to carry out these activities. Please see **Attachment K** of this application for further details on environmental liabilities, closure planning and financial provisions.

This information should form **Attachment N<sup>o</sup> C**.

## SECTION D: INFRASTRUCTURE & OPERATION

### D.1. Operational Information Requirements

Describe the plant, methods, processes, ancillary processes, abatement, recovery and treatment systems, and operating procedures for the activity, to include a copy of such plans, drawings or maps, (site plans and location maps, process flow diagrams), and such other particulars, reports and supporting documentation as are necessary to describe all aspects of the activity. Maps and drawings must be no larger than A3 size.

A development and operational history of the site should be included here.

**Attachment N<sup>o</sup> D** should contain a list of all unit operations (processes) to be carried out, including flow diagrams of each with any relevant additional information.

#### Plant Description

The plant manufactures a number of active pharmaceutical ingredients (API's) for medical applications. The API plant is multi-purpose for multiple products. The API's will be manufactured using standard chemical synthesis routes and equipment of proven design. The facility also includes a drug production building, which uses standard formulation operations including blending, milling, and tablet compression equipment. The facility also includes a number of supporting utilities and services.

#### Methods and Processes

##### Bulk Pharmaceutical Building

The production processes will be operated on batch mode and the equipment used to manufacture the products and intermediates will be glass-lined or stainless steel and of standard design for the industry. The following are brief descriptions of typical production processes involved in the manufacture of active pharmaceutical ingredients, not all of which are required for each product.

The operations to be undertaken in the Bulk Pharmaceutical Building include the following:

##### **Reactions**

Appropriate solvents will be weighed into a chemical reaction vessel, called a reactor. Specified quantities of raw materials will be added and heated to the required temperature range before a reactant is added at the required flow rate. Reaction conditions such as pressure, time, addition rate and temperature will be set for each product and in-process testing and sampling will be carried out.

##### **Crystallisation**

Crystallisation will be carried out on some products.

##### **Separation**

Separations will be required. These may be liquid-liquid separation of, for example, an aqueous and an organic solvent, using a phase splitter, or solid-liquid separation using a filter or centrifugation.

##### **Distillation**

A variety of distillations may be required, either at atmospheric pressure or under vacuum, in order to purify a material, separate materials, or recover solvents for disposal.



### **Drying**

Drying will be carried out in filter dryers or blender/dryers (with or without vacuum).

### **De-Lumping / Sizing**

De-lumping, that is grinding down of material to a uniform size, will be carried out using mills under specified operating conditions.

### **Drug Product Building**

The operations to be undertaken in the Drug Product building include the following:

#### **Blending**

Blending is the addition and mixing of powder raw materials with different properties. The objective is to have, on completion of the blending step, a final product that is homogenous (uniform). To achieve this, a number of pre-blending steps are necessary.

#### **Compression into tablets**

Tablets are formed, under pressure in a tablet press, from the blended powder.

#### **Tablet Coating**

Tablets are coated using the tablet coater.

Manufacturing flow diagrams for typical API and drug production processes have been included in Attachment D.

### **Site Utilities**

The following utilities will be generated and distributed on site:

- Various water utilities
- Propylene glycol heating/cooling system
- Nitrogen
- Compressed air to power certain controls and for an air supply to personnel protective equipment masks
- Site drainage systems
- Fire water retention pond
- Electrical Supply
- Steam/Condensate

#### **Public supply main water**

The water supply to the site will be from the Sligo Borough Council public supply main (300 mm diameter), which runs near to the site. The demand for water is approx. 230-300 m<sup>3</sup>/year.

#### **Process, softened and purified water**

Process water will initially be softened. The water will then pass through water purification equipment. The water purification plant will have a flow rate of up to 10.8m<sup>3</sup>/hr. The normal usage will be approximately 1m<sup>3</sup>/hr. Purified water will be supplied to the Bulk Pharmaceutical building and the Drug Product building.

#### **Cooling water**

Three cooling towers are located to the west of the utilities building. They are outdoors and at ground level. These cooling towers will be used for cooling the process and HVAC chilled water systems. The cooling towers will normally operate with two towers on duty and the third on standby.

### **Low pressure hot water**

Low pressure hot water will be used to provide space heating in the administration and laboratory building, the Drug Product building and the Bulk Pharmaceutical building. It will be generated in the plant room in each building.

### **Propylene glycol heating/cooling system**

Propylene glycol solution will be heated in a packaged unit located in the Bulk Pharmaceutical building. The glycol will also be cooled, when required, using glycol from the chillier units. The propylene glycol solution will be supplied to the jackets on vessels such as the reactors and the filter dryers, and will be used to heat the filter dryer agitator.

### **Nitrogen**

Nitrogen is stored on site in a bulk tank. It will be supplied to all the main process equipment and tanks to provide an inert medium and to fill the space above the liquid in the tanks, to prevent a build-up of vapours.

### **Instrument air/breathing air**

The generation plants for the instrument air and breathing air systems are located in the utility building.

### **Site Drainage Systems**

Separate sanitary drainage, storm water drainage and floor drain collection systems are provided on site.

### **Fire Water Retention Pond**

A firewater retention pond is located at the south-western part of the site. In the unlikely occurrence of a fire, the water used to fight the fire may come in contact with potential pollutants. In order to minimise the environmental impact from the firewater, the facility has been designed so that the firewater drains to the retention pond. The outlet of this retention pond closes upon activation of the firewater deluge systems.

### **Electrical Supply**

The 38 kV ESB sub-station at the existing Abbott Ireland site in Ballytivnan is used as the power source for the facility. The average energy use on-site is approximately 8000 MWH per year.

### **Steam**

There are 4 LPG boilers located in the utilities building. Two back-up kerosene fired steam-generating boilers, rated at 8000kg steam/hour, are also located in the utilities building. The boilers provide steam for process use. Steam will be supplied to the Bulk Pharmaceutical building, the Drug Product building and the laboratory. Kerosene for the boilers is stored in a single 70m<sup>3</sup> tank, located in a bund in the tank farm.

## **Buildings Overview**

### **Main Buildings**

The main buildings are as follows:

- Building 70 - Utilities building
- Building 40 - Bulk Pharmaceutical Building
- Building 20 - Drug Product Building
- Building 10 - Administration and laboratory building

## **Ancillary Buildings**

The ancillary facilities are as follows:

- Tank farm
- Tank unloading/loading Bay
- Process water storage tank
- Sprinkler pump house and fire water storage tank
- Emergency generator
- Air emissions abatement systems
- Aqueous waste treatment system
- Drum store
- Security building

## **Abatement**

There are a number of abatement systems in place across the site. These are outlined below.

### **Thermal Oxidiser**

The new direct fire thermal oxidiser will replace the existing TO currently on-site. This is a more energy efficient piece of equipment and will be used to treat both non-chlorinated and chlorinated solvent waste gases from the pharmaceutical production processes.

### **Cryogenic Condenser**

This system will be used as a back-up to the new TO. This piece of equipment is not suitable for the abatement of Volatile Organic Compounds which is why the TO will be the main abatement unit used on-site.

### **Scrubber**

The process scrubber will treat process solvent streams from the Bulk Pharmaceutical Building. The drum charging room will vent to the scrubber during all drum charging operations. It is expected the existing scrubber will be used less frequently due to the introduction of the new thermal oxidiser but will remain on site pending future developments.

### **Dust Extraction Systems - HEPA Filter**

There are 3 HEPA filters in place at the facility to extract dust containing active pharmaceutical ingredients from production areas.

## **Recovery and Treatment**

### **Solvent Treatment**

An aqueous waste solvent stripper is located on site. The purpose of this is to remove concentrated solvent material from aqueous streams. The concentrated solvent material is taken off-site for disposal via road tanker.

### **Waste Disposal**

All waste is segregated by waste type in a manner to prevent release and is clearly labelled. Aqueous waste and laboratory waste collected from around the site is stored in a dedicated hazardous waste storage area until ready for off-site shipment. This is a locked caged area. Hazardous waste generated from manufacturing buildings B20 and B40 and the laboratory areas are collected by the Total Waste Management (TWM) vendor or warehouse personnel. Waste is transported to a locked shipping container, located separate from the warehouse areas, where it is sorted and stored securely while awaiting offsite shipment. Hazardous waste of drug products or containers of Active

Pharmaceutical Ingredients (API) are never stored outside of a secure location. All waste shipped off-site shall be packaged to meet all applicable requirements and in a manner to prevent any release during transportation. No Hazardous waste shall leave the AbbVie site unless both the driver and the transport vehicle are fully compliant with the above requirements.

Flow diagrams of a typical API manufacturing process and drug production process on-site incorporating the unit operations described above are included in attachment D.1. New processes are approved by the EPA on a continuous basis as there is a high turnover of manufacturing and research and development processes at the facility. For this reason they are not included with this application.

## **Development & Operational History of the Site**

A review of the development history of the site is included in the 'Planning History and Environmental Impact Review Report' included as Attachment B.6.

## **Operator Performance**

AbbVie has established and maintains an Environmental Management System (EMS) which is accredited to the ISO 14001 International Standard.

The annual environmental report (AER) for the 2014 reporting period, the most recent AER for the site, shows that the AbbVie site is in compliance with the emission limit values (ELV) as stated in its Industrial Emissions Licence with the exception of one ELV exceedence for wastewater discharge to sewer. This exceedence was reported to the EPA in accordance with Condition 4 'Interpretation' and Condition 11 'Notifications, Records and Reports' of the site's Industrial Emissions Licence.

There were no complaints received by the AbbVie site in 2014.

In total there were 4 no. incidents recorded as follows:

- On two occasions, the monitoring equipment at the licensed emission point SE-1 went offline;
- On one occasion, the monitoring equipment at the licensed emission point A2-1(a) went offline;
- There was one ELV breach for wastewater discharge to sewer.

## **D.2 Additional requirements for waste Activities (not covered above or elsewhere) (All Class 11 of the First Schedule of the EPA Act 1992, as amended)**

Section D.2 is not applicable.

This section D.2 of the application form should be completed only by applicants applying for classes 11.1, 11.2, 11.3, 11.4, 11.5, 11.6 and 11.7 (i.e. waste activities) of the First Schedule to the EPA Act 1992, as amended.

### **D.2.1 Wastes to be accepted**

State what wastes will be accepted at the installation for recovery or disposal. Complete table Table D.2(i) and include in **Attachment No. D.2** of the application. The following general guidelines may assist in containing the size of Table D.2(i) where there is a long list of EWC codes proposed.

- For any individual waste stream, described by EWC code or main waste description (e.g. municipal solid waste, mixed recyclables, C&D waste), comprising more than 5% of total intake, complete a single row in table D.2(i).

- For every hazardous waste stream, describe by EWC code, complete a single row in table D.2(i).
- Other waste streams, where the list of waste is long, may be aggregated, according to a waste category, with each relevant EWC code provided.

An EWC code should be provided for every waste proposed for acceptance at the installation.

State whether any wastes to be accepted are classified as animal by-products in accordance with Regulation 1069/2009 and identify the relevant wastes.

The maximum annual tonnage of waste to be handled at the site should be indicated and the year to which the quantity relates indicated.

<b>Maximum Annual Tonnage (tonnes)</b>	
<b>Year</b>	

It should be noted that an applicant may be issued with a licence which restricts the type and quantity of wastes which may be accepted.

**D.2.2 Waste Storage and Closure Costs**

State the maximum amount of waste that will be held or stored at the installation at any one time. This should include waste in:

- reception, inspection and quarantine areas,
- storage pending treatment,
- storage after treatment, and
- vessels, chambers or tanks during treatment or processing.

State the cost of disposing of waste (including treated waste) held, in storage or in process at the installation. Do not provide the recovery/recycling cost and do not assume that the waste will have a positive monetary value (it may have degraded in the period before removal from the closed installation).

Complete the following table (consistently using either tonnes or cubic metres as your unit of measurement for all entries):

<b>Location of waste</b>	<b>Tonnes</b>	<b>Cubic metres</b>	<b>Unit cost (per tonne or m<sup>3</sup>) for - removal AND - disposal in case of sudden closure</b>	<b>Disposal route and/or technique</b>	<b>Notes, rationale, clarifications</b>
Holding areas					
Quarantine areas					
Inspection areas					
Storage areas					

(untreated waste)					
Storage areas (treated waste)					
Treatment chambers, vessels and tanks					
Other (add rows as necessary)					
<b>Total</b>					

\* add rows to the table as necessary

### D.2.3 Waste Acceptance Procedures

Provide a copy of the waste acceptance procedures employed or to be employed. Describe procedures for checking waste loads as they arrive at the installation. Describe procedures to be implemented in the event of a load of waste arriving at the installation that does not conform to waste acceptance procedures. The location of a quarantine area for handling suspect or non-compliant loads should be described and illustrated on a suitable site drawing.

For landfills and relevant incineration activities, describe how the requirements of *Municipal Solid Waste – Pre-treatment and Residuals Management: An EPA Technical Guidance Document* (EPA, 2009) will be implemented.

For landfills, the applicant should ensure that the requirements of Council Decision 2003/33/EC are addressed in waste acceptance procedures.

### D.2.4 Waste and material outputs from waste activities

Describe the waste and material outputs from the installation resulting from the treatment of waste. If no treatment is carried out on the waste, the waste outputs will be the same as the inputs.

If waste is treated, describe the nature and quantity of the treated waste and its onward fate/destination, and in particular whether it is sent for onward recovery or disposal operations.

If waste is treated and a material is produced that is no longer a waste, provide the rationale for such classification. The requirements of article 28 of the European Communities (Waste Directive) Regulations 2011 should be addressed in any such rationale.

### D.2.5 Principles of self-sufficiency and proximity

Describe how the proposed waste activities will contribute to the State's obligation to establish an integrated and adequate network of waste disposal installations and of installations for the recovery of mixed municipal waste collected from private households, including where such collection also covers such waste from other producers. Describe how the proposed waste activities will enable the State to move towards being more self-sufficient in the management of these wastes.

Supporting information should form **Attachment N<sup>o</sup> D**.

### D.3 Additional Requirements for landfills (not covered above or elsewhere) (Class 11.5 of the First Schedule of the EPA Act 1992, as amended)

This section D.3 of the application form should be completed only by applicants applying for classes 11.5 and 11.7 (landfills and underground storage facilities) of the First Schedule to the EPA Act 1992, as amended. This includes landfills that are associated with other industrial activities.

All landfills must comply with the requirements of the Landfill Directive (1999/31/EC). It is the applicant's responsibility to ensure that all relevant requirements of the Directive are addressed and information provided in **Attachment D.3** of the application.

For wastes to be disposed of by landfilling on-site at industrial installations, full details of the disposal site should be submitted (to include *inter alia*, site selection procedures, location maps, (no larger than A3) geology, hydrogeology, operational plan, containment, gas and leachate management, post-closure care).

Applicants should have regard to the requirements of the Landfill Manuals published by the Environmental Protection Agency.

#### D.3.1 Class of landfill

Complete Table D.3(i) and include in Attachment D.3 of the application. State which of the categories in Table D.3(i) is relevant to the current application.

**Table D.3(i) Class of landfill**

(a) landfill for hazardous waste	<input type="checkbox"/>
(b) landfill for non-hazardous waste	<input type="checkbox"/>
(c) landfill for inert waste	<input type="checkbox"/>

#### D.3.2 Scale of waste deposition

Complete Table D.3(ii) and include in Attachment D.3 of the application. State the total quantity of waste for which authorisation is sought to be deposited in the landfill.

**Table D.3(ii) Scale of waste deposition at the landfill**

Total quantity of waste to be deposited at the landfill	Tonnes*	Void in cubic metres (m <sup>3</sup> )
(a) Waste deposited to date		
(b) Total waste to be deposited over the lifetime of the development (including deposited to date)		

\* Explain any conversion/density factors used in calculating the tonnage from the void, or vice versa.

### **D.3.3 Liner System**

Complete Table D.3(iii) and include in Attachment D.3 of the application. Table D.3(iii) provides a checklist of items that should be described in greater detail in Attachment D.3.

### **D.3.4 Leachate Management**

Complete Table D.3(iv) and include in Attachment D.3 of the application. Table D.3(iv) provides a checklist of items that should be described in greater detail in Attachment D.3. Provide a list and illustrate on a site drawing the location of all leachate monitoring, extraction and lead detection boreholes or installations.

### **D.3.5 Landfill Gas Management**

Complete Tables D.3(v)a to D.3(v)d and include in Attachment D.3 of the application. The tables provide a checklist of items that should be described in greater detail in Attachment D.3. Provide an estimate of the volume of landfill gas which will be produced by the waste for the next 20 years.

### **D.3.6 Capping System**

Complete Table D.3(vi) and include in Attachment D.3 of the application. Table D.3(vi) provides a checklist of items that should be described in greater detail in Attachment D.3.

### **D.3.7 Meteorological Data**

State in Attachment D.3 what arrangements are proposed for the measurement of meteorological data at the landfill installation, or for the collation of relevant meteorological information from nearby facilities.

### **D.3.8 Cost of the landfill of waste**

Describe in Attachment D.3 how all of the costs involved in the setting up and operation of the landfill, including the cost of financial provision, and the estimated cost of the closure and aftercare of the site for a period of at least 30 years will be covered by the gate fee to be charged for the disposal of waste.



## SECTION E: EMISSIONS

### E.1. Emissions to Atmosphere

#### E.1.A. Details of all point emissions to atmosphere

Details of all point emissions to atmosphere should be supplied. Complete Table E.1(i) for Boiler Emissions and Table E.1(ii) and E.1(iii) for all other main emission points. Complete Table E.1(iv) for minor emission points and provide results of emission monitoring where available.

A summary list of the emission points, together with maps and/or drawings (no larger than A3), and supporting documentation should be included as **Attachment N<sup>o</sup> E.1**. Plans of emission elevations, relevant roof heights, etc., should also be included, as should detailed descriptions and schematics of all abatement systems.

All emission points are shown on Drawing No: IE0311237-22-DR-0002. (Attachment E.1)

The existing and new elevations of the new thermal oxidiser installation are shown on Drawing No: IE0311237-48-DR-0004. (Attachment E.1)

The applicant should address in particular any emission point where the substances listed in the Schedule of EPA (Industrial Emissions)(Licensing) Regulations 2013, S.I. No. 137 of 2013, are emitted.

For emissions outside the BAT guidance limit or BAT Conclusions levels, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the limits as set out in the BAT guidance note(s). These notes can be found on the EPA website at [www.epa.ie](http://www.epa.ie).

#### Boiler Emission Points

There are a total of six boiler emission points at the facility. These are denoted by reference numbers A1-1 to A1-6.

- A1-1, A1-2: Kerosene Boilers; used as back up for peak demand
- A1-3, A1-4, A1-5, A1-6: LPG Boilers; used for majority of the year

Details of these emission points can be found in tables E.1 (i).

#### Major Emission Points

The main emission points from the facility are as follows:

- A2-1(a): Old Thermal Oxidiser

Emission point A2-1(a), the exhaust for the existing TO, will be retained pending licencing of the new TO, emission point A2-1(c), following which it will be decommissioned. The decommissioning schedule will be agreed with the Agency.

- A2-1(b): Cryogenic Condenser; used as a back-up for the new TO
- A2-1(c): **New TO**; to be used full time at the facility, replacing the old TO
- A2-2: Scrubber;

- A2-3, A2-4, A2-5: Dust Extraction Systems

Details of these emissions points can be found in tables E.1 (ii) and E.1 (iii).

Existing minor emissions are listed in table E.1 (iv).

#### E.1.B. Fugitive and Potential emissions

Give summary details of fugitive and potential emissions in Table E.1(v).

In relation to activities listed in the Schedule of Council Directive 2010/75/EU (on Industrial Emissions) S.I. No.565 of 2012 on installations and activities using organic solvents;

- specify the relevant category of activity in the Schedule
- specify how the requirements in relation to fugitive emissions will be met.

For waste activities, dust and odour emissions should be described under the headings in this section.

Full details and any supporting information should form **Attachment E.1.**

Fugitive emissions from the facility will be primarily from the tanks in the tank farm. The following tanks will vent into the vent header that serves the new thermal oxidiser.

- TK-900 Dichloromethane Tank
- TK-901 Methanol Tank
- TK-902 Ethyl Acetate
- TK-903 Isopropyl Acetate
- TK-904 Aqueous Waste Tank
- TK-905 Solvent Waste Tank
- TK-906 Aqueous Waste Tank
- TK-907 Chlorinated Solvent Waste Tank
- TK-403 Aqueous Waste Tank
- TK-404 Solvent Waste Tank
- Tk-432 Mother Liquor Tank

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Possible fugitive emissions are low compared to the annual usage of VOCs and will not cause a significant environmental effect.

AbbVie produce an annual Solvent Management Plan, in order to comply with Condition 6.11 of their current licence Industrial Emissions Licence. This plan documents a solvent mass balance for the AbbVie installation and compares the calculated VOC emissions to determine solvent emissions from the installation and verify compliance with the stated limits in the Directive. The details of the latest Solvent Management Plan are included in the 2014 AER which is included with this application (Attachment B.13).

Fugitive and potential emissions are listed in table E.1 (v).

## E.2 Emissions to Surface Waters

Tables E.2(i) and E.2(ii) should be completed and provide results of emission monitoring where available.

A summary list of the emission points, together with maps/drawings (no larger than A3) and supporting documentation should be included as **Attachment N<sup>o</sup> E.2**.

The applicant should address in particular any emission point where the substances listed in the Schedule of EPA (Industrial Emissions) (Licensing) Regulations 2013 S.I. No. 137 of 2013, are emitted.

Details of all substances listed in the European Communities Environmental Objectives (Surface Waters) Regulations 2009, contained in any emission must be presented. All surface water runoff and storm water drains discharging to surface water bodies must be included. A National Grid Reference (12 digit, 6E, 6N) must be given for all discharge points the identity and type of receiving water (river, ditch, estuary, lake, etc.) must be stated.

Where relevant, describe proposed measures or controls that have been identified in a pollution reduction plan for the river basin district prepared in accordance with Part V of the EC Environmental Objectives (Surface Waters) Regulations 2009 for the reduction of pollution by priority substances or the ceasing or phasing out of emissions, discharges and losses of priority hazardous substances.

For emissions outside the BAT guidance limit or BAT Conclusions levels, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the limits as set out in the BAT guidance note(s).

There will be no impact on existing emissions to surface waters as a result of the new thermal oxidiser installation.

The proposed works increased the impermeable area of the site by approx. 1-2 % of the site area. The original surface water drainage system was originally designed to allow for future expansion. The sites surface water would continue to drain to the retention pond via a hydrocarbon interceptor before discharging to the on-site stream via a flow control device. The mitigation measures as a result of the installation would follow the same strategy as previously. Measures included control of surface water runoff, the use of hydrocarbon interceptor, bunded tanks/ drum storage, adherence to the facilities Environmental Management Programme, loading/unloading of the chemicals in bunded areas and regular testing of bunds, drains, lines and also continuous surface water monitoring.

## E.3 Emissions to Sewer

Tables E.3(i) and E.3(ii) should be completed and provide results of emission monitoring where available.

A summary list of the emission points, together with maps and/or drawings (no larger than A3) and supporting documentation should be included as **Attachment N<sup>o</sup> E.3**. Details of all List I and List II substances listed in the Annex to EU Directive 2006/11/EC (as amended), contained in any emission must be presented. All relevant information on

the receiving sewer, including any effluent treatment/abatement systems, not already described, with schematics as appropriate should also be included in **Attachment N<sup>o</sup>E.3**.

For emissions outside BAT guidance limit (where given), a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within any limits set out in the BAT guidance note(s).

The proposed installation will generate additional process wastewater due blow down from the new scrubber. The additional process wastewater volumes would be approximately 2m<sup>3</sup>/day. AbbVie's licence limit is 300m<sup>3</sup>/day. The average daily discharge is approximately 191m<sup>3</sup>/day, therefore even with the proposed increases, the daily discharges would still be well below the limit. Monitoring as per the licence would continue as before. Any emissions will be treated along with the rest of the sites effluent to comply with the emission limit values as set out in the licence before release to the public sewer.

Details of all emission to sewer are listed in tables E.3 (i) and E.3(ii).

#### **E.4 Emissions to Ground**

Describe in **Attachment N<sup>o</sup> E.4** the existing or proposed arrangements necessary to give effect to Council Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Council Directive 80/68/EEC on the protection of groundwater against pollution by certain dangerous substances.

The applicant should supply details of the nature and quality of any substance (agricultural and non-agricultural waste) to be landspread (slurry, effluent, sludges etc) as well as the proposed application rates, periods of application and mode of application (e.g., pipe discharge, tanker) having regard to the European Communities (Good Agricultural Practice for Protection of Waters) Regulations 2010, S.I. No 610 of 2010.

For emissions outside the BAT guidance limit, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the limits as set out in the BAT guidance note(s).

Not applicable. There are no emissions to ground.

