



Industrial Emissions Licence

APPLICATION FORM

Organisation: AbbVie Ireland NL B.V.

Reg. No.: P1087-01

Application Receipt Date: 05 September 2018

Environmental Protection Agency

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

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ABOUT THIS APPLICATION FORM

Application for an Industrial (including Intensive Agriculture) Licence or a Waste Licence or Review of a Licence

This application/review application covers three licence types; Industrial Emissions (IE), Integrated Pollution Control (IPC) and Waste, under the Environmental Protection Agency Act 1992 as amended and the Waste Management Act 1996 as amended.

This application has been developed by the EPA for the purposes of:

- Making an application to the EPA for a licence or review of a licence or revised licence. In this case, licence means Industrial Emissions (IE), Integrated Pollution Control (IPC) or Waste Licence.

Further information and guidance on the licence application and review process is available on the EPA's website at: www.epa.ie.

Your licence application/review and all supporting information should be submitted to the EPA via EDEN, hereafter called 'Application Form'.

About the Application Form

The 'Application Form' must be completed in accordance with the instructions included in EDEN and available on the EPA website. A valid application for a licence must contain the information prescribed in the relevant Licensing Regulations available on the EPA website. 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.

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 or Waste Management Act 1996 as amended and the associated Regulations. 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 Regulations, shall take precedence over any considerations mentioned in this 'Application Form' or on the website.

Public Access

Information supplied in this 'Application Form' including supporting documentation and attachments will be put on public display on the internet and is therefore open to inspection by any person.

Confidential Information

Should you consider information to be confidential, this information should be submitted in a separate enclosure to the headquarters of the EPA bearing the legend "In the event this information is deemed not to be held as confidential, it must be returned to". In the