#### **E.5 Noise Emissions**

Give particulars of the source, location, nature, level, and the period or periods during which the noise emissions are made or are to be made.

There have been no significant changes to the number and nature of noise emissions since the 2005 application for a licence review. The new thermal oxidiser is replacing an existing thermal oxidiser and the associated equipment will be added to the site register of noise emission sources and, once operational, will be monitored as part of the annual monitoring programme.

**Note:** Noise emissions from site are reported in the AER. Once operational, noise emissions from the new thermal oxidiser will be monitored as part of the annual noise survey. It is proposed to perform one last annual noise survey during the period when the new thermal oxidiser is operational and to cease annual environmental noise monitoring after this if the results are within the limits. The site has conducted annual

noise surveys since it first went operational and has an impeccable record with no emission limit failures. Attachment E.5 contains a record of the annual noise monitoring results for 2008 to 2014.

Table E.5 (i) should be completed, as relevant, for each source.

Supporting information should form **Attachment N<sup>o</sup> E.5**.

The Agency's *Guidance Note for Noise: Licence Applications, Surveys and Assessments in Relation to Scheduled Activities (NG4)* (2012) should be consulted (available on [www.epa.ie](http://www.epa.ie)) where a noise impact assessment is required. A planned programme of improvement towards meeting upgraded standards is required and should have due regard to the noise control and mitigation measures outlined in section 8 and appendix (IX) of the *Guidance Note*. This programme should highlight specific goals and a time scale, together with options for modification, upgrading or replacement, as required, to bring the emissions within the limits as set out in the *Guidance Note*.

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## E.6 Tabular Data on Emission Points

Applicants should submit the following information for each emission point:

Point Code	Point Type	Easting	Northing	Verified	Emission
Provide label ID's assigned in section E	A=Atmospheric SW=Surface Water SE = Sewer GW=Groundwater N = Noise SL=Soil/Ground WS=Waste	6E-digit GPS Irish National Grid Reference	6N-digit GPS Irish National Grid Reference	<del>Y = GPS used</del> N = GPS not used	e.g. SO <sub>2</sub> , HCl, NH <sub>3</sub>
A1-1	A	170604	337494	N	NO <sub>x</sub> , SO <sub>2</sub>
A1-2	A	170604	337494	N	NO <sub>x</sub> , SO <sub>2</sub>
A1-3	A	170604	337494	N	-
A1-4	A	170604	337494	N	-
A1-5	A	170604	337494	N	-
A1-6	A	170604	337494	N	-
A2-1(a)	A	170669	337475	N	NO <sub>x</sub> , SO <sub>2</sub> , CO, TOC
A2-1(b)	A	170637	337473	N	TOC
A2-1(c)	A	170674	337478	N	NO <sub>x</sub> , SO <sub>2</sub> , CO, TOC, Dioxins/Furan, HCl
A2-2	A	170634	337472	N	Chlorides (as HCl), Formic Acid
A2-3	A	170578	337466	N	Total Dust. Dust (as API)
A2-4	A	170586	337414	N	Total Dust. Dust (as API)
A2-5	A	170586	337414	N	Total Dust. Dust (as API)
SW1	SW	170340	337430	N	Clean Uncontaminated Surface Water
SE1	SE	170637	337413	N	BOD, COD, Temperature, pH, Toxicity, SS, NH <sub>3</sub> (as N), P, SO <sub>4</sub> , Chlorides, MDAS, FOG

An individual record (i.e. row) is required for each emission point. Acceptable file formats include Excel, Access or other upon agreement with the Agency. A standard Excel template can be downloaded from the EPA website at [www.epa.ie](http://www.epa.ie). This data should be submitted to the Agency on a separate CD-Rom containing sections B.2, E.6 and F.3.

A CD-ROM has been submitted with the application.

## SECTION F: CONTROL & MONITORING

### **Describe the proposed technology and other techniques for preventing or, where this is not possible, reducing emissions from the installation.**

Describe the measures to be taken under abnormal operating conditions, including start-up, shutdown, leaks, malfunctions, breakdowns and momentary stoppages.

Describe the measures to be taken to prevent or eliminate emissions and/or avoid pollution.

Describe what appropriate measures are to be taken where an Environmental Quality Standard requires stricter conditions than would be determined with reference to BAT

### **F.1: Treatment, Abatement and Control Systems**

Details of treatment/abatement systems (air and effluent emissions) should be included, together with schematics as appropriate.

For each Emission Point identified complete Table F.1 (i) and include detailed descriptions and schematics of all abatement systems.

Table F.1 (i) has been completed for each emission point.

**Attachment N<sup>o</sup> F.1** should contain any supporting information.

### **VOC Abatement Systems (Air)**

The site currently has a thermal oxidiser (TO) for handling non-chlorinated VOC streams and a Cryogenic abatement system for handling chlorinated VOC streams. AbbVie would like to direct all VOC laden streams to one unit. The volume of vented streams and the nature and quantity of VOCs in these streams were reviewed to establish the most suitable VOC abatement technology.

A new Direct Fired Thermal Oxidiser (DTO) with Waste Heat Recovery was installed with a capacity to treat 3,962 m<sup>3</sup>/hr of vent gas. The sizing basis for the TO includes for future expansion and also considers turndown capability to allow for worst case flows without burdening the site with unnecessarily high running costs.

Waste gases from the production cells will be collected in an existing vent header system. As part of the new TO installation project, the existing vent header system will be divided into sub-headers that will have independent operating conditions and Hazardous Area Classifications. The different process streams vented to the VOC abatement system vary in flow rate and content. By segregating and directing flows similar in nature to separate sub-headers, this will allow for the selection of different zones and configurations optimising the operation and performance of the header system.

The existing Cryogenic abatement unit is to be kept as part of the overall plant abatement infrastructure. Its primary function will be to act as back-up to the new TO. However, there is also a requirement to be able to direct Cells 1 and 3 to the Cryogenic unit for dedicated campaigns (while the main DTO is still in operation). The system integrator is to note that the capacity of the Cryogenic unit is 1/3 that of the new DTO. Therefore a need to manage the off-gas streams to the Cryogenic unit is a fundamental requirement of the vent header design.

The existing Thermal Oxidiser abatement unit is to be kept as part of the overall plant abatement infrastructure only for the purposes of commissioning support. Its primary

function will be to act as support to the new DTO during the commissioning phase. The system integrator is to note that the capacity of the thermal oxidiser unit is 2/3 that of the new DTO.

Note that on completion of the commissioning phase of the new DTO, the existing thermal oxidiser unit will be decommissioned.

### **New Thermal Oxidiser**

There is a requirement to use increased amounts of chlorinated solvents on site due to new pharmaceutical product manufacturing. VOC abatement technology assessments as well as Best Available Technique (BAT) reviews were carried out to choose the appropriate technology in order for AbbVie to meet its environmental emissions limits.

With regard to the BREF for "Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector", the BAT Conclusion 48 clearly indicates that:

*When halogenated VOCs are present, to suppress the generation of dioxins/furans (PCDD/F), oxidation conditions should be as follows:*

*- Residence time > 2 seconds, temperature > 1100 °C (850 °C when incinerating with less than 1 % of halogenated organic substances) and an oxygen content of > 3%. Some waste gas pre-treatment can be necessary, such as condensing the water vapour from a wet waste gas.*

As the process will be dealing with VOC streams with greater than 1% halogenated organic substances, this operating condition applies.

As such, the choice of technology should meet this condition, which while it can be fulfilled by direct fired thermal oxidisers, it cannot be fulfilled by the regenerative based systems. Therefore, the direct fired mode with its operating temperature of greater than 1,100°C and combustion chamber sized to give a two second residence time, was the preferred technology choice.

The principle of direct fired technology is relatively straight forward; the gases are fired into a combustion chamber and then held at the required temperature for the specified period of time, the size/volume of the chamber being directly proportional to the required operating temperature and residence time. As the chamber can be lined with a refractory brick or similar refractory coating, there are no technical limitations to achieving operating temperatures greater than 1100°C.

Although this solves the problem of the halogenated VOCs, the higher temperatures can cause an increase in thermal nitrogen oxides (NO<sub>x</sub>) for which there are licence limits set at 200mg/m<sup>3</sup>. To ensure continued compliance with the licence, additional flue gas treatment in the form of Selective Non-Catalytic Reduction (SNCR) technology will be employed as part of the abatement plant. With SNCR, a reducing agent, commonly an aqueous solution of urea is added to the flue gas which has been cooled to between 950°C-1100°C leading to a reduction in NO<sub>x</sub> through chemical reaction. This technology can reduce NO<sub>x</sub> levels by approximately 60-70%.

After the combustion processes, flue gas will be cooled in a quench system, before scrubbing of the flue gas to remove HCl. The flue gas will exit the quench/scrubber at a temperature of approx. 50°C where it will be reheated to approx. 150°C in a plume eliminator heat exchanger.



The flue gas will then exit the exhaust stack at approx. 150°C via a continuous emission monitoring system (CEMS). The system shall be designed to eliminate as far as practical any visual plume under normal operating conditions.

A new steam boiler has been installed to recover heat from the exhaust gas stream from the new thermal oxidiser and used to generate steam for use on site.

### Emergency Vent

In the event of an emergency scenario within the cells, the ability to manually override the vent management system in order to gain access to the vent header is to be allowed for at Cell level. The system integrator is to facilitate this requirement, however once selected all other users are removed from the vent header system (their respective vent valves will close) and the entire vent header system is frozen until the vent header system is reset.

Activation of the emergency vent will require investigation and the circumstances of the decision recorded, prior to resetting to the vent header system.

In the event of an emergency scenario at the abatement unit or vent header piping infrastructure, the vent header management system will default to the following:

- Process Lock down – no access to vent header
- Emergency Hold – All on-line users will be re-set to off-line (vent valves will close) and all off-gas streams within the vent header system will stay within the vent header network until the vent header is back on-line (due to emergency scenario being resolved / cleared) or an evacuation of the vent header system is received.
- An evacuation of the vent header system will result in all sub-header and main header nitrogen purge by-pass valves to open and flood the vent header piping network with 2.0 barg nitrogen. The TO emergency vent valve will open, and the contents of the vent header system will be released to atmosphere.

Any of the scenarios referenced above will require a complete re-set of the vent header system, via the vent header management system.

A flow diagram of the new thermal oxidiser plant is included in Attachment F.1(i)

The new thermal oxidiser test programme "Validation of Environmental Compliance for Direct Fired Thermal Oxidiser and Scrubber Unit at AbbVie Sligo" prepared by AWN Consulting is also included as Attachment F.1(ii).

This report also contains detailed information on the plant and treatment process and describes how the formation of PCDD/F (commonly called Dioxins) will be minimised by the key design criteria and will be proved during the commission test programme.

A detailed layout plan of the new thermal oxidiser skid is included in Attachment F.1(iii).

## **Existing Abatement Plant**

### **Cryogenic Condenser**

The CryoCondap ExStream system works by using direct contact with liquid nitrogen to cool the solvent laden gas stream. The volatile organic compounds (VOCs) condense out of the gas stream and freeze to form a snow which is removed by filters made from stainless steel. Periodically, the filters are cleaned using reverse pulses of compressed gas, causing the VOC snow to fall to the bottom of the filter vessel. A heater melts the snow and liquid VOCs are discharged to the bottom of the vessel and from there to the DCM waste solvent tank where it is subsequently transferred off-site for licensed disposal.

### **Process Scrubber**

The drum charging room will vent to the scrubber during all drum charging operations. The main process vents will be directed to the scrubber during acid sparging, acid charging into reactors, head tanks and reactor samplers. Venting of all other operations will be diverted to the thermal oxidiser.

The scrubber package includes a packed polypropylene column and integral sump tank containing 10% sodium hydroxide. The vent stream will be drawn into the base of the scrubber via a fan on the scrubber. The vent stream will be contacted counter-currently by the recirculating scrubbing liquor (10% sodium hydroxide). This caustic will neutralise the hydrochloric and formic acid reducing their concentration in the exiting stream to less than 10 mg/m<sup>3</sup>. A demister will be installed on the scrubber vent to reduce water droplet carryover. A continuous pH monitor will be provided on the re-circulation line to monitor the pH of the sump water. When the caustic is depleted, the sump contents are pumped to the aqueous waste tank and the caustic in the sump tank is replaced with fresh sodium hydroxide. Manual grab samples will also be taken of the sump contents to verify the continuous pH monitor. It is envisaged the caustic will have to be replaced on a weekly basis.

### **Dust Extraction Systems**

Bulk Pharmaceutical Building:

The central dust exhaust system will provide local extraction for all dispensing and milling operations, this system continuously extracts dust from these unit operations. Each operational unit e.g. milling glove box has a HEPA filter fitted which is 99.97% efficient. The central dust exhaust system provides extraction across these HEPA filters.

In addition the combined exhausts from each unit operation are exhausted through one final extract "policing" HEPA filter before being exhausted to atmosphere at emission point A2-3. This extract HEPA filter has a continuous differential pressure transmitter, which will be alarmed to the DCS system. A flow switch will be located on the central ducting alarming on low a flow rate.

The extract system fans will operate on a duty standby basis with automatic start-up of the standby fan if the running fan fails. A building management system (BMS) provides local indication to each split butterfly valve and glove box panel on extract fan failure, HEPA filter blockage or failure of the flow switch. This disables the operation of the Split butterfly if such alarms occur, also providing local indication that an alarm condition exists.

## Drug Product Building:

The central dust exhaust systems will provide local extraction for all dispensing milling and blending operations, including the make and break operation of the split butterfly valves in the Drug Product building. This central dust exhaust system continuously extracts dust from these unit operations.

The combined exhausts from each unit operation are exhausted through a dust collection system. The filters in the dust collection system are cleaned using an automatic reverse pulse cleaning mechanism. A bag in, bag out facility will be used to allow the safe change of the filter elements. Dust will be collected from the central dust exhaust system utilising a double bag and seal arrangement, which will provide a safe change replacement of drums. A control and monitoring system will be installed to indicate dust volumes within the sealed dust collection container. The extract air passes through a final "polishing" HEPA filter before exhausting to atmosphere at emission points A2-4 and A2-5. The filters operate at 99/97% efficiency.

The central dust collection system will be controlling using the building management system (BMS) with fault alarms communicated to the process control system (PCS)

In addition to the local extract system described above, each processing room will have HEPA filters installed on their extraction systems, which will in turn exhaust to atmosphere. These HEPA filters will operate at 99.97% efficiency.

## Emissions to Sewer

### **Aqueous Waste Solvent Stripper**

The objective of the waste stripper is to process liquid effluent arising from the process and ancillary areas. The main purpose is to remove solvent contaminants from the aqueous waste streams. This aqueous waste may contain up to 20% w/w solvent and the aqueous waste solvent stripper plant will reduce this organic level to less than 25 ppm enabling the waste to be discharged directly to foul sewer. The solvent stripper will also be used to dehydrate the solvent waste from the main plant, reducing the volume and increasing the calorific value of solvent waste sent off-site for disposal.

Process waste streams being discharged to sewer from the aqueous waste solvent stripper will be monitored prior to discharge to sewer.

Details of the abatement/treatment control for each emission point are outlined in table F.1 (i).

There have been no changes to the abatement systems for emissions to sewer since the 2005 review of the licence.

## F.2: Emissions Monitoring and Sampling Points

Identify monitoring and sampling points and outline proposals for monitoring **emissions**. Table F.2(i) should be completed (where relevant) for air emissions, emissions to surface waters, emissions to sewer, emissions to ground and waste emissions. Where **ambient** environment monitoring is carried out or proposed, Table F.2 (ii) should be completed as relevant for each environmental medium.

Apart from the new thermal oxidiser, it is proposed to monitor existing emissions as per current schedules.

A regulatory pre-condition associated with the installation of a new Thermal Oxidiser Package is the installation of a proprietary CEM's (Continuous Emission Monitoring) System. The existing CEM's installation associated with the original Thermal Oxidiser is no longer suitable for purpose and is to be de-commissioned in parallel with the original Thermal Oxidiser.

The new CEM's units will be expected to conform to all relevant practices and international standards, including but not limited to:

- I.S. EN14181
- EN14181 (Data Acquisition)
- 40 CFR (Protection of the Environment) Part 60
- 40 CFR (Protection of the Environment) Part 75

The CEM's unit (assuming a "Talas" or "Durag" data acquisition platform) will be expected will relay pre-nominated critical emission values to the Delta-V DCS from monitoring and alarm generation protocols.

Include details of monitoring/sampling locations and methods.

Details of the monitoring and sampling for each emission point are outlined in table F.2 (i).

**Attachment N<sup>o</sup> F.2** should contain any supporting information.

**F.3: Tabular Data on Monitoring and Sampling Points**

Applicants should submit the following information for each monitoring and sampling point:

<b>Point Code</b>	<b>Point Type</b>	<b>Easting</b>	<b>Northing</b>	<b>Verified</b>	<b>Pollutant</b>
Provide label ID's assigned in section F3	M=Monitoring S=Sampling	6E-digit GPS Irish National Grid Reference	6N-digit GPS Irish National Grid Reference	Y = GPS used N = GPS not used	e.g. SO <sub>2</sub> , HCl, NH <sub>3</sub>
A1-1	M/S	170604	337494	N	NO <sub>x</sub> , SO <sub>2</sub>
A1-2	M/S	170604	337494	N	NO <sub>x</sub> , SO <sub>2</sub>
A1-3	M/S	170604	337494	N	
A1-4	M/S	170604	337494	N	
A1-5	M/S	170604	337494	N	
A1-6	M/S	170604	337494	N	
A2-1(a)	M/S	170669	337475	N	NO <sub>x</sub> , SO <sub>2</sub> , CO, TOC
A2-1(b)	M/S	170637	337473	N	TOC
A2-1 (c)	M/S	170674	337478	N	NO <sub>x</sub> , SO <sub>2</sub> , CO, TOC, HCl, Dioxins/Fu rans
A2-2	M/S	170634	337472	N	Chlorides (as HCl), Formic Acid
A2-3	M/S	170578	337466	N	Total Dust. Dust (as API)
A2-4	M/S	170586	337414	N	Total Dust. Dust (as API)
A2-5	M/S	170586	337414	N	Total Dust. Dust (as API)
SW1	M/S	170340	337430	N	Clean Uncontami nated Surface Water
SE1	M/S	170637	337413	N	BOD, COD, Temperat ure, pH, Toxicity, SS, NH <sub>3</sub> (as N), P, SO <sub>4</sub> , Chlorides, MDAS,

Point Code	Point Type	Easting	Northing	Verified	Pollutant
					FOG
N1	M			N	Noise
N2	M			N	Noise
N3	M			N	Noise
N4	M			N	Noise
N5	M			N	Noise
N6	M			N	Noise
M1-1	S	170642	337488	N	pH, COD, Conductivity, Major Anions, Major Cations, Heavy Metals, Trace Organics
MW-2	S	170514	337428	N	
MW-3	S	170334	337391	N	
MW-4	S	170499	337329	N	

An individual record (i.e. row) is required for each monitoring and sampling point. Acceptable file formats include Excel, Access or other upon agreement with the Agency. A standard Excel template can be downloaded from the EPA website at [www.epa.ie](http://www.epa.ie). This data should be submitted to the Agency on a separate CD-Rom containing sections B.2, E.6 and F.3.

Point source monitoring/sampling refers to monitoring from specific emission points (e.g. from a boiler stack or outlet from a wastewater treatment plant). Examples of ambient monitoring includes monitoring of ambient air quality (e.g. boundary or off-site) or monitoring of river quality upstream/downstream of an effluent discharge.

A CD-ROM has been submitted with the application.

## SECTION G: RESOURCE USE AND ENERGY EFFICIENCY

### **G.1 Give a list of the raw and ancillary materials, substances, preparations, fuels and energy which will be produced by or utilised in the activity.**

The list(s) given should be very comprehensive, all materials used, fuels, intermediates, laboratory chemicals and product should be included.

Particular attention should be paid to materials and product consisting of, or containing, dangerous substances as described in the EU (Classification, Packaging, Labelling and Notification of Dangerous Substances) Regulations 2003 [SI 116/2003] as amended and Regulation (EC) No. 1272/2008. The list must classify these materials in accordance with both of these Regulations, and must specify the designated Risk Phrases (R-Phrases) and Hazard Statements. Hazard statements for each substance should be in accordance with Article 21 of the EC Regulation 1272/2008.

The list must identify any **Substances of Very High Concern (SVHC)** listed in Annex XIV of the REACH Regulations (Regulation (EC) No 1907/2006) as amended and indicate whether the use has been authorised or is exempted in accordance with the Regulation. In the case(s) of exempted use(s) the list must state the basis for each intended exempted use concerned.

Tables G.1 (i) and G.1(ii) must be completed.

A comprehensive list of all materials used on site is given in tables G.1 (i) and G.1 (ii).

Supporting information should be given in **Attachment N° G**.

For waste activities (class 11 of the First Schedule to the EPA Act 1992, as amended), do not include here the list of wastes to be accepted for recovery and disposal. This should be described in section D.2 of the application.

### **G.2 Energy Efficiency**

A description of the energy used in or generated by the activity must be provided in **Attachment N° G**. Outline the measures taken to ensure that energy is used efficiently having regard to the relevant decision on BAT conclusions and/or BAT guidance and where appropriate, an energy audit with reference to the EPA Guidance document on Energy Audits should be carried out.

Direct fire thermal oxidation of the waste gas streams is a simple and effective way to ensure that emissions requirements are maintained, but it comes at the expense of fuel consumption. By capturing some of the heat energy required for waste gas destruction, and by using this to generate steam for use elsewhere on the site, AbbVie can enhance its energy efficiency and minimise its overall operating costs. The new TO is designed to comply with AbbVie's ISO 50001 certification requirements, and will provide high level and constant performance. A number of energy efficient technologies are employed throughout the new TO, including:

- High efficiency motor pumps and fans (minimum IE2 and IE3 standard).
- Motors will be Variable Speed Drive (VSD) controlled.
- Equipment shall be insulated where possible to retain thermal energy.
- Appropriate metering shall be added to enable effective energy management including meter on fuel consumption, electrical consumption (e.g. power monitor

on main Motor Control Centre (MCC) panel), and measurement of "heat recovered".

- Lighting shall be energy efficient type and Passive Infrared Sensor (PIR) controlled where possible.

An energy efficiency audit of the site is carried out annually to identify all opportunities for energy use reduction and efficiency. These audits are carried out in accordance with the "Guidance Note on Energy Efficiency Auditing", published by the EPA.

AbbVie is committed to maintaining its membership with the Sustainable Energy Authority of Ireland (SEAI). As per the company's energy policy, this will be achieved by ensuring a continuous improvement philosophy to promote on-going energy efficiency and energy performance improvements. Under this policy AbbVie also intends to continuously identify, promote and fund energy efficient products and services, heat recovery projects, renewable energy, and cogeneration projects where it makes sense to do so and in order to deliver increased energy efficiency, energy cost reduction and a reduction in the CO2 footprint. AbbVie have set an energy reduction target of 20% CO2 and Water from baseline year 2013 to end of 2020.

The energy usage of the site in 2014 is detailed in the latest AER which is included as Attachment B.14.

A copy of AbbVie's Energy Policy and ISO 50001 Certificate are included in Attachment G.2.

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## SECTION H: MATERIALS HANDLING

### H.1 Raw Materials, Intermediates and Product Handling

All materials will have been listed in Tables G.1 (i) and G.(ii) of **Section G**.

Details of the storage conditions, location within the site, segregation system used and transport systems within the site should be outlined here in **Attachment N<sup>o</sup> H.1**. In addition, information relating to the integrity, impermeability and recent testing of pipes, tanks and bund areas should be outlined.

Raw materials and products are listed in Tables G.1 (i) and G.1(ii) of this application.

The loading and unloading of raw materials and packaging is carried out in designated areas, protected as may be appropriate against spillage and leachate run off.

There are designated buildings for drum storage and a number of external storage tanks at the facility. All storage tank and drum areas are bunded on-site.

Maintenance checks are carried out regularly on pipes, tanks and bunds to ensure integrity and impermeability.

### H.2 Waste Prevention

Describe in **Attachment N<sup>o</sup> H.2** the arrangements for the prevention of waste in accordance with Part III of the Waste Management Act 1996, as amended. Describe what measures will be taken to prevent the generation of waste to the extent possible. State whether the installation has participated in any projects under the National Waste Prevention Programme.

Waste management at this facility will be carried out in accordance with the Waste Management Act 1996, as amended. The arrangements in place are outlined below:

- Regular meetings are held with Department Managers to ensure that current and new processes are reviewed to minimise the creation of waste. If waste cannot be eliminated, suitable outlets are sourced where it can be recycled, treated or disposed (in that order).
- Good housekeeping is observed at all times. This will ensure that waste creation is minimised.
- The inventory is managed in a way that does not lead to the creation of waste, i.e. materials are only stocked as required, not in large quantities.
- All technologies and abatement equipment is operated efficiently, and is not generating additional waste. This is ensured through the preventative maintenance programme.
- Technological reviews based on engineering waste out of the process are incorporated through process reviews.
- Material substitution is considered through process reviews, i.e. hazardous materials are replaced by less hazardous materials.
- The site's Environmental Specialist incorporates all waste minimisation and recycling projects into the Environmental Management Plan EMP.

- In relation to the treatment and disposal of hazardous waste the Environmental Specialist shall, in consultation with the waste disposal company, recover, treat and/ or dispose of AbbVie waste in a manner that takes into consideration clean technology. For example solvent waste from the process will be stored in a bulk tank and taken off-site by road tanker for disposal.

### **H.3 Describe the arrangements for the recovery or disposal of solid and liquid wastes generated at the installation.**

Applicants should ensure that information is provided for each waste generated at the installation under each of the following headings:

- (a) Description & nature of waste
- (b) Source
- (c) European Waste Catalogue Code (Commission Decision 2000/532/EC, as amended)
- (d) Animal by-product category per EC Reg. 1069/2009 where relevant
- (e) Amount in tonnes per month
- (f) Location and method of disposal or recovery (on-site or off-site)

The following information should also be provided where appropriate:

- (g) Analysis of the waste (include test methods and Q.C.)
- (h) Its location of storage and the manner by which the integrity/impermeability of storage areas is maintained
- (i) Period or periods of generation of the waste

Where any waste would be classified as Hazardous Waste as defined in the Waste Management Act, 1996, as amended, this should be made clear in the information provided.

The Table H.3(i) should be completed with a single row for each waste generated at the installation. The table should be provided as part of **Attachment N° H.3**.

For waste activities (class 11 of the First Schedule to the EPA Act 1992, as amended), do not repeat the information already sought in section D.2.3 of the application form and presented in Attachment D.2 of the application.

Details of each waste generated in the installation are outlined in Table H.3(i) of this application.

### **H.4 Waste hierarchy**

Where waste is generated by the installation, describe in **Attachment N° H.4** how it will be in order of priority in accordance with section 21A of the Waste Management Act 1996, as amended, prepared for re-use, recycling, recovery or where that is not technically or economically possible, disposed of in a manner which will prevent or minimise any impact on the environment.

Section 29(2A) of the Waste Management Act 1996, as amended states that it shall be the duty of waste producers and holders to ensure that waste undergoes recovery operations in accordance with sections 21A and 32(1) of the Acts.

Describe how the waste hierarchy specified in article 21A of the Waste Management Act 1996, as amended, will be implemented at the installation. Describe how the waste generated at the installation will be managed in accordance with the waste hierarchy.

For waste whose generation cannot be prevented, describe what measures will be in place to ensure that waste is collected separately (if technically, environmentally and

economically practicable) and will not be mixed with other waste or other material with different properties.

AbbVie has considered preferred methods of waste minimisation, referred to as the hierarchy of waste management, which is outlined in the table below.

1	Elimination	Complete elimination of waste
2	Reduction at Source	Avoidance, reduction or elimination of waste, generally within the confines of the production unit, through changes in industrial processes or procedures.
3	Recycling	Use, reuse, recycling of waste for the original or some other purpose such as in input materials, materials recovery or energy production.
4	Treatment	Destruction, detoxification, neutralization, etc. of waste into less harmful substances.
5	Disposal	The release of waste into air, water or land in properly controlled or safe ways so as to render them harmless; secure land disposal may involve volume reduction, encapsulation, leachate containment and monitoring techniques.

AbbVie have a procedure to audit all waste disposal sites used by the facility for the disposal of waste generated during operations. AbbVie generates various waste streams and must manage these wastes using off-site facilities. The manner in which these wastes are managed and ultimately disposed of creates potential risks and liabilities for AbbVie. This procedure will outline the appropriate management of off-site facilities through a standardised method for evaluating and approving off-site waste disposal facilities. All waste disposal facilities used by AbbVie must be approved prior to use. This procedure is in accordance with Technical Standard T04.AV Waste Disposal Facility Selection, and the *Waste Management Act, 1996*, and associated statutory instruments.

All hazardous and non-hazardous waste is separated as outlined in the chart found in Attachment N<sup>o</sup> H.4. All waste is segregated by waste type in a manner to prevent release and is clearly labelled. Aqueous waste and laboratory waste collected from around the site is stored in a dedicated hazardous waste storage area until ready for off-site shipment. This is a locked caged area. Hazardous waste generated from manufacturing buildings B20 and B40 and the laboratory areas are collected by the Total Waste Management (TWM) vendor or warehouse personnel. Waste is transported to a locked shipping container, located separate from the warehouse areas, where it is sorted and stored securely while awaiting offsite shipment. Hazardous waste of drug products or containers of Active Pharmaceutical Ingredients (API) are never stored outside of a secure location. All waste shipped off-site shall be packaged to meet all applicable requirements and in a manner to prevent any release during transportation. No Hazardous waste shall leave AbbVie site unless both the driver and the transport vehicle are fully compliant with the above requirements.

## H.5 Waste recycling and recovery

Describe how the activities at the installation contribute to national targets for the recycling and recovery of waste, not least:

- the preparing for reuse and the recycling of paper, metal, plastic and glass; and
- the preparing for reuse, recycling and other material recovery, including backfilling operations using waste to substitute other materials, of non-hazardous construction and demolition waste excluding naturally occurring material defined in category 17 05 04 in the list of waste.

State whether and describe how food waste will be managed in accordance with the requirements, as may be relevant, of the Waste Management (Food Waste) Regulations 2009.

Supporting information should form **Attachment N<sup>o</sup> H.5**.

An Environmental Specialist is appointed to promote recycling and recovery on-site. The procedures for recycling of paper, metal, plastic and glass will be outlined in the site's EMP. All employees are advised on managing non-hazardous waste. The Environmental Specialist will ensure the effective continual improvement of the EMP, through setting realistic objectives and targets, and reviewing progress on a regular basis.

Food waste will be managed in accordance with the Waste Management (Food Waste) Regulations 2009. The canteen area has dedicated waste containers for food waste.

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## SECTION I: EXISTING ENVIRONMENT & IMPACT OF THE ACTIVITY

**Describe the conditions of the site of the installation.**

**Provide an assessment of the effects of any emissions on the environment, including on an environmental medium other than that into which the emissions are made.**

**Describe, where appropriate, measures for minimising pollution over long distances or in the territory of other states.**

### I.1. Assessment of atmospheric emissions

Describe the existing environment in terms of air quality with particular reference to ambient air quality standards.

Existing air quality at the site was established during the preparation of the EIS by measuring ambient concentrations of sulphur dioxide, nitrogen dioxide and smoke. All values were well within relevant air quality standards, indicating a satisfactory air quality in the area i.e. no source of contamination prior to site development.

The EPA manages the national ambient air quality network. The Air Framework Directive deals with each EU member state in terms of "Zones". The Air Quality Standards Regulations 2011 state "The Agency shall establish zones and agglomerations throughout the territory of the State for the purpose of air quality assessment and air quality management". The zones and agglomerations are defined as follows:

Zone A: Dublin Conurbation

Zone B: Cork Conurbation

Zone C: Other large cities and towns comprising Galway, Limerick, Waterford, Clonmel, Kilkenny, **Sligo**, Drogheda, Wexford, Athlone, Ennis, Bray, Naas, Carlow, Tralee, Dundalk, Navan, Letterkenny, Celbridge, Newbridge, Mullingar, Balbriggan

Zone D: Rural Ireland, i.e. the remainder of the State excluding Zones A, B and C.

In accordance with the above information, background concentrations were taken for Zone C (which includes Sligo) from the EPA document - "Air Quality in Ireland 2013, Key Indicators of Ambient Air Quality" when carrying out air quality impact assessments as part of the thermal oxidiser installation.

Provide a statement as to whether or not emissions of main polluting substances (as defined in the Schedule of EPA (Industrial Emissions)(Licensing) Regulations 2013, S.I. No. 137 of 2013) to the atmosphere are likely to impair the environment.

Give summary details and an assessment of the impacts of any existing or proposed emissions on the environment, including environmental media other than those into which the emissions are to be made.

Air dispersion modelling (Report No: IE0311237-22-RP-0001) was carried out for this licence review application to assess the impact from the introduction of the new thermal oxidiser. The modelling indicated that the emissions have no significant effect on the environment and do not breach statutory Air Quality Standards. Report is included in Attachment I.1.

**Attachment N° I.1** should also contain full details of any dispersion modelling of atmospheric emissions from the activity, where required. When carrying out dispersion modelling, regard should be had to the EPA "Air Dispersion Modelling from Industrial installations Guidance Note (AG4)" or similar guidelines from a recognised authority.

Describe, where appropriate, measures for minimising pollution over long distances or in the territory of other states.

### I.2. Assessment of Impact on Receiving Surface Water

Describe the existing environment in terms of water quality with particular reference to environmental quality objectives and standards and any objectives and standards laid down for protected areas. Table I.2(i) should be completed.

Provide a statement whether or not emissions of main polluting substances (as defined in the Schedule of EPA (Licensing)(Amendment) Regulations 2004, S.I. No. 394 of 2004) to water are likely to impair the environment.

Indicate whether or not the activity complies with the requirements of the EC Environmental Objectives (Surface Waters) Regulations 2009, S.I. No. 272 of 2009.

If the discharge is to water body that is already achieving high status, or if the discharge is to waters draining to the surface water bodies identified under the First Schedule of the *EC Environmental Objectives (Freshwater Pearl Mussel) Regulations 2009*, compliance must be with the 95%ile **high** status limits.

Give summary details and an assessment of the impacts of any existing or proposed emissions on the environment, including environmental media other than those into which the emissions are to be made.

Full details of the assessment and any other relevant information on the receiving environment should be submitted as **Attachment N° I.2.**

For emissions outside emission limit established according to the combined approach, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting the upgraded standards is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the limits established in accordance with the combined approach.

All surface water from the facility is discharged into a small stream that passes through the property entering at the western boundary and generally flows from east to west until it reaches the eastern boundary of premises where it turns south along the boundary. It then flows westwards and shortly afterwards discharges to the estuary at Cartron. It flows through culverts under the Ballytivnan Road and also another business premises. There is some evidence to suggest that its source is a spring in a nearby field east of the proposed development but the flow is added to by drainage ditches in the locality.

#### Source of Surface Water;

Surface water discharge will originate from the roofs of buildings, hard paved areas (cars and truck parks) and internal circulation roads. The maximum rate of surface water emissions is no more than 0.62 m<sup>3</sup>/s.

Uncontaminated surface water run-off typically has a BOD of 5 -10 mg/l and a suspended solids concentration of 10-15 mg/l. These concentrations increase to about 20mg/l and 30mg/l respectively at times during the year and particularly in early autumn when the

heavier rains flush decaying vegetation such as grass clippings and leaves from the land. Uncontaminated surface water is normally discharged directly to the nearest surface water drainage system as it does not cause contamination. It is standard modern good practice to exclude surface water from municipal foul drainage systems.

The receiving waters affected by the site include:

1. Sligo Harbour
2. Doonally River
3. Stream

The stream acts as the receiving waters for surface water emissions. Prior to any discharge the surface water will pass through the retention pond which allows for monitoring of the discharge. The surface water emission point reference is known as SW1.

#### Sligo Harbour

Sligo Harbour is part of Sligo Bay and is effectively the estuary of the Garavogue River. It approximates to an east-west rectangle with a length of about 6km and a width of about 2km. Almost 90% of the estuary dries out at low water on spring tides leaving a well-defined river channel along the northern side. The navigation channel was dredged in 1985 to give a depth of 2.7m (chart datum) at low water spring tide. The amplitudes of the tides are about 3.3m for mean spring and 1.5m for mean neap. The main entrance of the estuary is between Deadman's Point and Coney Island.

The bay and estuary form an important amenity being used for angling, bathing at a number of beaches, boating, shell-fisheries and navigation. Cummeen Strand is internationally important because of its significant goose population. Sligo Bay has not been designated a sensitive area.

#### Doonally River

Doonally River flows along the northern and north-western part of AbbVie's property and a short distance later then discharges to the estuary at Cartron. It is an important river with a substantial ecological interest. The river was sampled and analysed by Forbairt in 1997 and is deemed to be in good condition.

The location of the site in relation to the Doonally River is such that the possibility of drainage from the site reaching it is remote.

#### Stream

A small stream passes through the property entering at the eastern boundary and generally flowing from east to west until it reaches the eastern boundary of AbbVie's existing premises where it turns south along the boundary. It then flows westwards and shortly afterwards discharges to the estuary Cartron. It flows through culverts under the Ballytivnan Road and also at a nearby field east of the proposed development but the flow is added to by drainage ditches in the locality. The stream was sampled and analysed by Forbairt in 1997 and is deemed to be in good condition.

The capacity of this stream is determined by a culvert which passes under Ballytivnan Road and another culvert downstream of this.

## Impact on Receiving Waters from AbbVie;

As stated previously, the stream which runs along the eastern boundary of the property is the receiving waters for surface water emissions. The stream due to its size has very low, or zero, amenity value.

There is a small chance that Lampreys, that are important fish species which are listed on Annex II of the Habitats Directive, could occur in the small stream. The most likely of these to occur is the Brook Lamprey (*Lampetra planeri*) as it is non-migratory and occurs in small streams, particularly in the limestone regions of Ireland. As the River Lamprey and Sea Lamprey are migratory species, living part of their lives in the sea, it is very unlikely that they would be found in the small stream within the property owing to the culverted lower section.

Owing to the calcareous nature of the area, consideration must be given to the possibility of the occurrence of the freshwater crayfish (*Austropotamobius pallipes*) in the small stream within the property or in the Doonally River. This species is protected under the Wildlife Act, 1976 and is also listed on Annex II of the Habitats Directive. Crayfish have been recorded from the Garvoge River in Sligo Town and at another site in the vicinity of Lough Gill. While the water quality and habitat of the small stream appear suitable, the fact that it is relatively short in length and not connected to a larger river system may lower the likelihood of its occurrence.

There will be no waste water discharge to the stream. The only discharge to this stream is from the single emission point (SW1) - the uncontaminated surface water. This will have minimal adverse impact on the stream.

The proposed works around the new thermal oxidiser increase the impermeable area of the site by approx. 1-2 % of the site area. The original surface water drainage system was originally designed to allow for future expansion. The sites surface water would continue to drain to the retention pond via a hydrocarbon interceptor before discharging to the on-site stream via a flow control device.

The mitigation measures as a result of the installation would follow the same strategy as previously. Measures included control of surface water runoff, the use of hydrocarbon interceptor, bunded tanks/ drum storage, adherence to the facilities Environmental Management Programme, loading/unloading of the chemicals in bunded areas and regular testing of bunds, drains, lines and also continuous surface water monitoring.

It is deemed that the proposed thermal oxidiser installation will have negligible impact on the surface waters.



### I.3. Assessment of Impact of Sewage Discharge.

Give summary details and an assessment of the impacts of any existing or proposed emissions on the environment, including environmental media other than those into which the emissions are to be made.

With regard to Article 15 of the Industrial Emissions Directive (or Section 86A(8) of the EPA Act 1992, as amended), describe how the environment as a whole is provided an equivalent level of protection and will not lead to higher levels of pollution in the environment.

Full details of the assessment and any other supporting information should form **Attachment N° I.3.**

The proposed installation will generate additional process wastewater due blow down from the new scrubber. The additional process wastewater volumes will be approximately 2m<sup>3</sup>/day. AbbVie's licence limit is 300m<sup>3</sup>/day. The average daily discharge is approximately 191m<sup>3</sup>/day, therefore even with the proposed increases, the daily discharges would still be well below the limit. Monitoring as per the licence would continue as before. Any emissions will be treated along with the rest of the sites effluent to comply with the emission limit values as set out in the licence before release to the public sewer.

Sources of Sewer Discharge at AbbVie;

- Direct process waste water from production
- Indirect process waste water from production
- Utility waste water
- Sanitary waste water

This wastewater is discharged to sewer if its within the limits of the sites licence limits, and sent to treatment by Sligo County Council Waste Water Treatment Plant

Sligo County Council – Waste Water Treatment Plant (now Irish Water operated);

The sewerage network in Sligo is a combined drainage system which gets processed by the WWTP before being discharged to the Garavogue estuary. The following methods are carried out by the Waste Water Treatment Plant (WWTP) plant which has a design PE of 50,000:

- Preliminary treatment
- Storm overflow
- Primary treatment
- Secondary treatment - activated sludge
- Chemical dosing for phosphorus removal
- Tertiary treatment – UV treatment

In compliance with their license influent streams are monitored monthly to check levels of BOD, COD, Suspended Solids, Total Nitrogen and Total Phosphorous. This data is available online on the EPA website in the AER which the WWTP publish in compliance with their license (D0014-01).

The WWTP discharges the purified water to the Garavogue River estuary. The council also conduct ambient monitoring in eight locations to ensure that the water discharged from the WWTP has no adverse effects to the receiving waters. The results of that monitoring for the past five years are as follows:

Description	Ecological Status				
	2010	2011	2012	2013	2014
Station 1 – Blue Lagoon	Good	Good	Good	Good	Good
Station 2 – JFK Parade	Good	Good	Good	Good	Good
Station 3 – Key Street Car Park	Good	Good	Good	Good	Good
Station 4 – Hughes Bridge	Good	Good	Good	Good	Good
Station 5 – Deepwater Quay	Good	Good	Good	Good	Good
Station 6 – 1 mile Downstream of Outlet	Good	Good	Good	Good	Good
Station 7 – Cummeen Strand	Good	Good	Good	Good	Good
Station 8 – Rosses Point (End of Main Pier)	Good	Good	Good	Good	Good

The installation of the new thermal oxidiser will have negligible impact on the WWTP's ability to treat incoming effluent to BAT standards. In conclusion it is evident that the WWTP has no adverse effects to the receiving waters it discharges into based on the ambient monitoring results of the past five years. Consequently AbbVie's discharge into the Sligo County Council sewerage system will have no adverse effect on the receiving waters.

A letter of no objection is included from Sligo County Council in relation to Technical Amendment C which requested an increase in the discharge limit from the site 230m<sup>3</sup> to 300m<sup>3</sup> and an increase in the Temperature limit from 25°C to 40°C.

AbbVie continue to comply with the conditions that were set out in this letter as well the conditions of their current Industrial Emissions licence with the (Attachment I.3).

#### I.4 Assessment of Impact of Ground/Groundwater Emissions

##### Baseline Report

In the case of an activity that involves the use, production or release of relevant hazardous substances (as defined in section 3 of the EPA Act 1992 as amended), and having regard to the possibility of soil and groundwater contamination at the site of the installation, provide a baseline report in accordance with section 86B of the EPA Act 1992 as amended. Has the Agency indicated in pre-application discussions that a baseline report is required?

A baseline report shall contain the information necessary to determine the state of contamination of soil and groundwater at the time the report is drawn up in order that a quantified comparison may be made to the state of the site upon the permanent cessation of the industrial emissions directive activity.

Guidance in relation to baseline reports is available on the EPA website at [www.epa.ie](http://www.epa.ie).

The Baseline Report should be included in **Attachment I.4** and clearly labelled as such.

Describe the existing groundwater quality. Tables I.4 (i) should be completed.

There are no emissions to ground. The Baseline Report (Attachment I.4) attached to this licence review application contains information related to the current state of the groundwater. Biannual groundwater monitoring is carried out as per the conditions of the licence and report in the AER.

Give summary details and an assessment of the impacts of any existing or proposed emissions on the ground (aquifers, soils, sub-soils and rock environment), including any impact on environmental media other than those into which the emissions are to be made. This includes landspreading, land injection etc.

Land on which material may be landspread shall be identified on a suitable scaled map (1:10,560 and 1:50,000) and submitted as no greater than A3 size. All vulnerable (as a result of ground emissions) surface water bodies must be identified on these maps. Additional information should be included in **Attachment N° I.4**.

Not applicable. Land spreading is not undertaken by AbbVie.

**Attachment N° I.4** should also contain full details of any modelling carried out of the potential impact of emissions from the activity on groundwater.

Landspreading of Agricultural/Non Agricultural Wastes

Tables I.4(ii) and I.4.(iii) should be complete where applicable. Further information is available in the Application Guidance Document.

#### I.5 Ground and/or Groundwater Contamination

Summary details of known ground and/or groundwater contamination, historical or current, on or under the site must be given.

There are no emissions to ground.

The latest Bi-annual Groundwater Monitoring report submitted with this application provides detailed information on the current conditions of the site. In Summary, the groundwater monitoring results at the site show elevated concentrations of conductivity, chloride, sulphate, iron and manganese. Historically, slightly elevated concentrations of COD, orthophosphate, ammonia and sulphate have been seen in groundwater on site. This poor groundwater quality is most likely related to both agricultural activities up-gradient of the site (e.g. fertiliser application, lands spreading) and possibly a leaking foul sewer on site or in the vicinity of the site as evidenced by the elevated conductivity and chloride at MW-2 and MW-4. Full details of the methods, analysis and results are contained in the attached Baseline Report.

Indicate whether or not compliance with the requirements of the EC Environmental Objectives (Groundwater) Regulations 2010, S.I. No. 9 of 2010 can be achieved.

Full details including all relevant investigative studies, assessments, or reports, monitoring results, location and design of monitoring installations, plans, drawings, documentation, including containment engineering, remedial works, and any other supporting information should be included in **Attachment N° I.5**.

#### I.6 Assessment of the Environmental Impact of On-site Waste Recovery and/or Disposal.

Describe the arrangements for any on-site recovery and disposal of waste generated by the activity.

Give details and an assessment of the impact of any existing or proposed on-site waste recovery or disposal activities on the environment, including environmental media other than those into which the emissions are to be made.

Waste management at this facility will be carried out in accordance with the Waste Management Act 1996, as amended. The arrangements in place are outlined below:

- Regular meetings are held with Department Managers to ensure that current and new processes are reviewed to minimise the creation of waste. If waste cannot be eliminated, suitable outlets are sourced where it can be recycled, treated or disposed (in that order).
- Good housekeeping is observed at all times. This will ensure that waste creation is minimised.
- The inventory is managed in a way that does not lead to the creation of waste, i.e. materials are only stocked as required, not in large quantities.
- All technologies and abatement equipment is operated efficiently, and is not generating additional waste. This is ensured through the preventative maintenance programme.
- Technological reviews based on engineering waste out of the process are incorporated through process reviews.
- Material substitution is considered through process reviews, i.e. hazardous materials are replaced by less hazardous materials.
- The site's Environmental Specialist incorporates all waste minimisation and recycling projects into the Environmental Management Plan EMP.
- In relation to the treatment and disposal of hazardous waste the Environmental Specialist shall, in consultation with the waste disposal company, recover, treat and/ or dispose of AbbVie waste in a manner that takes into consideration clean technology. For example solvent waste from the process will be stored in a bulk tank and taken off-site by road tanker for disposal.
- Waste solvent is collected by the on-site solvent stripper, stored in tanks and transported off site for recovery. The operation of the solvent stripper has not changed significantly since the 2005 licence review application. The operation of the new thermal oxidiser will not have an impact on the solvent stripper collection system.

This information should form **Attachment N<sup>o</sup> I.6.**

### I.7 Noise Impact

Give details and an assessment of the impacts of any existing or proposed noise emissions on the environment, including environmental media other than those into which the emissions are to be made.

Baseline noise monitoring was carried out during the preparation of the original EIS at 3 No. locations around the site for a maximum of 60 minutes. Noise levels were generally low, though there was some local traffic and activity noise; i.e. no noise issues prior to site development.

Noise monitoring is carried out annually at 4 No. boundary locations as well as 3 No. locations off-site. Results of the 2014 noise monitoring which was submitted in the site's AER for 2014 show that the noise limits as set in the site's current Industrial Emissions Licence were fully complied with.

The new thermal oxidiser is replacing an existing thermal oxidiser. Predicted calculations indicate that there will be negligible impact from the new installation.

Once operational, noise emissions from the new thermal oxidiser will be monitored as part of the annual noise survey. It is proposed to perform one last annual noise survey during the period when the new thermal oxidiser is operational and to cease annual environmental noise monitoring after this if the results are within the limits. The site has conducted annual noise surveys since it first went operational and has an impeccable record with no emission limit failures or complaints. The results for the 2014 annual noise survey are included in the latest AER which is included as Attachment B.14.

#### Ambient noise measurements

Complete Table I.7 (i) in relation to the information required below:

- (i) State the maximum Sound Pressure Levels which will be experienced at typical points on the boundary of the operation. (State sampling interval and duration)
- (ii) State the maximum Sound Pressure Levels which will be experienced at typical noise sensitive locations, outside the boundary of the operation.
- (iii) Give details of the background (or residual) noise levels experienced at the site in the absence of noise from this operation.

Prediction models, maps (no larger than A3), diagrams and supporting documents, including details of noise attenuation and noise proposed control measures to be employed, should form **Attachment N° I.7**.

### **I.8 Environmental Considerations, Main alternatives and BAT**

**I.8a** Describe in outline the main alternatives to the proposed technology, techniques and measures which were studied having regard to the reference document on Economic and Cross-media Effects

A direct fired thermal oxidiser is the best technology for the proposed use.

Alternative technologies such as cryogenics, catalyst replacement and a regenerative thermal oxidation were evaluated as part of the project.

Jacobs Engineering carried out a VOC Abatement System Concept Study examining the suitability of each technology. It was concluded that thermal oxidation would be the technology of choice as it has proven to be robust and reliable and is utilised in the majority of API manufacturing sites in Ireland.

PM Group subsequently produced a report "Thermal Oxidiser Technology Assessment" (IE0311237-41-RP-0001) to assess which type of thermal oxidiser would meet AbbVie's requirements. This is included in Attachment I.8.

**I.8b** Identify in the table below all relevant decisions on BAT Conclusions (Commission Implementing Decision (CID)), BAT reference document(s) (BREFs) and EPA BAT guidance document(s) having regard to the activities and processes proposed or carried out at the installation.

These documents are available on the European IPPC bureau website at <http://eippcb.jrc.ec.europa.eu/reference/> and the EPA website [www.epa.ie](http://www.epa.ie).

Relevant BAT guidance documents applicable include:

<b>Title of Document</b>
BREF on Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector
BREF on Organic Fine Chemicals / EPA Note on BAT
BREF on General Principles of Monitoring
BREF on Energy Efficiency
BREF on Emissions from Storage

**1.8c** In order to determine BAT for the installation, tabulate using table I.8(i) below, all of the BAT conclusions from the relevant decision on BAT Conclusions (CID) or where this has not been adopted by the Commission of the European Union, the conclusions on BAT from the relevant BAT reference documents (BREF). To assist you with this, some pre-populated template documents are available for download on the EPA website <http://www.epa.ie/pubs/forms/lic/industrial%20emissions/>

For each BAT, in Table I.8(i), state whether it is applicable to your installation and describe how each BAT applies or not to your installation and provide information on your compliance with the requirement.

It may be useful to first identify all the 'Not Applicable' BATs and provide your reasoning in the 'Applicability Assessment' box as to why you consider this particular BAT is not applicable at/to your entire installation having regard to the scope/ definitions, general considerations and the information on applicability. (You may need to make reference to relevant processes/activities or individual emission points to provide a comprehensive response).

For each applicable BAT, state the status; 'Yes', 'Will be' or 'No' as appropriate, the use of each of these terms is described below. Information on compliance in the 'Applicability Assessment' box should include, where applicable, the following:

- (i) Identification of the relevant process/ activity or individual emission points that the BAT requirement applies to at your installation;
- (ii) Where BAT is to use one or a combination of listed techniques, specify the technique(s) implemented/proposed at your installation to achieve the BAT;
- (iii) In relation to emissions the emission level achieved at the installation under normal conditions as compared with the BAT associated Emission Levels (only applicable to decisions on BAT conclusions); and

- (iv) A comment on how the requirements are being met or will be met, e.g., a description of the technology/operational controls/management proposed to meet the requirements.

Use of terms:

- (a) 'Yes' – To be selected where the installation is currently compliant with this BAT requirement.
- (b) 'Will be' – To be selected where a further technique is required to be installed to achieve compliance with the BAT requirement. In this case you must also specify the date by which the installation will comply with the BAT Conclusion requirement.
- (c) 'No' – (only applicable to decisions on BAT Conclusions) To be selected where the achievement of emission level associated with BAT as described in a decision on BAT conclusions would lead to disproportionately higher costs compared to the environmental benefits due to –
- (i) the geographical location or the local environmental conditions of the installation concerned, or
  - (ii) the technical characteristics of the installation concerned.

Note: By selecting 'No' to an applicable emission level associated with a BAT requirement you are required to provide a detailed assessment that includes the reason and justification, in accordance with the requirements of Section 86A(6) of the EPA Act 1992 as amended.

Please note the following:

- I. Refer to the EPA BAT Guidance Note relevant to the sector for BAT associated emission levels in the circumstances where a relevant decision on BAT Conclusions has not been adopted by the European Commission i.e. no CID in place.
- II. Where a decision on BAT conclusion or conclusion on BAT from a BAT reference document does not apply to activities/ processes or certain aspects of an installation, refer to the relevant EPA BAT Guidance Note(s) for the determination of BAT.

### **I.8d Emerging Techniques**

State whether you propose to test and use an 'emerging technique' in particular those identified in the BAT reference documents relevant to the activity:

Yes       No

If yes, describe your proposal and include in **Attachment N° I.8d**.

### **I.8e Other relevant conclusions on BAT**

Please note that other reference documents may be relevant such as:

- (a) BREF on Common waste water and waste gas treatment/management systems in the Chemical Sector;
- (b) BREF on Emissions from Storage;
- (c) BREF on Energy Efficiency;
- (d) BREF on Industrial Cooling Systems;

[Comprehensive BAT Reviews have been performed and the applicability assessment tables are included in Attachment I.8](#)

Other documents that may be relevant:

- (a) REF on Economic and Cross-media Effects;
- (b) REF on Monitoring of Emissions from IED installations;
- (c) Landfill Directive 1999/31/EC etc.

In this case tabulate using table I.8(i) below all the relevant BAT conclusions. Complete a separate table for each BREF and follow the instructions given above. To assist you with this, some pre-populated template documents are available for download on the EPA website <http://www.epa.ie/pubs/forms/lic/industrial%20emissions/>

**I.8f** Describe any environmental considerations which have been made with respect to the use of cleaner technologies, waste minimisation and raw material substitution.

AbbVie has a continuous programme of investment to ensure that all appropriate environmental abatement technologies are in situ, maintained and in good working order. It has a range of policies and programmes in place on site to identify cleaner technologies, waste minimisation and material substitution.

- Environmental Management System
- Energy Audits
- Procedures and change control systems that consider environmental impacts from new processes

**I.8g** Describe the measures proposed or in place to ensure that:

- (a) The best available techniques are or will be used to prevent or eliminate or, where that is not practicable, generally reduce an emission from the activity;

A direct fired thermal oxidiser is the best technology for the proposed use. Extensive research has been carried out in the area of VOC abatement technologies.

- (b) no significant pollution is caused;

Direct fired thermal oxidation is a proven technology choice. It has proven to be robust and reliable and is utilized in the majority of API manufacturing sites in Ireland to manage compliance with air emission limits, hence no significant pollution will be caused.

- (c) waste production is avoided in accordance with the waste hierarchy in Council Directive 98/2008/EC on waste and section 21A of the Waste Management Act 1996, as amended; where waste is produced, it is prepared for re-use, recycled or recovered or, where that is technically and economically impossible, it is disposed of while avoiding or reducing any impact on the environment (applicants should provide this information in the context of sections 29(2A), 32 and 38(5A) of the Waste Management Act 1996, as amended);

Waste management at this facility will be carried out in accordance with the Waste Management Act 1996, as amended. This is discussed in detail in Section H.

- (d) energy and other resources are used efficiently;

AbbVie's Energy Policy and procedures are discussed in Section G.

- (e) the necessary measures are taken to prevent accidents and limit their consequences;



AbbVie has identified and assessed the potential for emergency situations on site and have developed an Emergency Preparedness and Response Plan for effective response to emergency situations including environmental incidents. The procedure includes the identification of potential emergency situations. The site periodically tests its emergency preparedness to improve its effectiveness of its response activities and procedures, and revise documents as appropriate after testing. (SOP SLI-EHS-018 Emergency Preparedness and Response Procedure)

- (f) the necessary measures are taken upon definitive cessation of activities to avoid any pollution risk and return the site of operation to a satisfactory state.

A Closure Plan has been prepared that details the measures to be undertaken at the site in order to prevent possible environmental damage as a result of cessation activities at the site. It also details remedial and corrective actions that may have to be carried out should environmental pollution occur at the site.

The scope of this plan addresses the key issues, which would occur in an orderly shutdown of all or part the site activities; i.e. well planned and well financed. It is envisaged that a complete shutdown would take place on a phased basis over an estimated time period of 9-12 months.

The scope of the plan includes the following major activities:

- Setting up a management structure to oversee the Closure Plan;
- Cessation of all production activities;
- Removal of all remaining raw materials, intermediates and final products from the site;
- Cleaning and decontamination of all equipment and buildings;
- Shutting down of all environmental and utility systems;
- Completion of report on all aspects of the site within 60 days of completion of plan activities;
- Maintaining an on-going security and environmental monitoring service.

Supporting information should form **Attachment N<sup>o</sup> I.8a to g.**

**Table I.8 (i) CONCLUSIONS ON BAT** (One table for each relevant BAT reference document)

<b>Title of Document</b>			
<b>BAT reference Number</b>	<b>BAT Statement</b>	<b>Applicability Assessment</b>	<b>State technique and whether it is in place or state schedule for implementation</b>
<i>e.g. BAT 1</i>	<i>BAT is to implement and adhere to an environmental management system (EMS) that incorporates all of the following features:....</i>	<i>Applicable</i>	<i>Standardised EMS in place</i>
<b>Title of Document</b> <i>e.g Emissions from storage BREF</i>			
<i>5.1.1.2</i>	<i>BAT is to cover open top tank by applying a floating cover, flexible or tent cover or a rigid cover</i>	<i>One open top tank on-site</i>	<i>Proposed to cover with floating cover in 2015</i>


Comprehensive BAT Reviews have been performed and the applicability assessment tables are included in Attachment I.8



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## SECTION J: ACCIDENT PREVENTION & EMERGENCY RESPONSE

Describe the existing or proposed measures, including emergency procedures, to minimise the impact on the environment of an accidental emission or spillage.

Also outline what provisions have been made for response to emergency situations outside of normal working hours, i.e., during night-time, weekends and holiday periods.

Supporting information should form **Attachment N<sup>o</sup> J**.

AbbVie has identified and assessed the potential for emergency situations on site and have developed an Emergency Preparedness and Response Plan for effective response to emergency situations including environmental incidents. The procedure includes the identification of potential emergency situations. The site periodically tests its emergency preparedness to improve its effectiveness of its response activities and procedures, and revise documents as appropriate after testing. (SOP SLI-EHS-018 Emergency Preparedness and Response Procedure)

In order to ensure that all potential emergency situations have been identified consideration is given to emergencies which could occur during both normal and abnormal conditions.

Emergency planning is reviewed as part of management of change as changes in operations can introduce new potential emergencies. (SOP SLI-EHS-060 EHS Management of Change)

The site assesses how emergency situations will impact all persons and consider all employees, contractors, visitors, emergency services, the EPA, Local Authorities, and neighbours and other members of the public.

Emergency response at the site focuses on the prevention of ill health, injury, environmental damage and on the minimisation of adverse EHS consequences.

The emergency response plan also identifies legal and corporate requirements.

A copy of the emergency preparedness and response plan is maintained at emergency centres for ready available use by the ERT team, senior management and the emergency services.

AbbVie reviews its emergency preparedness and response at a minimum on an annual basis and also;

- During management reviews
- Following organisational changes
- As a result of management of change or identification of corrective or preventative actions
- Following an activation of the emergency response procedure
- Following drills or tests that identified deficiencies in the emergency response
- Changes in legal or corporate requirements
- Following external changes impacting the emergency response

When changes are made in emergency preparedness and response procedures, these changes are communicated to personnel and functions that are impacted by the change through the EHS department and their training needs will be evaluated.

The emergency response plan is included as **Attachment J**.

## **SECTION K: REMEDIATION, DECOMMISSIONING, RESTORATION & AFTERCARE**

Describe the existing or proposed measures to minimise the impact on the environment after the activity or part of the activity ceases operation, including provision for post-closure care of any potentially polluting residuals.

There is an explicit requirement in EU and Irish law for financial provision for landfills and extractive waste facilities. For new activities subject to the requirements of the Landfill Directive (1999/31/EC) and the Extractive Waste Directive (2006/21/EC) that are not already licensed by the Agency, state whether the following have been prepared:

- an Environmental Liabilities Risk Assessment (ELRA);
- a Closure, Restoration and Aftercare Management Plan (CRAMP); and
- a proposal for Financial Provision that covers all liabilities identified in the ELRA and CRAMP.

Regard should be had by applicants to relevant Agency guidance on these matters.

Copies of any relevant documents and any supporting information should be included as Attachment No. K.

The Agency may prioritise other sectors (e.g. contaminated land, risk of waste facility closure liabilities, risk based on Seveso classification) and require the preparation of a proposal for financial provision before making a decision on a licence application. Applicants are advised to discuss the requirement for financial provision with the Agency prior to making an application.

The Environmental Liabilities Risk Assessment (ELRA) and Closure Plan were updated in accordance with 2014 EPA Guidance "Assessing and Costing Environmental Liabilities" as part of this licence review application. The document is included in Attachment K (PM Report No. IE0311237-22-RP-0007).

A Financial Provision instrument will be agreed with the EPA following acceptance of the costs associated with the updated ELRA and Closure Plan.

Supporting information should be included as **Attachment No. K.**

## SECTION L: STATUTORY REQUIREMENTS

Indicate how the requirements of section 83(5)(a)(i) to (v) and (vii) to (xa) of the Act of 1992 shall be met, having regard, where appropriate, to any relevant specification issued by the Agency under section 5(3)(b) of that Act or any applicable best available techniques (BAT) conclusions adopted in accordance with Article 13(5) of the Industrial Emissions Directive and the reasons for the selection of the arrangements proposed.

*83(5) The Agency shall not grant a licence or revised licence for an activity—*

*(a) unless it is satisfied that;*

*(i) any emissions from the activity will not result in the contravention of any relevant air quality standard specified under section 50 of the Air Pollution Act 1987, and will comply with any relevant emission limit value specified under section 51 of the Air Pollution Act 1987.*

Air dispersion modelling was carried out for this licence review application to take account for the introduction of the new new thermal oxidiser. The modelling indicated that the emissions have no significant effect on the environment and do not breach statutory Air Quality Standards.

*(ii) any emissions from the activity will comply with, or will not result in the contravention of, any relevant quality standard for waters, trade effluents and sewage effluents and standards in relation to treatment of such effluents prescribed under section 26 of the Local Government (Water Pollution) Act 1977, 23 [No. 27.] Protection of the Environment Act [2003] 2003. Pt.2 S.15 24.*

The proposed new development will not result in any change to emissions to surface water or sewer. The aqueous waste streams will be tested in accordance with Condition 6.7 of the licence to ensure they are suitable for release to sewer. Emissions to surface water will continue to comply with the conditions of the current Industrial Emissions Licence.

*(iii) any emissions from the activity or any premises, plant, methods, processes, operating procedures or other factors which affect such emissions will comply with, or will not result in the contravention of, any relevant standard including any standard for an environmental medium prescribed under regulations made under the European Communities Act 1972, or under any other enactment.*

The relevant standards for emissions to air and water have been discussed in Section E: Emissions. Emissions from the facility will not result in the contravention of any relevant standard including any standard for an environmental medium prescribed under Regulations made under the European communities Act, 1972, or under any other enactment.

*(iv) any noise from the activity will comply with, or will not result in the contravention of, any regulations under section 106.*

The operation of the facility does not contribute to elevated noise levels at noise sensitive locations surrounding the site. Furthermore, the plant does not contribute to tonal or impulsive components at these locations. The proposed changes will not result in a significant increase in noise emissions from the facility. Therefore, it is concluded that the facility will continue to comply with section 106 of the EPA act, 1992.

*(v) any emissions from the activity will not cause significant environmental pollution.*

The preceding sections of this licence application demonstrate that the operation of the facility does not and will not cause any significant environmental pollution.

*(vi) the best available techniques will be used to prevent or eliminate or, where that is not practicable, generally to reduce an emission from the activity.*

The plant utilises BAT. The new thermal oxidiser is BAT for the abatement of emissions to air.

*(vii) having regard to Part III of the Act of 1996, production of waste in the carrying on of the activity will be prevented or minimised or, where waste is produced, it will be recovered or, where that is not technically or economically possible, disposed of in a manner which will prevent or minimise any impact on the environment.*

The management of waste at the facility is described in Section H.2 to H5 of this application. Waste Management forms part of the site sites waste management policy which ensures the proper management of waste on site. This ensures that waste is managed based on the waste management hierarchy and ensures that all waste is handled, stored, labelled, transported and treated/disposed off-site in accordance with statutory requirements and best practice. Only contractors with the appropriate waste permits and/or licences are used to transport and treat/dispose of the waste. All of the above ensures that any potential impact on the environment resulting from waste generated by the facility is prevented or minimised.

*(viii) energy will be used efficiently in the carrying on of the activity.*

An energy audit was carried out in April 2014. In carrying out the audit, the auditors conducted a series of meetings with key site personnel. Energy and utility data provided by Abbvie was reviewed and a series of tours were conducted around the site. The objective of the audit was to establish how much energy is being used, where it is being used, the principal users and to identify potential areas where energy savings could possibly be made.

The energy audit presents an overview of energy management on the site and makes recommendations on energy management. Energy management is incorporated into the Environmental Management System and therefore is part of the continual improvement programme for the site. The new thermal oxidiser has been designed to use energy efficiency.

*(ix) necessary measures will be taken to prevent accidents in the carrying on of the activity and, where an accident occurs, to limit its consequences for the environment and, in so far as it does have such consequences, to remedy those consequences.*

An accident prevention plan is in place at the Abbvie facility along with specific accident response procedures. Procedures implemented on site regarding these situations will be adhered after the proposed project is complete. The proposed changes do not alter the requirements of these procedures.

*(x) necessary measures will be taken upon the permanent cessation of the activity (including such a cessation resulting from the abandonment of the activity) to avoid any risk of environmental pollution and return the site of the activity to a satisfactory state.*

The site will be decommissioned in accordance with the relevant national and international law in force at the time and in accordance with best practice. An Environmental Liabilities Risk Assessment (ELRA) and Closure Plan have been prepared for the site which details decommissioning/residuals management. The implementation of the Closure Plan will ensure the site is decommissioned in a safe and environmentally sound manner such that any risk of environmental pollution is avoided, the site is

returned to a satisfactory state and that there is no residual risk to human health or the environment. The ELRA and Closure Plan have been prepared in compliance with condition 10 and condition 12.3 of the current licence.

*(xi) the applicant or licensee or transferee, as the case may be, is a fit and proper person to hold a licence.*

AbbVie and the management are fit and proper persons, with the necessary skills, experience and resources to operate the facility in full compliance with the licence requirements. This is discussed in more detail in Section C: Management of the Installation.

Indicate whether or not the activity is carried out, or may be carried out, or is located such that it is liable to have an adverse effect on -

- (a) a site placed on a list in accordance with Part 3 of S.I. 477 of 2011, or
- (b) a site where consultation has been initiated in accordance with Article 5 of the EU Habitats Directive (92/43/EEC).

No part of the facility site or its immediate surroundings is covered by a scientific or conservation designation as recognised by S.I. No. 477/2011 - European Communities (Birds and Natural Habitats) Regulations 2011, The Heritage Service such as a Natural Heritage Area (NHA), a Special Protection Area (SPA) or a Special Area of Conservation (SAC). Air dispersion modelling has shown that emissions to atmosphere from the facility will not give rise to ground level concentrations of pollutants which could have an adverse impact on any designated area. Emissions to other media will not change with the proposed development i.e. effluent, surface water, noise.

Undertake a screening for Appropriate Assessment and state whether the activity, individually or in combination with other plans or projects, is likely to have a significant effect on a European Site(s), in view of best scientific knowledge and the conservation objectives of the site(s). Where it cannot be excluded, on the basis of objective scientific information, following screening for Appropriate Assessment, that an activity, either individually or in combination with other plans or projects, will have a significant effect on a European Site, provide a Natura Impact Statement, as defined in Regulation 2(1) of the European Communities (Birds and Natural Habitats) Regulations (S.I. No. 477 of 2011). Where based on the screening it is considered that an Appropriate Assessment is not required, provide a reasoned response.

Screening for Appropriate Assessment was undertaken as part of this licence review application. The conclusions from the screening report are that there will be no adverse effect on (a) a site placed on a list in accordance with Part 3 of S.I. 477 of 2011, or on (b) a site where consultation has been initiated in accordance with Article 5 of the EU Habitats Directive (92/43/EEC). A copy of the screening report is included in attachment B.6.

Indicate whether or not the activity is liable to have an adverse effect on water quality in light of the European Communities Environmental Objectives (Surface Water) Regulations 2009 (S.I. No. 272 of 2009).

The activity is not liable to have an adverse effect on water quality in light of the European Communities Environmental Objectives (Surface Waters) Regulations 2009 (S.I. No. 272 of 2009). The operation of the new thermal oxidiser will not change this conclusion.

Indicate whether or not the activity is liable to have an adverse effect on water quality in light of the European Communities Environmental Objectives (Ground Water) Regulations 2010 (S.I. No. 9 of 2010).

The activity is not liable to have an adverse effect on water quality in light of the European Communities Environmental Objectives (Ground Waters) Regulations 2010 (S.I. No. 9 of 2010). The operation of the new thermal oxidiser will not change this conclusion.

Indicate whether any of the substances specified in the Schedule of the EPA (Industrial Emissions)(Licensing) 2013, S.I. No. 137 of 2013, are discharged by the activity to the relevant medium.

Substances emitted to air and water from the facility which fall under the Schedule of the EPA (Licensing) (Amendment) Regulations, 2004 are listed in the Table below.

<b>Environmental Medium</b>	<b>Substance</b>
Air (Refer to Tables E.1(ii), (iii) and (iv))	Sulphur dioxide and other Sulphur compounds
	Oxides of Nitrogen and other Nitrogen compounds
	Carbon Monoxide
	Volatile Organic Compounds
	Dust
Water (Refer to Table E.2(ii))	Materials in Suspension Substances which can have an unfavourable influence on oxygen balance (BOD)

The abatement/control technologies used to prevent / minimise the emissions of these substances can be considered BAT and the emissions of these substances from the facility will not cause any significant environmental pollution.



Indicate if the best environmental practices are in place for control of diffuse emissions from the installation as set out in the following legislation:

- (a) a BAT Conclusions Implementing Decision published by the EC.

A review has been completed of BAT associated with the new thermal oxidiser. The BREFS are summarised in section I.8.

- (b) a specification prepared by the Agency in accordance with Section 5 of the *Environmental Protection Agency Act 1992* as amended;

The abatement of emissions to air by the new thermal oxidiser is considered BAT.

- (c) the *Urban Waste Water Treatment Regulations 2001 (S.I. No. 254 of 2001)* as amended by the *Urban Waste Water Treatment (Amendment) Regulations 2004 (S.I. No. 440 of 2004)* or any future amendment thereof;

S.I. No. 254 of 2001 is not applicable to the activity.

- (d) the *European Communities (Good Agricultural Practice for Protection of Waters) Regulations 20 (S.I. No. 610 of 2010)* or any future amendment thereof;

S.I. No. 610 of 2010 is not applicable to the activity.

- (e) the *Local Government (Water Pollution) Act, 1977 (Control of Cadmium Discharges) Regulations 1985 (S.I. No. 294 of 1985)*;

S.I. No. 294 of 1985 is not applicable to the activity.

- (f) the *Local Government (Water Pollution) Act, 1977 (Control of Hexachlorocyclohexane and Mercury Discharges) Regulations 1986 (S.I. No. 55 of 1986)*;

S.I. No. 55 of 1986 is not applicable to the activity.

- (g) the *Local Government (Water Pollution) Acts, 1977 and 1990 (Control of Carbon Tetrachloride, DDT and Pentachlorophenol Discharges) Regulations 1994 (S.I. No. 43 of 1994)*; and,

S.I. No. 43 of 1994 is not applicable to the activity.

- (h) measures or controls identified in a pollution reduction plan for the river basin district prepared in accordance with Part V of the *EC Environmental Objectives (Surface Waters) Regulations 2009 S.I. No. 272 of 2009* for the reduction of pollution by priority substances or the ceasing or phasing out of emissions, discharges and losses of priority hazardous substances.

S.I. No. 43 of 1994 is not applicable to the activity.

Supporting information should be included as **Attachment N<sup>o</sup> L** with reference to where the information can be found in the application.

**SECTION M: DECLARATION**

**Declaration**

I hereby make application for a ~~licence~~ revised licence, pursuant to the provisions of the Environmental Protection Agency Act, 1992, as amended, and Regulations made thereunder.

I certify that the information given in this application is truthful, accurate and complete.

I give consent to the EPA to copy this application for its own use and to make it available for public inspection via the EPA's website. This consent relates to this application itself and to any further information, submission, objection, or submission to an objection whether provided by me as Applicant or any person acting on the Applicant's behalf.

**Signed by:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
(on behalf of the organisation)

**Print signature name:** \_\_\_\_\_

**Position in organisation:** \_\_\_\_\_

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Company stamp or seal:

## **ANNEX 1: TABLES/ATTACHMENTS**

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**TABLE D.2 (i) Waste Acceptance (type and quantities) Not Applicable – No waste acceptance activities**

Rows should be added to the table as necessary.

EWC Code	Waste description (the <u>actual</u> description of the waste, not the text accompanying the EWC code)	Tonnes per annum (existing)	Tonnes per annum (proposed)

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**TABLE D.3 (III) LINER SYSTEM** Not Applicable – No landfill activities

	y/n
Provide information in Attachment D.3 to fulfil Annex 1 of the Landfill Directive	
Is the type of liner system specified?	
Has a Quality Control Plan been specified?	
Has a Quality Assurance Plan been specified?	
Has independent, third-party supervision, testing and controls been specified?	
Have basal gradients for all cells and access ramps to the cells been designed?	
Has a leak detection system been specified?	

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**TABLE D.3(IV) LEACHATE MANAGEMENT ARRANGEMENTS** Not Applicable – No landfill activities

	y/n
Is there a Leachate Management Plan?	
Have annual quantities of leachate been calculated?	
Has the total quantity of leachate been calculated?	
Has the size of the cells been specified taking account of the water balance calculations?	
Has a leachate collection system been specified?	
Has a leachate storage system been specified?	
Has a system for monitoring the level of leachate in the waste been designed?	
Is leachate recirculation proposed/practised?	
Has leachate treatment on-site been specified?	
Has leachate removal been specified?	

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**Table D.3(v)a. Landfill Gas Management** Not Applicable – No landfill activities

	y/n
Is there a Landfill Gas Management Plan?	
Is there a passive venting system?	
Does the passive system cover all of the filled area?	
Have gas alarm systems been installed in the site buildings?	
Have measures been installed to prevent landfill gas migration (e.g. barriers)?	
Has a time-scale been proposed for the installation of landfill gas infrastructure?	
Is gas flaring undertaken at the site?	
Is there an active (i.e., pumped) landfill gas extraction system?	
Does the active system cover all of the filled area?	
Is landfill gas used to generate energy at the site?	
Have emissions from the flarestack and utilisation plant been assessed for source, composition, quantity and level and rate? See section F of the application form for requirements.	
Has a maintenance programme for the control system been specified?	
Has a condensate removal system been designed?	

**Table D.3(v)b Landfill Gas Monitoring for existing landfill gas flares and utilisation plants**

Not Applicable – No landfill activities

Parameter	Concentration (mg/Nm <sup>3</sup> )	Frequency of Analysis	Method of Analysis
<b>Inlet</b>			
Methane (CH <sub>4</sub> ) % v/v			
Carbon dioxide (CO <sub>2</sub> ) %v/v			
Oxygen (O <sub>2</sub> ) % v/v			
<b>Outlet</b>			
Volumetric Flow Rate			
SO <sub>2</sub>			
Nox			
CO			
Particulates			
TA Luft Class I, II, III organics			
Hydrochloric acid			
Hydrogen Fluoride			

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**Table D.3(v)c Landfill Gas Monitoring** Not Applicable – No landfill activities

Parameter	Proposed Frequency of Analysis		Method of Analysis
	Gas boreholes, vents, wells and perimeter locations	Installation Office	
Methane (CH <sub>4</sub> ) % v/v			
Carbon Dioxide (CO <sub>2</sub> ) % v/v			
Oxygen (O <sub>2</sub> ) % v/v			
Atmospheric Pressure			
Temperature			

**Table D.3(v)d Landfill Gas Infrastructure** Not Applicable – No landfill activities

Equipment	Monitoring Frequency	Monitoring Action
Gas Collection System		
Gas Control System		

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**Table D.3 (vi) Capping System Not Applicable – No landfill activities**

	y/n
Has the daily cover been specified?	
Has the intermediate cover been specified?	
Has the temporary capping been specified?	
Has the Capping System been designed and does it meet the requirements of the Landfill Directive Annex 1 (3.3)?	
Does the Capping System include a flexible membrane liner?	
Have all capping materials been specified?	
Has a Method Statement for construction been produced?	
Has a Quality Control Plan been produced?	
Has a Quality Assurance Plan been produced?	
Has a programme for monitoring landfill stability been developed?	
Has a programme for monitoring landfill settlement been developed?	

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**Table E.1 (i) BOILER EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)**Emission Point:**

Emission Point Ref. N <sup>o</sup> :	A1-1	
Location:	North of Utilities Building	
Grid Ref. (12 digit, 6E,6N):	170604E 337494N	
<b>Vent Details</b>	Diameter: 0.61	Height above Ground(m): 26
Date of commencement of emission:	Date of licence re-issue	

**Characteristics of Emission:**

<b>Boiler rating</b>			
Steam Output:	8000		kg/hr
Thermal Input:	6.31		MW
<b>Boiler fuel</b>			
Type:	Kerosene		
Maximum rate at which fuel is burned	186		kg/hr
% sulphur content:	N/A		
NOx	90.4		mg/Nm <sup>3</sup>
			0°C. 3% O <sub>2</sub> (Liquid or Gas), 6% O <sub>2</sub> (Solid Fuel)
Maximum volume* of emission	13047		m <sup>3</sup> /hr
			0°C, 3 % O <sub>2</sub> (liquid or gas), 6 % O <sub>2</sub> (solid fuel)
Minimum efflux velocity			m.sec <sup>-1</sup>
Temperature	°C(max)	°C(min)	113.5 °C(avg)

\* Volume flow limits for emissions to atmosphere shall be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa), dry gas; 3% oxygen for liquid and gas fuels; 6% oxygen for solid fuels.

(i) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up/shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

**Table E.1 (i) BOILER EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)**Emission Point:**

Emission Point Ref. N <sup>o</sup> :	A1-2	
Location:	North of Utilities Building	
Grid Ref. (12 digit, 6E,6N):	170604E 337494N	
<b>Vent Details</b>	Diameter: 0.61	Height above Ground(m): 26
Date of commencement of emission:	Date of licence re-issue	

**Characteristics of Emission:**

<b>Boiler rating</b>		
Steam Output:	8000	kg/hr
Thermal Input:	6.31	MW
<b>Boiler fuel</b>		
Type:	Kerosene	
Maximum rate at which fuel is burned	186	kg/hr
% sulphur content:	N/A	
NOx	51.4	0°C, 3% O <sub>2</sub> (Liquid or Gas), 6% O <sub>2</sub> (Solid Fuel)
Maximum volume* of emission	13047	m <sup>3</sup> /hr 0°C, 3 % O <sub>2</sub> (liquid or gas), 6 % O <sub>2</sub> (solid fuel)
Minimum efflux velocity		m.sec <sup>-1</sup>
Temperature	°C(max)	°C(min)
		106 °C(avg)

\* Volume flow limits for emissions to atmosphere shall be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa), dry gas; 3% oxygen for liquid and gas fuels; 6% oxygen for solid fuels.

(i) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up/shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

**Table E.1 (i) BOILER EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)**Emission Point:**

Emission Point Ref. N <sup>o</sup> :	A1-3	
Location:	North of Utilities Building	
Grid Ref. (12 digit, 6E,6N):	170604E 337494N	
<b>Vent Details</b>	Diameter: 0.61	Height above Ground(m): 26
Date of commencement of emission:	Date of licence re-issue	

**Characteristics of Emission:**

<b>Boiler rating</b>			
Steam Output:	1500		kg/hr
Thermal Input:	N/A		MW
<b>Boiler fuel</b>			
Type:	Kerosene & LPG		
Maximum rate at which fuel is burned	N/A		kg/hr
% sulphur content:	N/A		
NOx	N/A		mg/Nm <sup>3</sup>
			0°C, 3% O <sub>2</sub> (Liquid or Gas), 6% O <sub>2</sub> (Solid Fuel)
Maximum volume* of emission	N/A		m <sup>3</sup> /hr
			0°C, 3 % O <sub>2</sub> (liquid or gas), 6 % O <sub>2</sub> (solid fuel)
Minimum efflux velocity	N/A		m.sec <sup>-1</sup>
Temperature	°C(max)	°C(min)	°C(avg)

\* Volume flow limits for emissions to atmosphere shall be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa), dry gas; 3% oxygen for liquid and gas fuels; 6% oxygen for solid fuels.

(i) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up/shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

**Table E.1 (i) BOILER EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)**Emission Point:**

Emission Point Ref. N°:	A1-4	
Location:	North of Utilities Building	
Grid Ref. (12 digit, 6E,6N):	170604E 337494N	
<b>Vent Details</b>	Diameter: 0.61	Height above Ground(m): 26
Date of commencement of emission:	Date of licence re-issue	

**Characteristics of Emission:**

<b>Boiler rating</b>			
Steam Output:	N/A		kg/hr
Thermal Input:	1.038		MW
<b>Boiler fuel</b>			
Type:	LPG		
Maximum rate at which fuel is burned	81.1		kg/hr
% sulphur content:	N/A		
NOx	N/A		mg/Nm <sup>3</sup>
			0°C. 3% O <sub>2</sub> (Liquid or Gas), 6% O <sub>2</sub> (Solid Fuel)
Maximum volume* of emission	N/A		m <sup>3</sup> /hr
			0°C, 3 % O <sub>2</sub> (liquid or gas), 6 % O <sub>2</sub> (solid fuel)
Minimum efflux velocity	N/A		m.sec <sup>-1</sup>
Temperature	°C(max)	°C(min)	°C(avg)

\* Volume flow limits for emissions to atmosphere shall be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa), dry gas; 3% oxygen for liquid and gas fuels; 6% oxygen for solid fuels.

(i) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up/shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

**Table E.1 (i) BOILER EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)**Emission Point:**

Emission Point Ref. N <sup>o</sup> :	A1-5	
Location:	North of Utilities Building	
Grid Ref. (12 digit, 6E,6N):	170604E 337494N	
<b>Vent Details</b>	Diameter: 0.61	Height above Ground(m): 26
Date of commencement of emission:	Date of licence re-issue	

**Characteristics of Emission:**

<b>Boiler rating</b>			
Steam Output:	N/A		kg/hr
Thermal Input:	1.038		MW
<b>Boiler fuel</b>			
Type:	LPG		
Maximum rate at which fuel is burned	81.1		kg/hr
% sulphur content:			
NOx	N/A		mg/Nm <sup>3</sup>
			0°C, 3% O <sub>2</sub> (Liquid or Gas), 6% O <sub>2</sub> (Solid Fuel)
Maximum volume* of emission	N/A		m <sup>3</sup> /hr
			0°C, 3 % O <sub>2</sub> (liquid or gas), 6 % O <sub>2</sub> (solid fuel)
Minimum efflux velocity	N/A		m.sec <sup>-1</sup>
Temperature	°C(max)	°C(min)	°C(avg)

\* Volume flow limits for emissions to atmosphere shall be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa), dry gas; 3% oxygen for liquid and gas fuels; 6% oxygen for solid fuels.

(i) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up/shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

**Table E.1 (i) BOILER EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)**Emission Point:**

Emission Point Ref. N°:	A1-6	
Location:	North of Utilities Building	
Grid Ref. (12 digit, 6E,6N):	170604E 337494N	
<b>Vent Details</b>	Diameter: 0.61	Height above Ground(m): 26
Date of commencement of emission:	Date of licence re-issue	

**Characteristics of Emission:**

<b>Boiler rating</b>			
Steam Output:	N/A		kg/hr
Thermal Input:	0.966		MW
<b>Boiler fuel</b>			
Type:	LPG		
Maximum rate at which fuel is burned	75.5		kg/hr
% sulphur content:	N/A		
NOx	N/A		mg/Nm <sup>3</sup>
			0°C. 3% O <sub>2</sub> (Liquid or Gas), 6% O <sub>2</sub> (Solid Fuel)
Maximum volume* of emission	N/A		m <sup>3</sup> /hr
			0°C, 3 % O <sub>2</sub> (liquid or gas), 6 % O <sub>2</sub> (solid fuel)
Minimum efflux velocity	N/A		m.sec <sup>-1</sup>
Temperature	°C(max)	°C(min)	°C(avg)

\* Volume flow limits for emissions to atmosphere shall be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa), dry gas; 3% oxygen for liquid and gas fuels; 6% oxygen for solid fuels.

(i) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up/shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--



**TABLE E.1(ii) MAIN EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)

Emission Point Ref. N <sup>o</sup> :	A2-1(a)
Source of Emission:	Existing Thermal Oxidiser
Location:	Eastern Side of Utilities Building
Grid Ref. (12 digit, 6E,6N):	170669E 337475N
Vent Details Diameter:	0.4
Height above Ground(m):	10
Date of commencement:	To be decommissioned following the commissioning phase of the new thermal oxidiser

**Characteristics of Emission:**

(i) Volume to be emitted:			
Average/day	Nm <sup>3</sup> /d	Maximum/day	95088 Nm <sup>3</sup> /d
Maximum rate/hour	3962 Nm <sup>3</sup> /h	Min efflux velocity	m.sec <sup>-1</sup>
(ii) Other factors			
Temperature	°C(max)	°C(min)	150 °C(avg)
For Combustion Sources: Volume terms expressed as : <input type="checkbox"/> wet. <input type="checkbox"/> dry. _____ %O <sub>2</sub>			

(iii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg) *	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
	*To be decommissioned following the commissioning phase of the new thermal oxidiser

**TABLE E.1(iii): MAIN EMISSIONS TO ATMOSPHERE - Chemical characteristics of the emission** (1 table per emission point)**Emission Point Reference Number:** A2-1(a) Existing Thermal Oxidiser

Parameter	Prior to treatment <sup>(1)</sup>				Brief description of treatment	As discharged <sup>(1)</sup>					
	mg/Nm <sup>3</sup>		kg/h			mg/Nm <sup>3</sup>		kg/h.		kg/year	
	Avg	Max	Avg	Max		Avg	Max	Avg	Max	Avg	Max
NOx					Direct Fire Thermal Oxidiser Treatment		200				
SOx							70				
CO							300				
TA Luft Class I Organics							20 at mass flows >0.1 kg/h				
TA Luft Class II Organics							100 at mass flows >0.5 kg/h				
TOC							20				
Mass Sum of 2-Methoxyethanol and Dimethylformamide							2 at mass flow rates >0.01kg/h				

1. Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa). Wet/dry should be the same as given in Table E.1(ii) unless clearly stated otherwise.

**TABLE E.1(ii) MAIN EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)

Emission Point Ref. N <sup>o</sup> :	A2-1(b)
Source of Emission:	Cryogenic Condenser
Location:	Easter Side of Utilities Building
Grid Ref. (12 digit, 6E,6N):	170637E 337473N
Vent Details Diameter:	0.4
Height above Ground(m):	10
Date of commencement:	Since 2005 Licence Review

**Characteristics of Emission:**

(i) Volume to be emitted:			
Average/day	Nm <sup>3</sup> /d	Maximum/day	21600 Nm <sup>3</sup> /d
Maximum rate/hour	900 Nm <sup>3</sup> /h	Min efflux velocity	m.sec <sup>-1</sup>
(ii) Other factors			
Temperature	°C(max)	°C(min)	10 °C(avg)
For Combustion Sources: Volume terms expressed as : <input type="checkbox"/> wet. <input type="checkbox"/> dry. _____ %O <sub>2</sub>			

(iii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
------------------------------	--

**TABLE E.1(iii): MAIN EMISSIONS TO ATMOSPHERE - Chemical characteristics of the emission** (1 table per emission point)**Emission Point Reference Number:** A2-1(b) Cryogenic Condenser

Parameter	Prior to treatment <sup>(1)</sup>				Brief description of treatment	As discharged <sup>(1)</sup>					
	mg/Nm <sup>3</sup>		kg/h			mg/Nm <sup>3</sup>		kg/h.		kg/year	
	Avg	Max	Avg	Max		Avg	Max	Avg	Max	Avg	Max
TA Luft Class I Organics TA Luft Class II Organics TOC Mass Sum od 2- Methoxyethnaol and Dimethyforamide					Cryogenic Condenser Treatment		20 at mass flows >0.1 kg/h 100 at mass flows >0.5 kg/h 20 2 at mass flow rats >0.01kg/h				

- Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa). Wet/dry should be the same as given in Table E.1(ii) unless clearly stated otherwise.

**TABLE E.1(ii) MAIN EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)

Emission Point Ref. N <sup>o</sup> :	A2-1(c)
Source of Emission:	<b>NEW</b> Thermal Oxidiser
Location:	Eastern Side of Utilities Building
Grid Ref. (12 digit, 6E,6N):	170674E 337478N
Vent Details Diameter:	0.32
Height above Ground(m):	15
Date of commencement:	

**Characteristics of Emission:**

(i) Volume to be emitted:			
Average/day	Nm <sup>3</sup> /d	Maximum/day	Nm <sup>3</sup> /d
		95088	
Maximum rate/hour	3962 Nm <sup>3</sup> /h	Min efflux velocity	m.sec <sup>-1</sup>
(ii) Other factors			
Temperature	150°C(max)	°C(min)	°C(avg)
For Combustion Sources: Volume terms expressed as : <input type="checkbox"/> wet. <input type="checkbox"/> dry. _____%O <sub>2</sub>			

(iii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

**TABLE E.1(iii): MAIN EMISSIONS TO ATMOSPHERE - Chemical characteristics of the emission** (1 table per emission point)**Emission Point Reference Number:** A2-1(c) **New Thermal Oxidiser**

Parameter	Prior to treatment <sup>(1)</sup>				Brief description of treatment	As discharged <sup>(1)</sup>					
	mg/Nm <sup>3</sup>		kg/h			mg/Nm <sup>3</sup>		kg/h.		kg/year	
	Avg	Max	Avg	Max		Avg	Max	Avg	Max	Avg	Max
NOx					Direct Fire Thermal Oxidiser Treatment	N/A	200				
SOx						N/A	70				
CO						N/A	300				
TOC						N/A	20				
HCl						N/A	10				
Dioxins/Furans						N/A	0.1ng/m <sup>3</sup> (6-8 Hour Sample)				

- Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa). Wet/dry should be the same as given in Table E.1(ii) unless clearly stated otherwise.

**TABLE E.1(ii) MAIN EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)

Emission Point Ref. N <sup>o</sup> :	A2-2
Source of Emission:	Scrubber
Location:	Easter Side of Utilities Building
Grid Ref. (12 digit, 6E,6N):	170634E 337472N
Vent Details Diameter:	0.21
Height above Ground(m):	11.2
Date of commencement:	-

**Characteristics of Emission:**

(i) Volume to be emitted:			
Average/day	Nm <sup>3</sup> /d	Maximum/day	19200 Nm <sup>3</sup> /d
Maximum rate/hour	800 Nm <sup>3</sup> /h	Min efflux velocity	m.sec <sup>-1</sup>
(ii) Other factors			
Temperature	°C(max)	°C(min)	20°C(avg)
For Combustion Sources: Volume terms expressed as : <input type="checkbox"/> wet. <input type="checkbox"/> dry. _____ %O <sub>2</sub>			

(iii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

**TABLE E.1(iii): MAIN EMISSIONS TO ATMOSPHERE - Chemical characteristics of the emission** (1 table per emission point)**Emission Point Reference Number:** A2-2

Parameter	Prior to treatment <sup>(1)</sup>				Brief description of treatment	As discharged <sup>(1)</sup>								
	mg/Nm <sup>3</sup>		kg/h			mg/Nm <sup>3</sup>		kg/h.		kg/year				
	Avg	Max	Avg	Max		Avg	Max	Avg	Max	Avg	Max			
Chlorides (as HCl) Formic Acid					Acid Scrubber		10							
							10							

1. Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa). Wet/dry should be the same as given in Table E.1(ii) unless clearly stated otherwise.

**TABLE E.1(ii) MAIN EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)

Emission Point Ref. N <sup>o</sup> :	A2-3
Source of Emission:	Dust Extraction System
Location:	Building 40
Grid Ref. (12 digit, 6E,6N):	170578E 337466N
Vent Details Diameter:	0.5
Height above Ground(m):	15.4
Date of commencement:	-



**Characteristics of Emission:**

(i) Volume to be emitted:				
Average/day	10176	Nm <sup>3</sup> /d	Maximum/day	432000 Nm <sup>3</sup> /d
Maximum rate/hour	18000	Nm <sup>3</sup> /h	Min efflux velocity	27.3 m.sec <sup>-1</sup>
(ii) Other factors				
Temperature	°C(max)	°C(min)	20 °C(avg)	
For Combustion Sources: Volume terms expressed as : <input type="checkbox"/> wet. <input type="checkbox"/> dry. _____ %O <sub>2</sub>				

(iii) Period or periods during which emissions are made, or are to be made including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

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**TABLE E.1(iii): MAIN EMISSIONS TO ATMOSPHERE - Chemical characteristics of the emission** (1 table per emission point)**Emission Point Reference Number:** A2-3

Parameter	Prior to treatment <sup>(1)</sup>				Brief description of treatment	As discharged <sup>(1)</sup>					
	mg/Nm <sup>3</sup>		kg/h			mg/Nm <sup>3</sup>		kg/h.		kg/year	
	Avg	Max	Avg	Max		Avg	Max	Avg	Max	Avg	Max
Pharmaceutical Dust					HEPA Filter	N/A	1 with activities below 0.15				

1. Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa). Wet/dry should be the same as given in Table E.1(ii) unless clearly stated otherwise.

**TABLE E.1(ii) MAIN EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)

Emission Point Ref. N <sup>o</sup> :	A2-4
Source of Emission:	Central Dust Extraction System
Location:	Building 20
Grid Ref. (12 digit, 6E,6N):	170586E 337414N
Vent Details Diameter:	0.5
Height above Ground(m):	16.9
Date of commencement:	Date of licence re-issue

**Characteristics of Emission:**

(i) Volume to be emitted:				
Average/day	Nm <sup>3</sup> /d	Maximum/day	168480	Nm <sup>3</sup> /d
Maximum rate/hour	4020 Nm <sup>3</sup> /h	Min efflux velocity	10.7	m.sec <sup>-1</sup>
(ii) Other factors				
Temperature	°C(max)	°C(min)		20 °C(avg)
For Combustion Sources: Volume terms expressed as : <input type="checkbox"/> wet. <input type="checkbox"/> dry. _____ %O <sub>2</sub>				

(iii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

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**TABLE E.1(iii): MAIN EMISSIONS TO ATMOSPHERE - Chemical characteristics of the emission** (1 table per emission point)**Emission Point Reference Number:** A2-4

Parameter	Prior to treatment <sup>(1)</sup>				Brief description of treatment	As discharged <sup>(1)</sup>					
	mg/Nm <sup>3</sup>		kg/h			mg/Nm <sup>3</sup>		kg/h.		kg/year	
	Avg	Max	Avg	Max		Avg	Max	Avg	Max	Avg	Max
Pharmaceutical Dust					HEPA Filter	N/A	1 with activities below 0.15				

1. Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa). Wet/dry should be the same as given in Table E.1(ii) unless clearly stated otherwise.

**TABLE E.1(ii) MAIN EMISSIONS TO ATMOSPHERE** (1 Page for each emission point)

Emission Point Ref. N <sup>o</sup> :	A-2-5
Source of Emission:	Synthroid Dust Extract System
Location:	Building 20
Grid Ref. (12 digit, 6E,6N):	170586E 337414N
Vent Details Diameter:	0.715
Height above Ground(m):	15.2
Date of commencement:	

**Characteristics of Emission:**

(i) Volume to be emitted:				
Average/day	Nm <sup>3</sup> /d	Maximum/day	72000	Nm <sup>3</sup> /d
Maximum rate/hour	3000 Nm <sup>3</sup> /h	Min efflux velocity	2.2	m.sec <sup>-1</sup>
(ii) Other factors				
Temperature	°C(max)	°C(min)		20 °C(avg)
For Combustion Sources: Volume terms expressed as : <input type="checkbox"/> wet. <input type="checkbox"/> dry. _____ %O <sub>2</sub>				

(iii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 24 _____ hr/day _____ 365 _____ day/yr
---------------------------	--

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**TABLE E.1(iii): MAIN EMISSIONS TO ATMOSPHERE - Chemical characteristics of the emission** (1 table per emission point)**Emission Point Reference Number:** A2-5

Parameter	Prior to treatment <sup>(1)</sup>				Brief description of treatment	As discharged <sup>(1)</sup>					
	mg/Nm <sup>3</sup>		kg/h			mg/Nm <sup>3</sup>		kg/h.		kg/year	
	Avg	Max	Avg	Max		Avg	Max	Avg	Max	Avg	Max
Dust Dust (as API)					HEPA Filter	N/A	1 0.15	0.007 0.001			

1. Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C,101.3kPa). Wet/dry should be the same as given in Table E.1(ii) unless clearly stated otherwise.

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**TABLE E.1(iv): EMISSIONS TO ATMOSPHERE - Minor atmospheric emissions**

Emission point Reference Numbers	Description	Emission details <sup>1</sup>				Abatement system employed
		material	mg/Nm <sup>3(2)</sup>	kg/h.	kg/year	
A3-1	Laboratory Fume Hoods	Trace levels of organic solvents	N/A	N/A	N/A	N/A
A3-2	AA Instrument (Laboratory)	Atomised Samples	N/A	N/A	N/A	N/A
A3-3	Canteen	Cooking Fumes	N/A	N/A	N/A	N/A
A3-4	Hydrogenator	Trace levels of organic solvents	50	0.5	N/A	Liquid Ring Vacuum Seal
A3-5	Drum Charge Room	Trace levels of organic solvents	50	0.5	N/A	None
A3-6	Glove Box Dust Extract (Building 20) Flow Rate 180 Nm <sup>3</sup> /hr	Pharmaceutical Dust	1 with activities below 0.15	0.001	N/A	HEPA Filter
A3-7	SPP1 & SPP2 Flow Rate 600 Nm <sup>3</sup> /hr	Pharmaceutical Dust	1 with activities below 0.15	0.001	N/A	HEPA Filter
A3-8	Drying Air Extract from IBC Wash Room Flow Rate 11520 Nm <sup>3</sup> /hr	Pharmaceutical Dust	1 with activities below 0.15	0.001	N/A	HEPA Filter

1 The maximum emission should be stated for each material emitted, the concentration should be based on the maximum 30 minute mean.

2 Concentrations should be based on Normal conditions of temperature and pressure, (i.e. 0°C/101.3kPa). Wet/dry should be clearly stated. Include reference oxygen conditions for combustion sources.

**TABLE E.1(v): EMISSIONS TO ATMOSPHERE – Fugitive and Potential atmospheric emissions**

Emission point ref. no. (as per flow diagram)	Description	Malfunction which could cause an emission	Emission details (Potential max. emissions) <sup>1</sup>		
			Material	mg/Nm <sup>3</sup>	kg/hour

Fugitive emissions from tanks will be collected in vent header and treated in new thermal oxidiser.

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**TABLE E.2(i): EMISSIONS TO SURFACE WATERS**

(One page for each emission)

**Emission Point:** Not Applicable – No change

Emission Point Ref. N <sup>o</sup> :	SW-1		
Source of Emission:	Storm Water		
Location of discharge :	Southwest of site after Attenuation Pond		
Grid Ref. (12 digit, 6E,6N):	170340E, 337430N		
Name of receiving waters and water body code:	Stream to East and South of site then into estuary at Carton		
Flow rate in receiving waters:		_____	m <sup>3</sup> .sec <sup>-1</sup> Dry Weather Flow
		_____	m <sup>3</sup> .sec <sup>-1</sup> 95%ile flow
Available assimilative capacity:			kg/day

**Emission Details:**

(i) Volume to be emitted			
Normal/day	m <sup>3</sup>	Maximum/day	m <sup>3</sup>
Maximum rate/hour	0.62 m <sup>3</sup>		

(ii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg)	_____ 60 _____ min/hr _____ 224 _____ hr/day _____ 365 _____ day/yr
---------------------------	---

**TABLE E.2(ii): EMISSIONS TO SURFACE WATERS - Characteristics of the emission** (1 table per emission point)

**Emission point reference number:** SW-1

Parameter	Prior to treatment				As discharged				% Efficiency
	Max. hourly average (mg/l)	Max. daily average (mg/l)	kg/day	kg/year	Max. hourly average (mg/l)	Max. daily average (mg/l)	kg/day	kg/year	
Uncontaminated Surface water run-off									

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**TABLE E.3(i): EMISSIONS TO SEWER** (One page for each emission)**Emission Point:**

Emission Point Ref. N <sup>o</sup> :	SE 1
Location of connection to sewer:	South of site close to southern boundary
Grid Ref. (12 digit, 6E,6N):	170637E 337413N
Name of sewage undertaker:	Irish Water

**Emission Details:**

(i) Volume to be emitted					
Normal/day	191	m <sup>3</sup>	Maximum/day	300	m <sup>3</sup>
Maximum rate/hour	12.5	m <sup>3</sup>			

(ii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg)	_____60_____ min/hr _____24_____ hr/day _____365_____ day/yr
---------------------------	--

**TABLE E.3(ii): EMISSIONS TO SEWER - Characteristics of the emission** (1 table per emission point)**Emission point reference number:** SE 1

Parameter	Prior to treatment				As discharged				% Efficiency
	Max. hourly average (mg/l)	Max. daily average (mg/l)	kg/day	kg/year	Max. hourly average (mg/l)	Max. daily average (mg/l)	kg/day	kg/year	
BOD					N/A	450			
COD					N/A	1300			
Suspended Solids					N/A	350			
Ammonia (as N)					N/A	25			
Total Phosphorus (as P)					N/A	10			
Sulphate (SO <sub>4</sub> )					N/A	1500			
Chlorides					N/A	8000			
Detergents (as MBAS)					N/A	20			
Fats, Oils, Grease					N/A	10			

**TABLE E.4(i): EMISSIONS TO GROUND** (1 Page for each emission point)

**Emission Point or Area:** Not Applicable – No emissions to ground

Emission Point/Area Ref. N°:	
Emission Pathway: (borehole, well, percolation area, soakaway, landspreading, etc.)	
Location :	
Grid Ref. (12 digit, 6E,6N):	
Elevation of discharge: (relative to Ordnance Datum)	
Aquifer classification for receiving groundwater body:	
Groundwater vulnerability assessment (including vulnerability rating):	
Identity and proximity of groundwater sources at risk (wells, springs, etc):	
Identity and proximity of surface water bodies at risk:	

**Emission Details:**

(i) Volume to be emitted			
Normal/day	m <sup>3</sup>	Maximum/day	m <sup>3</sup>
Maximum rate/hour	m <sup>3</sup>		

(ii) Period or periods during which emissions are made, or are to be made, including daily or seasonal variations (*start-up /shutdown to be included*):

Periods of Emission (avg)	_____min/hr _____hr/day _____day/yr
---------------------------	-------------------------------------

**TABLE E.4(ii): EMISSIONS TO GROUND - Characteristics of the emission** (1 table per emission point)**Emission point/area reference number:** Not Applicable – No emissions to ground

Parameter	Prior to treatment				As discharged				% Efficiency
	Max. hourly average (mg/l)	Max. daily average (mg/l)	kg/day	kg/year	Max. hourly average (mg/l)	Max. daily average (mg/l)	kg/day	kg/year	

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**Table E.5(i): NOISE EMISSIONS - Noise sources summary sheet**

Source	Emission point Ref. No	Equipment Ref. No	Sound Pressure <sup>1</sup> dBA at reference distance	Octave bands (Hz) Sound Pressure <sup>1</sup> Levels dB(unweighted) per band									Impulsive or tonal qualities	Periods of Emission <sup>2</sup>
				31.5	63	125	250	500	1K	2K	4K	8K		
<b>New Thermal Oxidiser Equipment</b>														
Combustion Air Fans		VV141 VV241	55	-	-	-	-	-	-	-	-	-	None	24 Hour
ID Fans		VR117 VR217	75	-	-	-	-	-	-	-	-	-	None	24 Hour
Scrubber Pumps		PG542 P101 P111	<75	-	-	-	-	-	-	-	-	-	None	24 Hour
Boiler Feed Water Pumps		PG542 P101 P111	<75	-	-	-	-	-	-	-	-	-	None	24 Hour
<b>Existing Equipment</b>														
Cooling Tower		CT-716A	80dB	N/A	75	75	72	69	65	62	59	51	None	24 Hour
Cooling Tower		CT-716B	80dB	N/A	75	75	72	69	65	62	59	51	None	24 Hour
Cooling Tower		CT-716C	80dB	N/A	75	75	72	69	65	62	59	51	None	24 Hour
Pump		CP-716-PU1	80dB	N/A	68	69	71	71	74	71	67	61	None	24 Hour
Pump		CP-716-PU2	80dB	N/A	68	69	71	71	74	71	67	61	None	24 Hour
Pump		CP-716-PU3	80dB	N/A	68	69	71	71	74	71	67	61	None	24 Hour
Pump		CP-731-PU1	80dB	N/A	68	69	71	71	74	71	67	61	None	24 Hour
Pump		CP-731-PU2	80dB	N/A	68	69	71	71	74	71	67	61	None	24 Hour
Pump		CP-731A-PU1	80dB	N/A	68	69	71	71	74	71	67	61	None	24 Hour
Pump		CP-731B-	80dB	N/A	68	69	71	71	74	71	67	61	None	24 Hour

Source	Emission point Ref. No	Equipment Ref. No	Sound Pressure <sup>1</sup> dBA at reference distance	Octave bands (Hz) Sound Pressure <sup>1</sup> Levels dB(unweighted) per band								Impulsive or tonal qualities	Periods of Emission <sup>2</sup>	
				31.5	63	125	250	500	1K	2K	4K			8K
		PU1												
Process Chiller		CP-731A	80dB	N/A	64	64	67	75	76	73	62	62	None	24 Hour
Process Chiller		CP-731B	80dB	N/A	64	64	67	75	76	73	62	62	None	24 Hour
Compressor		CP-721A	80dB	N/A	65	70	69	67	70	75	72	65	None	24 Hour
Compressor		CP-721B	80dB	N/A	65	70	69	67	70	75	72	65	None	24 Hour
HVAC Chiller		70-H-CP-01	80dB	N/A	64	64	67	75	76	73	62	62	None	24 Hour
HVAC Chiller		70-H-CP-02	80dB	N/A	64	64	67	75	76	73	62	62	None	24 Hour
Boiler		BL-711A	80dB	N/A	75	70	64	63	61	59	59	59	None	24 Hour
Boiler		BL-711B	80dB	N/A	75	70	64	63	61	59	59	59	None	24 Hour
Emergency Gen			80dB	N/A	72	73	73	73	71	69	66	61	None	Test / emergency
N2 Filling		PAK-TK-771	90dB	N/A	-	-	-	-	-	-	-	-	None	Occasional

1. For items of plant, sound power levels may be used.
2. Periods of emission should state if the plant item in question operates on a continuous or intermittent basis. If intermittent then further details of the hours of operation and any potential impulsive components associated with the source should be clearly identified.



**TABLE F.1(i): ABATEMENT / TREATMENT CONTROL****Emission point reference number:** A2-1(a) Existing Thermal Oxidiser (To be decommissioned)

Control <sup>1</sup> parameter	Monitoring to be carried out <sup>2</sup>	Equipment <sup>3</sup>	Equipment back-up
Burner flame operation	Continuous	Flame Sensor	Spares Available
Inlet and outlet temperature	Continuous	Thermocouple	Spares Available
Inlet and exhaust air flow	Continuous	Flow meter	Spares Available
Pressure of flue gas	Continuous	Pressure transmitter	Spares Available
Temperature	Continuous	Thermocouple	Spares Available

<sup>1</sup> List the operating parameters of the treatment / abatement system which control its function.

<sup>2</sup> List the monitoring of the control parameter to be carried out.

<sup>3</sup> List the equipment necessary for the proper function of the abatement / treatment system.

**Emission point reference number:** A2-1(b) Cryogenic condenser

Control <sup>1</sup> parameter	Monitoring to be carried out <sup>2</sup>	Equipment <sup>3</sup>	Equipment back-up
Temperature	Continuous	Thermocouple	Spares Available
Pressure Drop	Continuous	Pressure transmitter	Spares Available

<sup>1</sup> List the operating parameters of the treatment / abatement system which control its function.

<sup>2</sup> List the monitoring of the control parameter to be carried out.

<sup>3</sup> List the equipment necessary for the proper function of the abatement / treatment system.

**Emission point reference number:** A2-1(c) New Thermal Oxidiser

Control <sup>1</sup> parameter	Monitoring to be carried out <sup>2</sup>	Equipment <sup>3</sup>	Equipment back-up
Burner flame operation	Continuous	Flame Sensor	Spares Available
Inlet and outlet temperature	Continuous	Thermocouple	Spares Available
Inlet and exhaust air flow	Continuous	Flow meter	Spares Available
Pressure of flue gas	Continuous	Pressure transmitter	Spares Available
Temperature	Continuous	Thermocouple	Spares Available

<sup>1</sup> List the operating parameters of the treatment / abatement system which control its function.

<sup>2</sup> List the monitoring of the control parameter to be carried out.

<sup>3</sup> List the equipment necessary for the proper function of the abatement / treatment system.

**Emission point reference number:** A2-2 (Scrubber)

Control <sup>1</sup> parameter	Monitoring to be carried out <sup>2</sup>	Equipment <sup>3</sup>	Equipment back-up
pH – scrubber liquid	Continuous	pH meter and recorder	Spares Available
Liquid flow	Continuous	Flow indicator	Spares Available
Air flow	Continuous	Differential pressure gauge	Spares Available

<sup>1</sup> List the operating parameters of the treatment / abatement system which control its function.

<sup>2</sup> List the monitoring of the control parameter to be carried out.

<sup>3</sup> List the equipment necessary for the proper function of the abatement / treatment system.

**Emission point reference number:** A2-3

Control <sup>1</sup> parameter	Monitoring to be carried out <sup>2</sup>	Equipment <sup>3</sup>	Equipment back-up
HEPA filter efficiency	Continuous differential pressure	Pressure sensor and alarm	Spares Available
Air flow	Annually	Pilot tube and manometer	Spares Available

<sup>1</sup> List the operating parameters of the treatment / abatement system which control its function.

<sup>2</sup> List the monitoring of the control parameter to be carried out.

<sup>3</sup> List the equipment necessary for the proper function of the abatement / treatment system.

**Emission point reference number:** A2-4

Control <sup>1</sup> parameter	Monitoring to be carried out <sup>2</sup>	Equipment <sup>3</sup>	Equipment back-up
HEPA filter efficiency	Continuous differential pressure	Pressure sensor and alarm	Spares Available
Air flow	Annually	Pilot tube and manometer	Spares Available

<sup>1</sup> List the operating parameters of the treatment / abatement system which control its function.

<sup>2</sup> List the monitoring of the control parameter to be carried out.

<sup>3</sup> List the equipment necessary for the proper function of the abatement / treatment system.

**Emission point reference number:** A2-5

Control <sup>1</sup> parameter	Monitoring to be carried out <sup>2</sup>	Equipment <sup>3</sup>	Equipment back-up
HEPA filter efficiency	Continuous differential pressure	Pressure sensor and alarm	Spares Available
Air flow	Annually	Pilot tube and manometer	Spares Available

<sup>1</sup> List the operating parameters of the treatment / abatement system which control its function.

<sup>2</sup> List the monitoring of the control parameter to be carried out.

<sup>3</sup> List the equipment necessary for the proper function of the abatement / treatment system.

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**TABLE F.2(i) : EMISSIONS MONITORING AND SAMPLING POINTS**

( 1 table per monitoring point)

**Emission Point Reference No. : A1-1Boiler**

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
SOx	Biannually	Available	Flue gas analyser	Standard Methods
NOx	Biannually	Available	Flue gas analyser	Standard Methods
CO	Biannually	Available	Flue gas analyser	Standard Methods
Particulates	Annually	Available	Isokinetic/Gravimeter	Standard Methods
Combustion Efficiency	Biannually	Available	Flue gas analyser	Standard Methods

**Emission Point Reference No. : A1-2 Boiler**

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
SOx	Biannually	Available	Flue gas analyser	Standard Methods
NOx	Biannually	Available	Flue gas analyser	Standard Methods
CO	Biannually	Available	Flue gas analyser	Standard Methods
Particulates	Annually	Available	Isokinetic/Gravimeter	Standard Methods
Combustion Efficiency	Biannually	Available	Flue gas analyser	Standard Methods

**Emission Point Reference No. : A1-3, A1-4, A1-5, A1-6 Boilers**

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
SOx	Biannually	Available	Flue gas analyser	Standard Methods
NOx	Biannually	Available	Flue gas analyser	Standard Methods
CO	Biannually	Available	Flue gas analyser	Standard Methods
Particulates	Annually	Available	Isokinetic/Gravimeter	Standard Methods
Combustion Efficiency	Biannually	Available	Flue gas analyser	Standard Methods

**Emission Point Reference No. : A2-1(a) Existing Thermal Oxidiser**

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
Oxides of Sulphur (as SO <sub>2</sub> )	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Nitrogen of Oxides (as NO <sub>2</sub> )	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Carbon Monoxide	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Oxygen	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Total Organic Carbon (as C)	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Temperature	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Flow	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
2-Methoxyethanol and Dimethylformamide	Monthly, when in use	Available	To be agreed with the agency	To be agreed with the agency
TA Luft Class I Organics	Quarterly	Available	Adsorption/GC-MS or other method to be agreed by the agency	
TA Luft Class II Organics	Quarterly	Available	Adsorption/GC-MS or other method to be agreed by the agency	

**Emission Point Reference No. : A2-1(b) Cryogenic Condenser**

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
TA Luft Class I Organics	Monthly	Available	Adsorption/GC-MS or other method to be agreed by the agency	
TA Luft Class II Organics	Monthly	Available	Adsorption/GC-MS or other method to be agreed by the agency	

**Emission Point Reference No. : A2-1(c) New Thermal Oxidiser**

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
Oxides of Sulphur (as SO <sub>2</sub> )	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Nitrogen of Oxides (as NO <sub>2</sub> )	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Carbon Monoxide	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Oxygen	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Total Organic Carbon (as C)	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Temperature	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
Flow	Continuous	Available	CEMS Analysis	MCERT CEMS Analysis
TA Luft Class I Organics	Quarterly	Available	Adsorption/GC-MS or other method to be agreed by the agency	Standard Methods
TA Luft Class II Organics	Quarterly	Available	Adsorption/GC-MS or other method to be agreed by the agency	Standard Methods
HCl	Quarterly	Available	Standard Methods	Standard Methods
Dioxins	Bi-Annually	Available	Standard methos	Standard Methods

**Emission Point Reference No. : A2-2 Scrubber**

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
Chlorides (as HCl)	Monthly	Available	Standard Methods	Standard Methods
Formic Acid	Monthly	Available	Standard Methods	Standard Methods

**Emission Point Reference No. :** A2-3 Dust Extraction

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
Dust (as Active Pharmaceutical Ingredients)	Annually	Available	Isokinetic/Gravimetric	Standard Methods

**Emission Point Reference No. :** A2-4 Dust Extraction

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
Dust (as Active Pharmaceutical Ingredients)	Annually	Platform Available	Isokinetic/Gravimetric	Standard Methods

**Emission Point Reference No. :** A2-5 Dust Extraction

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
Dust (as Active Pharmaceutical Ingredients)	Annually	Platform Available	Isokinetic/Gravimetric	Standard Methods

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**Emission Point Reference No. : SW1 – Surface Water**

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
pH	Continuous	Available	pH electrode/meter	Standard Methods
TOC	Continuous	Available	TOC analyser	Standard Methods
COD	Weekly	Available	Standard Method	Standard Methods
Visual Inspection	Daily	Available	Sample and examine for colour and odour	Standard Methods

**Emission Point Reference No. : SE1 - Sewer**

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
Flow	Continuous	Available	On-Line flow meter with recorder	Standard Methods
pH	Continuous	Available	pH electrode/meter with recorder	Standard Methods
Temperature	Daily	Available	Thermometer	Standard Methods
TOC	Continuous	Available	On-line TOC meter with recorder	Standard Methods
COD	daily	Available	Standard Method	Standard Methods
BOD	Weekly	Available	Standard Method	Standard Methods
Suspended Solids	Daily	Available	Gravimeter	Standard Methods
Total Nitrogen (Kjeldahl, nitrate, nitrite)	Monthly	Available	Standard Method	Standard Methods
Ammonia (asN)	Weekly	Available	Ion selective electrode	Standard Methods
Total Phosphorous (as P)	Weekly	Available	Standard Method	Standard Methods
Chlorides	Monthly	Available	Standard Method	Standard Methods
Sulphates (as SO4)	Monthly	Available	Standard Method	Standard Methods
Total Heavy Metals	Annually	Available	Atomic Absorption/ICP	Standard Methods
Organic Solvents	Quarterly	Available	Gas Chromatography	Standard Methods
Oils, Fats and Greases	Quarterly	Available	Standard Method	Standard Methods
Detergents (asMBAS)	Quarterly	Available	Standard Method	Standard Methods
Pharmaceutical Actives	Annually and as required by the Agency under Condition 6.7	Available	To be agreed with the Agency	Standard Methods
Toxicity	Annually	Available	To be agreed with the Agency	Standard Methods

**Emission Point Reference No. :** MW1, MW2, MW3, MW4 - Groundwater

Parameter	Monitoring frequency	Accessibility of Sampling Points	Sampling method	Analysis method / technique
pH	Biannually	Available	pH electrode/meter	Standard Methods
COD	Biannually	Available	Standard Method	Standard Methods
Conductivity	Biannually	Available	Standard Method	Standard Methods
Major anions	Biannually	Available	Standard Method	Standard Methods
Major cations	Biannually	Available	Standard Method	Standard Methods
Heavy metals	Biannually	Available	Atomic Absorption	Standard Methods
Trace organics	Biannually	Available	(1) US EPA Method 542.2 - Measurement of purgeable organic compounds in water by capillary column gas chromatography / mass spectrometry. (2) Non-purgeable organic compounds by GC or GC/MS	Standard Methods

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**TABLE F.2(ii): AMBIENT ENVIRONMENT MONITORING AND SAMPLING POINTS** ( 1 table per monitoring point)

**Monitoring Point Reference No:** N/A

Parameter	Monitoring frequency	Accessibility of Sampling point	Sampling method	Analysis method / technique
		<p style="color: red; transform: rotate(-45deg); font-size: small;">For inspection purposes only. Consent of copyright owner required for any other use.</p>		

**Table G.1(i) Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site**

Ref. N <sup>o</sup> or Code	Material/ Substance <sup>(1)</sup>	CAS Number	Danger <sup>(2)</sup> Category	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	R <sup>(3)</sup> - Phrase	S <sup>(3)</sup> - Phrase	Hazard Statement <sup>(4)</sup>
1	Dichloromethane, Methylene Chloride	75-09-2	Hazardous, Irritant, Toxic	28	7.6	production/manufacturing	40	23, 24, 25, 36, 37	315, 319, 335, 336, 351, 373
2	Triethylamine	121-44-8	Flammable, Corrosive	1.04	2.4	production/manufacturing	No Data	No Data	225, 302, 312, 314, 332
3	Propane Phosphonic Anhydride	68957-94-8	Highly Flammable, Corrosive	1.845		production/manufacturing	11, 34, 34, 37, 66, 67	16, 23.3, 25, 26, 29, 33, 36/37/39, 45	225, 290, 314, 336
4	Ethanol	64-17-5	Flammable	11.3	14.3	production/manufacturing	11	7, 16	225
5	Ethyl Acetate	141-78-6	Flammable, Irritant	20.29	143	production/manufacturing	11, 36, 66, 67	16, 26, 33	225, 319, 336
6	Dimethylformamide	68-12-2	Toxic	9.65		production/manufacturing	61, 20, 36	53, 45	226, 312, 319, 332, 360,
7	Isopropylalcohol	67-63-0	Highly flammable, irritant	18.62	98	production/manufacturing	11, 36, 67	7, 16, 24, 25, 26	225, 319, 336
8	Isopropylacetate	108-21-4	Highly flammable, irritant	42.761	17	production/manufacturing	11, 36, 66, 67	16, 26, 29, 33	225, 315, 319, 336
9	Tetrahydrofuran (with BHT)	109-99-9	Highly flammable, irritant	13.773	72	production/manufacturing	11, 19, 36/37	6.3, 16, 29, 33	225, 319, 335, 351
10	Pyridine, anhydrous 99.8 %	110-86-1	Flammable, Harmful	2.27		production/manufacturing	11, 20, 21, 22	26, 28	225, 302, 312, 315, 319, 332
11	Maize Starch	9005-84-9	-	2.216		production/manufacturing	No Data	No Data	None
12	Lactose	63-42-3	-	2.026		production/manufacturing	No Data	No Data	None

Ref. N <sup>o</sup> or	Material/ Substance <sup>(1)</sup>	CAS Number	Danger <sup>(2)</sup> Category	Amount Stored	Annual Usage	Nature of Use	R <sup>(3)</sup> - Phrase	S <sup>(3)</sup> - Phrase	Hazard Statement <sup>(4)</sup>
14	Hydrochloric Acid 37% ACS	7647-01-0	Corrosive, Irritant	0.011		production/manufacturing	34	26, 45	290, 314, 335
15	2-Methyl THF	96-47-9	Highly Flammable, Corrosive, Irritant	8.132		production/manufacturing	10, 36/37/8	9, 16, 24/25, 33	225, 302, 315, 318
16	N-Methylpyrrolidinone	872-50-4	Irritant, Toxic	7.008	3.6	production/manufacturing	36/38	2, 41, 64	315, 319, 335, 360D
17	Alcohol SD 3A 200 Proof	64-17-5	Highly Flammable, Irritant, Toxic	6.252		production/manufacturing	11	2, 7, 16	225, 302, 319, 371
18	Ethanol (Denatured with Toluene)	64-17-5	Highly Flammable, Irritant, Toxic	6.032		production/manufacturing	11	2, 7, 16	225, 302, 319, 371
19	Sodium Hydroxide Pellets	1310-73-2	Corrosive	2.781		production/manufacturing	35	26, 37/39, 45	290, 314
20	Diazabicycloundecene	6674-22-2	Corrosive, Highly Toxic	2.228		production/manufacturing	22, 34	24, 25	290, 301, 314, 412
21	2-Methoxyethanol	109-86-4	Flammable, Irritant, Toxic	2.029		production/manufacturing	10, 38, 41, 48/20	22, 26, 36/37, 53	226, 302, 312, 332, 360FD, 370, 373
22	Sodium Bicarbonate USP	144-55-8	-	0.874		production/manufacturing	None	None	None
23	Continuous Liner	N/A	N/A	1.859		production/manufacturing	N/A	N/A	N/A
24	Hydrochloric Acid Reagent Grad	7647-01-0	Corrosive, Irritant	1.61		production/manufacturing	34	26, 45	290, 314, 335
25	Sodium Bicarbonate ACS	144-55-8	-	0.0016		production/manufacturing	None	None	None
26	Armorflex Continuous Liner	N/A	N/A	n/a		production/manufacturing	N/A	N/A	N/A
27	Carbonyldiimidazole	530-62-1	Corrosive, Harmful	1.004		production/manufacturing	36/37/38	24/25	302, 314
28	Citric Acid Anhydrous	77-92-9	Irritant	1.245		production/manufacturing	36/37/38	26, 37/39	319

Ref. N° or	Material/ Substance <sup>(1)</sup>	CAS Number	Danger <sup>(2)</sup> Category	Amount Stored	Annual Usage	Nature of Use	R <sup>(3)</sup> - Phrase	S <sup>(3)</sup> - Phrase	Hazard Statement <sup>(4)</sup>
29	Filter Agent Celpure P1000	68855-54-9	Toxic	0.001		production/manufacturing	48/20/21/22	22, 26	373
30	Cellulose, Microcryst., NF/EP (PH 102)	9004-34-6	-	1.0782		production/manufacturing	None	None	None
31	N-Methylmorpholine (NMM)	109-02-4	Highly Flammable, Corrosive, Irritant	1.041		production/manufacturing	11, 20/21/22/34	16, 26, 36/37/39, 45	225, 302, 314
32	Alcohol Methyl	67-56-1	Highly Flammable, Toxic	16.756		production/manufacturing	11, 23/24/25, 39/23/24/25	7, 16, 36/37, 45	225, 301, 311, 331, 370
33	Sodium Chloride ACS Reagent	7647-14-5	-	1.330		production/manufacturing	36	26	None
34	Phosphoric Acid 0268	7664-38-2	Corrosive	2.968		production/manufacturing	34	26, 27/28, 36/37/39, 6	290, 314
<b>Amount Stored (pieces of equipment)</b>									
35	8 Gal.Poly Drum	N/A	-	1		Equipment used in production/manufacturing	N/A	N/A	N/A
36	Bag, Plastic (31" X 46")	N/A	-	4630		Equipment used in production/manufacturing	N/A	N/A	N/A
37	Fibre Drum (82.4 LTS)	N/A	-	127		Equipment used in production/manufacturing	N/A	N/A	N/A
38	Drum Seal	N/A	-	550		Equipment used in production/manufacturing	N/A	N/A	N/A
39	Non-Releasable Nylon Tie	N/A	-	14900		Equipment used in production/manufacturing	N/A	N/A	N/A
40	Releasable Tie (230mm)	N/A	-	14400		Equipment used in production/manufacturing	N/A	N/A	N/A
41	Zeta Plus R30SP Cellulose	N/A	-	46		Equipment used in production/manufacturing	N/A	N/A	N/A

Ref. N <sup>o</sup> or	Material/ Substance <sup>(1)</sup>	CAS Number	Danger <sup>(2)</sup> Category	Amount Stored	Annual Usage	Nature of Use	R <sup>(3)</sup> - Phrase	S <sup>(3)</sup> - Phrase	Hazard Statement <sup>(4)</sup>
42	Size 2 Maroon Cap Red Body	N/A	-	27337000		Equipment used in production/manufacturing	N/A	N/A	N/A
43	Size 4 Yellow Cap Red Body	N/A	-	11067000		Equipment used in production/manufacturing	N/A	N/A	N/A
44	Size 4 Orange Opaque Cap Red Body	N/A	-	4500000		Equipment used in production/manufacturing	N/A	N/A	N/A
45	Size 4 Red Opaque Cap Red Body	N/A	-	39512000		Equipment used in production/manufacturing	N/A	N/A	N/A
46	Drum Liner Flatbag LDPE	N/A	-	18877		Equipment used in production/manufacturing	N/A	N/A	N/A
47	Stopper 20mm	N/A	-	14263		Equipment used in production/manufacturing	N/A	N/A	N/A
48	Aluminium Crimp Seal 20mm	N/A	-	29191		Equipment used in production/manufacturing	N/A	N/A	N/A
49	Argon, Grade BIP Plus	N/A	-	8		Equipment used in production/manufacturing	N/A	N/A	N/A
50	Nitrogen Grade 4.8 (99.998%)	N/A	-	12		Equipment used in production/manufacturing	N/A	N/A	N/A
51	Biotage Chromatography Column	N/A	-	4		Equipment used in production/manufacturing	N/A	N/A	N/A
52	Amber USP Type 1 Glass Vial 5M	N/A	-	2644		Equipment used in production/manufacturing	N/A	N/A	N/A
53	Amber USP Type 1 Glass Vial	N/A	-	0.41		Equipment used in production/manufacturing	N/A	N/A	N/A
54	Biotage Column 150M	N/A	-	3		Equipment used in production/manufacturing	N/A	N/A	N/A
55	Tote Box 35L HDPE Box PP Lid	N/A	-	1746		Equipment used in production/manufacturing	N/A	N/A	N/A
56	HDPE 16 Gal. Drum	N/A	-	294		Equipment used in production/manufacturing	N/A	N/A	N/A
57	Paricalcitol FG Label	N/A	-	4000		Equipment used in production/manufacturing	N/A	N/A	N/A
58	Biotage Column	N/A	-	6		Equipment used in	N/A	N/A	N/A

Ref. N <sup>o</sup> or	Material/ Substance <sup>(1)</sup>	CAS Number	Danger <sup>(2)</sup> Category	Amount Stored	Annual Usage	Nature of Use	R <sup>(3)</sup> - Phrase	S <sup>(3)</sup> - Phrase	Hazard Statement <sup>(4)</sup>
	150L					production/manufacturing			

Notes: 1. In cases where a material comprises a number of distinct and available dangerous substances, please give details for each component substance.

2. Article 2(2) of S.I. No. 116/2003.

3. Schedules 9 and 10 of S.I. No. 62/2004 (as amended by S.I. No. 271/2008)

4. EC Regulation 1272/2008 (Chemicals Act 2008 (13 of 2008) and 2010)

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Table G.1(ii) Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site

Ref. N <sup>o</sup> or Code	Material/ Substance	Odour			Pollutants (Tick and specify Group/Family Number)				Controlled Substances	Relevant hazardous substance <sup>(3)</sup>
		Odorous Yes/No	Description	Threshold $\mu\text{g}/\text{m}^3$	EC EO (Surface Waters) Regulations 2009		EC EO Groundwater) Regulations 2010		REACH SVHC <sup>(2)</sup>	y/n
					Specific pollutants	Priority (hazardous) substances	Hazardous <sup>1</sup>	Non-hazardous <sup>1</sup>		
1	Dichloromethane	Yes	Chloroform like	No Data	N/A	N/A	Yes	N/A	N/A	Yes
2	Triethylamine	Yes	Strong ammonia like	No Data	N/A	N/A	N/A	N/A	N/A	N/A
3	Propane	Yes	Ether like	No Data	N/A	N/A	N/A	N/A	N/A	N/A
4	Phosphonic Anhydride Ethanol	Yes	Sweet alcohol like	No Data	N/A	N/A	UD	N/A	N/A	N/A
5	Ethyl Acetate	Yes	Slightly fruity	No Data	N/A	N/A	N/A	N/A	N/A	N/A
6	Dimethylformamide	No	Slight amine-like	No Data	N/A	N/A	N/A	N/A	Yes	N/A
7	Isopropylalcohol	No	Slight alcoholic	No Data	N/A	N/A	N/A	N/A	N/A	N/A
8	Isopropylacetate	No	Sweet	No Data	N/A	N/A	N/A	N/A	N/A	N/A
9	Tetrahydrofuran (with BHT)	Yes	Ethereal	No	N/A	N/A	N/A	N/A	N/A	N/A

Ref. N <sup>o</sup> or	Material/	Odour			Pollutants (Tick and specify Group/Family Number)				Controlled Substances	Relevant hazardous substance <sup>(3)</sup>
10	Pyridine, anhydrous 99.8 %	No Data	No Data	<1 ppm	N/A	N/A	N/A	N/A	N/A	N/A
11	Maize Starch	Yes	Varying	No Data	N/A	N/A	N/A	N/A	N/A	N/A
12	Lactose	No Data	No Data	No Data	N/A	N/A	N/A	N/A	N/A	N/A
13	Methylene Chloride	Yes	Sweet	No Data	N/A	N/A	N/A	N/A	N/A	N/A
14	Hydrochloric Acid 37% ACS	Yes	Pungent, Irritating	<10 ppm	N/A	N/A	N/A	N/A	N/A	N/A
15	2-Methyl THF	Yes	Ether like	No Data	N/A	N/A	N/A	N/A	N/A	N/A
16	N-Methylpyrrolidone	Yes	Amine like	No Data	N/A	N/A	N/A	N/A	<b>Yes</b>	N/A
17	Alcohol SD 3A 200 Proof	Yes	Alcoholic	No Data	N/A	N/A	N/A	N/A	N/A	N/A
18	Ethanol (Denatured with Toluene)	Yes	Alcoholic	No Data	N/A	N/A	N/A	N/A	N/A	N/A
19	Sodium Hydroxide Pellets	No	None	No Data	N/A	N/A	<b>UD</b>	N/A	N/A	<b>UD</b>
20	Diazabicycloundecene	Yes	Pungent	No Data	N/A	N/A	N/A	N/A	N/A	N/A
21	2-Methoxyethanol	Yes	Aromatic	2.4 ppm	N/A	N/A	N/A	N/A	<b>YES</b>	N/A
22	Sodium Bicarbonate USP	No	None	No Data	N/A	N/A	N/A	N/A	N/A	N/A
23	Continuous	No	None	No Data	N/A	N/A	N/A	N/A	N/A	N/A

Ref. N <sup>o</sup> or	Material/	Odour			Pollutants (Tick and specify Group/Family Number)				Controlled Substances	Relevant hazardous substance <sup>(3)</sup>
24	Liner Hydrochloric Acid Reagent Grad	Yes	Pungent, Irritating	<10 ppm	N/A	N/A	N/A	N/A	N/A	N/A
25	Sodium Bicarbonate ACS	No	None	No Data	N/A	N/A	N/A	N/A	N/A	N/A
26	Armorflex Continuous Liner	No	None	No Data	N/A	N/A	N/A	N/A	N/A	N/A
27	Carbonyldiimidazole	No	None	No Data	N/A	N/A	N/A	N/A	N/A	N/A
28	Citric Acid Anhydrous	No	None	No Data	N/A	N/A	<b>UD</b>	N/A	N/A	<b>UD</b>
29	Filter Agent Celpure P1000	No	None	No Data	N/A	N/A	N/A	N/A	N/A	N/A
30	Cellulose, Microcryst., NF/EP (PH 102)	No	None	No Data	N/A	N/A	N/A	N/A	N/A	N/A
31	N-Methylmorpholine (NMM)	Yes	Penetrating, ammonia like	No Data	N/A	N/A	N/A	N/A	N/A	N/A
32	Alcohol Methyl	Yes	Alcohol like	100 ppm	N/A	N/A	N/A	N/A	N/A	N/A
33	Sodium Chloride ACS Reagent	No	None	No Data	N/A	N/A	<b>UD</b>	N/A	N/A	<b>UD</b>
34	Phosphoric Acid 0268	No	None	No Data	N/A	N/A	N/A	<b>Yes</b>	N/A	N/A

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- Note 1: The EPA Classification of Hazardous and Non-Hazardous Substances in Groundwater, December 2010.
- Note 2: Where relevant, specify whether the substance is on the Authorisation List (Annex XIV Regulation (EC) No 1907/2006 as amended) or Restriction List (Annex XVII Regulation (EC) No 1907/2006 as amended). Also, indicate whether the use has been authorised or exempted in accordance with Regulation (EC) No 1907/2006 as amended.
- Note 3: Relevant hazardous substances are those substances or mixtures defined within Article 3 of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures which, as a result of their hazardousness, mobility, persistence and biodegradability (as well as other characteristics), are capable of contaminating soil or groundwater.

\*UD = Undetermined

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**TABLE H.3(i): Generation of waste at the installation and its management**

Waste description	EWC Code (use asterisk to indicate whether hazardous waste or not)	Category per Animal By- products Regulation 1069/2009	Source of waste	Quantity generated (tonnes per month)* Tonnes per year	Location of recovery of disposal (on-site, off-site, exported)	Method of recovery or disposal (e.g. recycling, energy recovery, other incineration, landfill)
Hydrochloric Acid	06 01 02*	n/a	Production areas	0.584	Exported	Incineration on land
Other Acids	06 01 06*	n/a	Production areas	0.711	Exported	Incineration on land
Other Bases	06 02 05*	n/a	Production areas	0.703	Exported	Incineration on land
Aqueous washing liquids and mother liquors	07 05 01*	n/a	Production areas	385.16	Exported	Incineration on land
Aqueous washing liquids and mother liquors	07 05 01*	n/a	Production areas	1521.924	Exported	Incineration on land
Aqueous washing liquids and mother liquors	07 05 01*	n/a	Production areas	119.38	Exported	Incineration on land
Organic halogenated solvents, washing liquids and mother liquors	07 05 03*	n/a	Production areas	48.71	Exported	Incineration on land
Other organic solvents, washing liquids and mother liquors	07 05 04*	n/a	Production areas	63.72	Exported	Solvent Reclamation / Regeneration
Other organic solvents, washing liquids and mother liquors	07 05 04*	n/a	Production areas	180.746	Exported	Incineration on Land
Other organic solvents, washing liquids and	07 05 04*	n/a	Production areas	189.79	Off-Site	Use as Fuel

mother liquors						
Solid waste containing dangerous substances	07 05 13*	n/a	Production areas	28.102	Exported	Incineration on Land
Waste adhesives and sealants containing organic solvents or other dangerous substances	08 04 09*	n/a	Production areas	0.287	Exported	Incineration on Land
Other hydraulic oils	13 01 13*	n/a	Production areas	0.139	Exported	Incineration on Land
Other insulating and heat transmission oils	13 03 10*	n/a	Production areas	5.546	Exported	Landspreading
Paper and cardboard packaging	15 01 01	n/a	Offices, Production areas and Utilities	6.508	Off-Site	Organic Substance Recycling / Reclamation
Mixed packaging	15 01 06	n/a	Offices, Production areas and Utilities	20.99	Off-Site	Organic Substance Recycling / Reclamation
Packaging containing residues of or contaminated by dangerous substances	15 01 10*	n/a	Production areas	0.022	Exported	Incineration on Land
Packaging containing residues of or contaminated by dangerous substances	15 01 10*	n/a	Production areas	22.775	Exported	Incineration on Land
Absorbents, filter materials (including oil filters not otherwise specified), wiping	15 02 02*	n/a	Production areas	33.268	Exported	Incineration on Land

cloths, protective clothing contaminated by dangerous substances						
Discarded equipment containing hazardous components (16) other than those mentioned in 16 02 09 to 16 02 12	16 02 13*	n/a	Production areas	1.956	Off-Site	Metal Recycling / Reclamation
Inorganic wastes containing dangerous substances	16 03 03*	n/a	Production areas	1.172	Exported	Incineration on Land
Gases in pressure containers (including halons) containing dangerous substances	16 05 04*	n/a	Production areas	0.034	Exported	Incineration on Land
Laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals	16 05 06*	n/a	Laboratory	1.126	Exported	Incineration on Land
Laboratory chemicals, consisting of or containing dangerous substances,	16 05 16*	n/a	Laboratory	0.069	Exported	Incineration on Land

including mixtures of laboratory chemicals						
Discarded inorganic chemicals consisting of or containing dangerous substances	16 05 07*	n/a	Production areas	1.042	Exported	Incineration on Land
Oxidising substances, not otherwise specified	16 09 04*	n/a	Production areas	0.146	Exported	Incineration on Land
Wastes whose collection and disposal is subject to special requirements in order to prevent infection	18 01 03*	n/a	Production areas	0.5	Off-Site	Physico Chemical Treatment
Biodegradable kitchen and canteen waste	20 01 08	n/a	Canteen	2.508	Off-Site	Organic Substance Recycling / Reclamation
Fluorescent tubes and other mercury containing waste	20 01 21*	n/a	Production areas	0.128	Off-Site	Metal Recycling / Reclamation
Wood other than that mentioned in 20 01 37	20 01 38	n/a	Production areas, Delivery area	2.2	Off-Site	Organic Substance Recycling / Reclamation
Plastics	20 01 39	n/a	Canteen, Offices, Production areas and Utilities	0.53	Off-Site	Organic Substance Recycling / Reclamation
Metals	20 01 40	n/a	Production areas, Utilities	1.34	Off-Site	Metal Recycling / Reclamation
Phosphoric and phosphorous acid	06 01 04*	n/a	Production areas	0.307	Exported	Incineration on Land
Sodium and	06 02 04*	n/a	Production areas	0.281	Exported	Incineration on Land



potassium hydroxide						
Other organic solvents, washing liquids and mother liquors	07 05 04*	n/a	Production areas	22.42	Off-Site	Use as Fuel
Glass	20 01 02	n/a	Canteen, Offices, Production areas and Utilities	0.22	Off-Site	Inorganic Substance Recycling / Reclamation
Mixed municipal waste	20 03 01	n/a	Canteen, Offices, Production areas and Utilities	32.557	Off-Site	Landfill
Bulky waste	20 03 07	n/a	Utilities, Production areas	17.9	Off-Site	Use as Fuel

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Table I.2(i) SURFACE WATER QUALITY

(Sheet 1 of 2) Monitoring Point/ Grid Reference: SW1 (170340E, 337430N)

Parameter	Results (mg/l)				Sampling method <sup>2</sup> (grab, drift etc.)	Normal Analytical Range <sup>2</sup>	Analysis method / technique
	Date	Date	Date	Date			
pH	Annual Average			7.95	pH Electrode		Standard methods
Temperature	Annual Average			14.1	Temperature probe		Standard methods
Electrical conductivity EC							
Total Ammonia as N							
Chemical oxygen demand	Annual Average			10	Weekly Grab		Standard methods
Biochemical oxygen demand							
Dissolved oxygen DO							
Orthophosphate as P							
Nitrate as N							
Nitrite as N							
Calcium Ca							
Cadmium Cd							
Chromium Cr							
Chloride Cl							
Copper Cu							
Iron Fe							
Lead Pb							
Magnesium Mg							
Manganese Mn							
Mercury Hg							

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## Surface Water Quality (Sheet 2 of 2)

Parameter	Results (mg/l)				Sampling method (grab, drift etc.)	Normal Analytical Range	Analysis method / technique
	Date	Date	Date	Date			
Nickel Ni							
Potassium K							
Sodium Na							
Sulphate SO <sub>4</sub>							
Zinc Zn							
Total alkalinity (as CaCO <sub>3</sub> )							
Total organic carbon TOC							
Total oxidised nitrogen TON							
Nitrite NO <sub>2</sub>							
Nitrate NO <sub>3</sub>							
Faecal coliforms ( /100mls)							
Total coliforms ( /100mls)							
Phosphate PO <sub>4</sub>							

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**Table I.4(i) GROUNDWATER QUALITY**

(Sheet 1 of 2) Monitoring Point/ Grid Reference: MW 1

Parameter	Results (mg/l)			Sampling method (composite etc.)	Normal Analytical Range	Analysis method / technique
	8 <sup>th</sup> of May 2014 & 12 of Nov 2014	6 <sup>th</sup> of May 2015				
	Max	Average	Average			
pH	7.2	7.1	7.9	pH electrode/meter		
Temperature	12	12	N/A	Thermometer		
Electrical conductivity EC	882	606	314	pH electrode/meter		
Total Ammonium as N	<0.27	<0.27	<0.27	Ion Selective Electrode		
Nitrite as N	N/A	N/A	N/A	N/A		
Nitrate as N	N/A	N/A	N/A	N/A		
Orthophosphate as P	0.25	0.25	<0.02	N/A		
Dissolved oxygen DO	N/A	N/A	N/A	N/A		
Residue on evaporation (180°C)	N/A	N/A	N/A	N/A		
Aluminium Al	1.93	1.17	0.1	Atomic Absorption/ICP		
Arsenic As	0.0018	0.0022	0.0015	Atomic Absorption/ICP		
Boron B	N/A	N/A	N/A	N/A		
Calcium Ca	185	151	54.4	Atomic Absorption/ICP		
Cadmium Cd	<0.0006	<0.0006	<0.0006	Atomic Absorption/ICP		
Chromium Cr	<0.002	<0.002	<0.002	Atomic Absorption/ICP		
Chloride Cl	28	27.75	19.4	Standard Method		
Copper Cu	0.015	0.012	<0.009	Atomic Absorption/ICP		

<b>Cyanide Cn, total</b>	N/A	N/A	N/A	N/A		
<b>Iron Fe</b>	3.66	2.08	<0.23	Atomic Absorption/ICP		
<b>Lead Pb</b>	0.014	0.01	<0.006	Atomic Absorption/ICP		
<b>Magnesium Mg</b>	25.4	26.5	5.7	Atomic Absorption/ICP		
<b>Manganese Mn</b>	1.4	2.48	0.017	Atomic Absorption/ICP		
<b>Mercury Hg</b>	<0.0001	<0.0001	<0.0001	Atomic Absorption/ICP		
<b>Nickel Ni</b>	0.008	0.012	0.008	Atomic Absorption/ICP		
<b>Potassium K</b>	2.1	2.19	3.83	Atomic Absorption/ICP		
<b>Sodium Na</b>	13.4	14.9	10.9	Atomic Absorption/ICP		
<b>Sulphate SO<sub>4</sub></b>	109	63.4	29.4	Atomic Absorption/ICP		

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## Groundwater Quality (sheet 2 of 2)

Parameter	Results (mg/l)			Sampling method (composite etc.)	Normal Analytical Range	Analysis method / technique
	8 <sup>th</sup> of May 2014 & 12 of Nov 2014	6 <sup>th</sup> of May 2015				
	Max	Average	Average			
Phosphate PO <sub>4</sub>	N/A	N/A	N/A	N/A		
Zinc Zn	0.024	0.03	<0.018	Atomic Absorption/ICP		
Total alkalinity (as CaCO <sub>3</sub> )	N/A	N/A	350	N/A		
Total organic carbon TOC	N/A	N/A	N/A	N/A		
Total oxidised nitrogen TON	N/A	N/A	N/A	N/A		
Barium Ba	N/A	N/A	N/A	N/A		
Fluoride F	0.451	0.44	0.202	Atomic Absorption/ICP		
Phenol	N/A	N/A	N/A	N/A		
Phosphorus P	N/A	N/A	N/A	N/A		
Selenium Se	<0.0016	<0.0016	0.00129	Atomic Absorption/ICP		
Silver Ag	0.0092	0.0095	<0.0007	Atomic Absorption/ICP		
Nitrite NO <sub>2</sub>	0.025	0.025	<0.025	Ion Selective Electrode		
Nitrate NO <sub>3</sub>	1	1	1.05	Ion Selective Electrode		
COD	14	10	14	Standard Method		
Cobalt	0.002	0.002	<0.002	Atomic Absorption/ICP		
Tin	<0.007	<0.007	<0.007	Atomic Absorption/ICP		
Antimony	<0.0016	<0.0016	0.0014	Atomic Absorption/ICP		
Faecal coliforms (	N/A	N/A	N/A	N/A		

/100mls)					
Total coliforms ( /100mls)	N/A	N/A	N/A	N/A	
Water level (m OD)	N/A	N/A	N/A	N/A	

(Sheet 1 of 2) Monitoring Point/ Grid Reference: MW 2

Parameter	Results (mg/l)			Sampling method (composite etc.)	Normal Analytical Range	Analysis method / technique
	8 <sup>th</sup> of May 2014 & 12 of Nov 2014	Average	6 <sup>th</sup> of May 2015			
	Max	Average	Average			
pH	7.2	7.15	7.4	pH electrode/meter		
Temperature	12.9	12.9	N/A	Thermometer		
Electrical conductivity EC	950	651	698	pH electrode/meter		
Total Ammonium as N	<0.27	<0.27	<0.27	Ion Selective Electrode		
Nitrite as N	N/A	N/A	N/A	N/A		
Nitrate as N	N/A	N/A	N/A	N/A		
Orthophosphate as P	0.1	0.06	<0.02	N/A		
Dissolved oxygen DO	N/A	N/A	N/A	N/A		
Residue on evaporation (180°C)	N/A	N/A	N/A	N/A		
Aluminium Al	0.98	1.65	0.4	Atomic Absorption/ICP		
Arsenic As	0.005	0.0085	0.003	Atomic Absorption/ICP		
Boron B	N/A	N/A	N/A	N/A		
Calcium Ca	161	141	112	Atomic Absorption/ICP		
Cadmium Cd	0.0006	0.0006	<0.0006	Atomic Absorption/ICP		
Chromium Cr	0.003	0.003	<0.002	Atomic		

				Absorption/ICP		
<b>Chloride Cl</b>	65.5	53.8	75.0	Standard Method		
<b>Copper Cu</b>	0.014	0.018	0.024	Atomic Absorption/ICP		
<b>Cyanide Cn, total</b>	N/A	N/A	N/A	N/A		
<b>Iron Fe</b>	3.1	5.5	1.55	Atomic Absorption/ICP		
<b>Lead Pb</b>	0.014	0.022	0.007	Atomic Absorption/ICP		
<b>Magnesium Mg</b>	14.1	14.5	13.2	Atomic Absorption/ICP		
<b>Manganese Mn</b>	0.92	1.65	0.509	Atomic Absorption/ICP		
<b>Mercury Hg</b>	<0.0001	<0.0001	<0.0001	Atomic Absorption/ICP		
<b>Nickel Ni</b>	0.0031	0.054	0.015	Atomic Absorption/ICP		
<b>Potassium K</b>	3.95	4.42	2.53	Atomic Absorption/ICP		
<b>Sodium Na</b>	37.7	39.8	36.9	Atomic Absorption/ICP		
<b>Sulphate SO<sub>4</sub></b>	159	103.8	58.7	Atomic Absorption/ICP		

## GROUNDWATER QUALITY (SHEET 2 OF 2)

Parameter	Results (mg/l)			Sampling method (composite etc.)	Normal Analytical Range	Analysis method / technique
	8 <sup>th</sup> of May 2014 & 12 of Nov 2014		6 <sup>th</sup> of May 2015			
	Max	Average	Average			
<b>Phosphate PO<sub>4</sub></b>	N/A	N/A	N/A	N/A		
<b>Zinc Zn</b>	0.055	0.08	0.04	Atomic Absorption/ICP		
<b>Total alkalinity (as CaCO<sub>3</sub>)</b>	N/A	N/A	205	N/A		
<b>Total organic carbon TOC</b>	N/A	N/A	N/A	N/A		



<b>Total oxidised nitrogen TON</b>	N/A	N/A	N/A	N/A		
<b>Barium Ba</b>	N/A	N/A	N/A	N/A		
<b>Fluoride F</b>	0.302	0.285	0.328	Atomic Absorption/ICP		
<b>Phenol</b>	N/A	N/A	N/A	N/A		
<b>Phosphorus P</b>	N/A	N/A	N/A	N/A		
<b>Selenium Se</b>	0.0017	0.0018	<0.0008	Atomic Absorption/ICP		
<b>Silver Ag</b>	0.0009	0.0011	<0.0007	Atomic Absorption/ICP		
<b>Nitrite NO<sub>2</sub></b>	0.025	0.025	<0.025	Ion Selective Electrode		
<b>Nitrate NO<sub>3</sub></b>	7.8	5.5	2.4	Ion Selective Electrode		
<b>COD</b>	12	9.5	<5	Standard Method		
<b>Cobalt</b>	0.01	0.0177	0.005	Atomic Absorption/ICP		
<b>Tin</b>	<0.007	<0.007	<0.007	Atomic Absorption/ICP		
<b>Antimony</b>	<0.0016	<0.0016	<0.0012	Atomic Absorption/ICP		
<b>Faecal coliforms ( /100mls)</b>	N/A	N/A	N/A	N/A		
<b>Total coliforms ( /100mls)</b>	N/A	N/A	N/A	N/A		
<b>Water level (m OD)</b>	N/A	N/A	N/A	N/A		

(Sheet 1 of 2) Monitoring Point/ Grid Reference: MW 3

Parameter	Results (mg/l)			Sampling method (composite etc.)	Normal Analytical Range	Analysis method / technique
	8 <sup>th</sup> of May 2014 & 12 of Nov 2014	6 <sup>th</sup> of May 2015				
	Max	Average	Average			
pH	7.1	7.05	7.0	pH electrode/meter		
Temperature	11.7	11.7	N/A	Thermometer		
Electrical conductivity EC	855	652	774	pH electrode/meter		
Total Ammonium as N	<0.27	<0.27	<0.27	Ion Selective Electrode		
Nitrite as N	N/A	N/A	N/A	N/A		
Nitrate as N	N/A	N/A	N/A	N/A		
Orthophosphate as P	0.02	0.02	<0.02	N/A		
Dissolved oxygen DO	N/A	N/A	N/A	N/A		
Residue on evaporation (180°C)	N/A	N/A	N/A	N/A		
Aluminium Al	0.56	0.6	0.8	Atomic Absorption/ICP		
Arsenic As	0.002	0.003	0.006	Atomic Absorption/ICP		
Boron B	N/A	N/A	N/A	N/A		
Calcium Ca	154	165	163	Atomic Absorption/ICP		
Cadmium Cd	<0.0006	<0.0006	<0.0006	Atomic Absorption/ICP		
Chromium Cr	<0.002	<0.002	0.002	Atomic Absorption/ICP		
Chloride Cl	32	29	55.0	Standard Method		
Copper Cu	<0.009	<0.009	<0.009	Atomic Absorption/ICP		
Cyanide Cn, total	N/A	N/A	N/A	N/A		
Iron Fe	2.65	3.61	17.7	Atomic Absorption/ICP		
Lead Pb	0.007	0.008	0.01	Atomic		

				Absorption/ICP		
<b>Magnesium Mg</b>	16.8	18.2	18.9	Atomic Absorption/ICP		
<b>Manganese Mn</b>	0.208	0.269	0.087	Atomic Absorption/ICP		
<b>Mercury Hg</b>	<0.0001	<0.0001	<0.0001	Atomic Absorption/ICP		
<b>Nickel Ni</b>	0.0009	0.0009	0.01	Atomic Absorption/ICP		
<b>Potassium K</b>	1.82	1.87	2.21	Atomic Absorption/ICP		
<b>Sodium Na</b>	14.5	15.2	18.5	Atomic Absorption/ICP		
<b>Sulphate SO<sub>4</sub></b>	33.6	31	41.4	Atomic Absorption/ICP		

**Groundwater Quality (sheet 2 of 2)**

Parameter	Results (mg/l)			Sampling method (composite etc.)	Normal Analytical Range	Analysis method / technique
	8 <sup>th</sup> of May 2014 & 12 of Nov 2014		6 <sup>th</sup> of May 2015			
	Max	Average	Average			
<b>Phosphate PO<sub>4</sub></b>	N/A	N/A	N/A	N/A		
<b>Zinc Zn</b>	<0.018	<0.018	<0.018	Atomic Absorption/ICP		
<b>Total alkalinity (as CaCO<sub>3</sub>)</b>	N/A	N/A	386	N/A		
<b>Total organic carbon TOC</b>	N/A	N/A	N/A	N/A		
<b>Total oxidised nitrogen TON</b>	N/A	N/A	N/A	N/A		
<b>Barium Ba</b>	N/A	N/A	N/A	N/A		
<b>Fluoride F</b>	0.154	0.134	0.187	Atomic Absorption/ICP		
<b>Phenol</b>	N/A	N/A	N/A	N/A		
<b>Phosphorus P</b>	N/A	N/A	N/A	N/A		
<b>Selenium Se</b>	0.0019	0.0021	0.00423	Atomic		

				Absorption/ICP		
<b>Silver Ag</b>	<0.0007	<0.0007	<0.0007	Atomic Absorption/ICP		
<b>Nitrite NO<sub>2</sub></b>	0.025	0.025	<0.025	Ion Selective Electrode		
<b>Nitrate NO<sub>3</sub></b>	1.5	1.25	2.14	Ion Selective Electrode		
<b>COD</b>	9	7	<5	Standard Method		
<b>Cobalt</b>	<0.002	<0.002	0.003	Atomic Absorption/ICP		
<b>Tin</b>	<0.007	<0.007	<0.007	Atomic Absorption/ICP		
<b>Antimony</b>	<0.0016	<0.0016	<0.0012	Atomic Absorption/ICP		
<b>Faecal coliforms ( /100mls)</b>	N/A	N/A	N/A	N/A		
<b>Total coliforms ( /100mls)</b>	N/A	N/A	N/A	N/A		
<b>Water level (m OD)</b>	N/A	N/A	N/A	N/A		

(Sheet 1 of 2) Monitoring Point/ Grid Reference: MW 4

Parameter	Results (mg/l)			Sampling method (composite etc.)	Normal Analytical Range	Analysis method / technique
	8 <sup>th</sup> of May 2014 & 12 of Nov 2014	Max	Average			
<b>pH</b>	7.2	7.2	7.2	pH electrode/meter		
<b>Temperature</b>	12.2	12.2	N/A	Thermometer		
<b>Electrical conductivity EC</b>	894	661	784	pH electrode/meter		
<b>Total Ammonium as N</b>	<0.27	<0.27	<0.27	Ion Selective Electrode		
<b>Nitrite as N</b>	N/A	N/A	N/A	N/A		
<b>Nitrate as N</b>	N/A	N/A	N/A	N/A		
<b>Orthophosphate as P</b>	0.02	0.02	<0.02	N/A		

<b>Dissolved oxygen DO</b>	N/A	N/A	N/A	N/A		
<b>Residue on evaporation (180°C)</b>	N/A	N/A	N/A	N/A		
<b>Aluminium Al</b>	1.38	2.25	1.3	Atomic Absorption/ICP		
<b>Arsenic As</b>	0.0046	0.0078	0.0027	Atomic Absorption/ICP		
<b>Boron B</b>	N/A	N/A	N/A	N/A		
<b>Calcium Ca</b>	232	352	187	Atomic Absorption/ICP		
<b>Cadmium Cd</b>	<0.006	<0.006	<0.0006	Atomic Absorption/ICP		
<b>Chromium Cr</b>	0.003	0.003	0.003	Atomic Absorption/ICP		
<b>Chloride Cl</b>	47.7	43.9	55.0	Standard Method		
<b>Copper Cu</b>	0.017	0.025	0.040	Atomic Absorption/ICP		
<b>Cyanide Cn, total</b>	N/A	N/A	N/A	N/A		
<b>Iron Fe</b>	3.13	6.03	2.37	Atomic Absorption/ICP		
<b>Lead Pb</b>	0.015	0.023	0.013	Atomic Absorption/ICP		
<b>Magnesium Mg</b>	25.2	27.2	26.2	Atomic Absorption/ICP		
<b>Manganese Mn</b>	1.334	2.56	1.01	Atomic Absorption/ICP		
<b>Mercury Hg</b>	<0.0001	<0.0001	<0.0001	Atomic Absorption/ICP		
<b>Nickel Ni</b>	0.012	0.019	0.009	Atomic Absorption/ICP		
<b>Potassium K</b>	2.15	2.33	2.32	Atomic Absorption/ICP		
<b>Sodium Na</b>	20.9	23.4	22.0	Atomic Absorption/ICP		
<b>Sulphate SO<sub>4</sub></b>	211	129.9	51.6	Atomic Absorption/ICP		

Parameter	Results (mg/l)			Sampling method (composite etc.)	Normal Analytical Range	Analysis method / technique
	8 <sup>th</sup> of May 2014 & 12 of Nov 2014	Max	Average			
<b>Phosphate PO<sub>4</sub></b>	N/A	N/A	N/A	N/A		
<b>Zinc Zn</b>	0.024	0.03	0.04	Atomic Absorption/ICP		
<b>Total alkalinity (as CaCO<sub>3</sub>)</b>	N/A	N/A	350	N/A		
<b>Total organic carbon TOC</b>	N/A	N/A	N/A	N/A		
<b>Total oxidised nitrogen TON</b>	N/A	N/A	N/A	N/A		
<b>Barium Ba</b>	N/A	N/A	N/A	N/A		
<b>Fluoride F</b>	0.649	0.622	0.665	Atomic Absorption/ICP		
<b>Phenol</b>	N/A	N/A	N/A	N/A		
<b>Phosphorus P</b>	N/A	N/A	N/A	N/A		
<b>Selenium Se</b>	0.002	0.0024	<0.0008	Atomic Absorption/ICP		
<b>Silver Ag</b>	0.00087	0.0098	0.002	Atomic Absorption/ICP		
<b>Nitrite NO<sub>2</sub></b>	0.025	0.025	0.025	Ion Selective Electrode		
<b>Nitrate NO<sub>3</sub></b>	0.025	0.025	<1	Ion Selective Electrode		
<b>COD</b>	9	7.5	8	Standard Method		
<b>Cobalt</b>	0.004	0.005	0.003	Atomic Absorption/ICP		
<b>Tin</b>	<0.007	<0.007	<0.007	Atomic Absorption/ICP		
<b>Antimony</b>	<0.0016	<0.0016	<0.00012	Atomic Absorption/ICP		
<b>Faecal coliforms ( /100mls)</b>	N/A	N/A	N/A	N/A		

<b>Total coliforms ( /100mls)</b>	N/A	N/A	N/A	N/A		
<b>Water level (m OD)</b>	N/A	N/A	N/A	N/A		

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**TABLE I.4(ii): LIST OF OWNERS/FARMERS OF LAND** Not Applicable

Land Owner	Townlands where landspreading	Map Reference	Fertiliser P requirement for each farm
			*NMP must take account of on-farm slurry

Total P requirement of the client List \_\_\_\_\_

**TABLE I.4(ii): LANDSPREADING** Not Applicable

Land Owner/Farmer \_\_\_\_\_

Map Reference \_\_\_\_\_

Field ID	Total Area (ha)	(a) Usable Area (ha)	Soil P Test Mg/l	Date of P test	Crop	P Required (kg P/ha)	Volume of On-Farm Slurry Returned (m <sup>3</sup> /ha)	Estimated P in On-Farm Slurry (kg P/ha)	(b) Volume to be Applied (m <sup>3</sup> /ha)	P Applied (kg P/ha)	Total Volume of imported slurry per plot (m <sup>3</sup> )

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**TOTAL VOLUME THAT CAN BE IMPORTED ON TO THE FARM:**

Concentration of P in landspread material	- kg P/m <sup>3</sup>
Concentration of N in landspread material	- kg N/m <sup>3</sup>



**Table I.7(i): AMBIENT & BACKGROUND NOISE ASSESSMENT****Need to carry out an assessment for tonal and impulsive noise<sup>1</sup>**

	National Grid Reference (6N, 6E)	Sound Pressure Levels (dB)					
		L <sub>Aeq</sub>		L <sub>A10</sub>		L <sub>A90</sub>	
		Ambient	Background <sup>2</sup>	Ambient	Background <sup>2</sup>	Ambient	Background <sup>2</sup>
<b>1. SITE BOUNDARY<sup>3</sup></b>							
Location 1:							
Location 2:							
Location 3:							
Location 4:							
<b>2. NOISE SENSITIVE LOCATIONS<sup>3</sup></b>							
Location 1:							
Location 2:							
Location 3:							
Location 4:							

1. Refer to section 5 of the Agency's *Guidance Note for Noise: Licence Applications, Surveys and Assessments in Relation to Scheduled Activities (NG4)* (2012).
2. Background noise levels should be determined in the absence of site specific noise. Where an installation is operational on a 24hr basis, estimates may be given for background noise levels, but this should be noted.
3. All locations should be identified on accompanying drawings.

## ANNEX 2: CHECKLIST FOR Regulation 9 COMPLIANCE

Regulation 9 of the Environmental Protection Agency (Industrial Emissions)(Licensing) Regulations, 2013 sets out the statutory requirements for information to accompany a licence application. The Application Form is designed in such a way as to set out these questions in a structured manner and not necessarily in the order presented in Regulation 9. In order to ensure a legally valid application in respect of Regulation 9 requirements, all Applicants should complete the following checklist and submit it with the completed Application Form.

Regulation 9(2)		Section in Application	Checked by Applicant ✓
(a)	<p>Give:</p> <p>(i) the name, address and telephone number of the applicant and, if different, any address to which correspondence relating to the application should be sent and, if the applicant is a body corporate, the address of its registered or principal office,</p> <p>(ii) The location or postal address (including, where appropriate, the name of the relevant townland or townlands) of the premises to which the activity relates,</p> <p>(iii) The name of the planning authority in whose functional area the activity is or will be carried on, and</p> <p>(iv) In the case of a discharge of any trade effluent or other matter (other than domestic sewage or storm water) to a sewer of a sanitary authority, give the name of the sanitary authority in which the sewer is vested or b which it is controlled</p>	<p>B.1</p> <p>B.1</p> <p>B.6</p> <p>B.7</p>	<p>✓</p>
(b)	<p>give -</p> <p>(i) in the case of an established activity, the number of employees and other persons working or engaged in connection with the activity on the date after which a licence is required and during normal levels of operation, or</p> <p>(ii) in any other case, the gross capital cost of the activity to which the application</p>	<p>B.5</p> <p>B.5</p>	<p>✓</p>

Regulation 9(2)		Section in Application	Checked by Applicant ✓
	relates,		
(c)	specify the relevant class or classes in the First Schedule to the Act to which the industrial emissions directive activity relates,	B.3	✓
(d)	<p>In accordance with Section 87(1B)(a) of the EPA Act of 1992, as amended in the case where an application for permission for the development comprising or for the purposes of the industrial emissions directive activity to which the application for the licence relates is currently under consideration by the planning authority concerned or An Bord Pleanála, a written confirmation from the planning authority or An Bord Pleanála, as appropriate, of that fact together with either:</p> <p>(i) a copy of the environmental impact statement, 2 hard copies and 2 electronic copies or in such form as may be specified by the Agency, that was required to be submitted with the application for planning permission, or</p> <p>(ii) a written confirmation from the planning authority or An Bord Pleanála that an environmental impact assessment is not required by or under the Act of 2000,</p>	N/A	✓
(e)	<p>In accordance with section 87(1B)(b) of the EPA Act of 1992, as amended, in the case where permission for the development comprising or for the purposes of the industrial emissions directive activity to which the application for the licence relates has been granted, a copy of the grant of permission together with either:</p> <p>(i) a copy of the environmental impact statement, 2 hard copies and 2 electronic copies or in such form as may be specified by the Agency, that was required to be submitted with the application for permission, or</p> <p>(ii) a written confirmation from the planning authority or An Bord Pleanála that an environmental impact assessment was not required by or under the Act of 2000,</p>	Attachment B.6	✓
(f)	specify the raw and ancillary materials, substances, preparations, fuels and energy which will be produced by or utilised in the activity,	Section G	✓

<b>Regulation 9(2)</b>		<b>Section in Application</b>	<b>Checked by Applicant ✓</b>
(g)	describe the plant, methods, processes, ancillary processes, abatement, recovery and treatment systems, and operating procedures for the activity,	Section D	✓
(h)	indicate how the requirements of section 83(5)(a)(i) to (v) and (vii) to (xa) of the Act shall be met, having regard, where appropriate, to any relevant specification issued by the Agency under section 5(3)(b) of that Act or any applicable best available techniques (BAT) conclusions adopted in accordance with Article 13(5) of the Industrial Emissions Directive and the reasons for the selection of the arrangements proposed,	Section L	✓
(i)	give particulars of the source, nature, composition, temperature, volume, level, rate, method of treatment and location of emissions, and the period or periods during which the emissions are, or are to be, made,	Section E	✓
(j)	identify monitoring and sampling points and outline proposals for monitoring emissions and the environmental consequences of any such emissions,	Section F	✓
(k)	provide: (i) details, and an assessment, of the impacts of any existing or proposed emissions on the environment as a whole, including on an environmental medium other than that or those into which the emissions are, or are to be, made, and (ii) details of the proposed measures to prevent or eliminate, or where that is not practicable, to limit, reduce or abate emissions,	Section F	✓
(l)	describe in outline the main alternatives to the proposed technology, techniques and measures which were studied by the applicant,	Section I	✓

<b>Regulation 9(2)</b>		<b>Section in Application</b>	<b>Checked by Applicant ✓</b>
(m)	describe the condition of the site of the installation,	<i>Section I</i>	✓
(n)	Provide, when requested by the Agency, in the case of an activity that involves the use, production or release of relevant hazardous substances (as defined in section 3 of the Act of 1992) and having regard to the possibility of soil and groundwater contamination at the site of the installation, a baseline report in accordance with section 86B of the Act of 1992,	<i>Section I</i>	✓
(o)	specify the measures to be taken to comply with an environmental quality standard where such a standard requires stricter conditions to be attached to a licence than would otherwise be determined by reference to best available techniques,	<i>N/A</i>	
(p)	describe the measures to be taken for minimising pollution over long distances or in the territory of other states,	<i>N/A</i>	
(q)	describe the measures to be taken under abnormal operating conditions, including start-up, shutdown, leaks, malfunctions, breakdowns and momentary stoppages,	<i>Section F</i>	✓
(r)	describe the measures to be taken on and following the permanent cessation of the activity or part of the activity to avoid any risk of environmental pollution and to return the site of the activity to a satisfactory state or the state established in the baseline report if such is required under section 86B of the Act of 1992,	<i>Section K</i>	✓
(s)	describe the arrangements for the prevention of waste in accordance with Part III of the Act of 1996, and where waste is generated by the installation, how it will be in order of priority in accordance with section 21A the Act of 1996, prepared for re-use, recycling, recovery or where that is not technically or economically possible, disposed	<i>Section H</i>	✓

<b>Regulation 9(2)</b>		<b>Section in Application</b>	<b>Checked by Applicant ✓</b>
	of in a manner which will prevent or minimise any impact on the environment,		
(t)	specify, by reference to the relevant European Waste Catalogue codes as prescribed by Commission Decision 2000/532/EC of 3 May 2000, the quantity and nature of the waste or wastes produced or to be produced by the activity, or the quantity and nature of waste or waste accepted or to be accepted at the installation,	Section G	✓
(u)	state whether the activity consists of, comprises, or is for the purposes of an establishment to which the European Communities (Control of Major Accident Hazards involving Dangerous Substances) Regulations, 2006(S.I. No. 74 of 2006) apply,	N/A	
(v)	describe, in the case of an activity which gives rise, or could give rise, to an emission containing a hazardous substance which is discharged to an aquifer and is specified in the Annex to Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances, the arrangements necessary to comply with said Council Directive,	N/A	
(w)	include a non-technical summary of information provided in relation to the matters specified in subparagraphs (c) to (x) of this paragraph ,	Section A	✓
(x)	include any other information required under Article 11 of the Industrial Emissions Directive.		

<b>Regulation 9(4)</b> An application for a licence shall be accompanied by -		<b>Section in Application</b>	<b>Checked by Applicant ✓</b>
(a)	a copy of the relevant page of the newspaper in which the notice in accordance with Regulation 5 has been published,	<i>Attachment B</i>	✓
(b)	a copy of the text of the site notice erected or fixed on the land or structure in accordance with Regulation 6,	<i>Attachment B</i>	✓
(c)	a copy of the notice given to the planning authority under section 87(1)(a) of the EPA Act of 1992, as amended	<i>Attachment B</i>	✓
(d)	a copy of such plans, including a site plan and location map, and such other particulars, reports and supporting documentation as are necessary to identify and describe -		
	(i) the activity	<i>Attachment B</i>	✓
	(ii) the position of the site notice in accordance with Regulation 6,	<i>Attachment B</i>	✓
	(iii) the point or points from which emissions are made or are to be made, and	<i>Attachment E</i>	✓

	(iv) monitoring and sampling points, and	<i>Attachment E</i>	✓
(e)	a fee specified in accordance with section 99A of the EPA Act of 1992, as amended.	<i>Section B</i>	✓

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<b>Regulation 9(5)</b>		<b>Checked by Applicant ✓</b>
<p>A signed original and 1 hardcopy and 2 electronic copies of the application as required under paragraphs (1) and (2) or under paragraphs (1) and (3), where the application concerns a review of a licence, and the accompanying documents and particulars as required under paragraph (4) shall be submitted to the headquarters of the Agency. The 2 electronic copies of all application documentation and particulars must be in searchable PDF format on CD Rom in structured in accordance with the "Instructions for Licence Applicant".</p> <p><a href="http://www.epa.ie/pubs/forms/lic/industrial%20emissions/instructionsforapplicantsreapplicationform.html">http://www.epa.ie/pubs/forms/lic/industrial%20emissions/instructionsforapplicantsreapplicationform.html</a></p>	✓	
Hardcopies submitted.	✓	
CD version submitted.	✓	

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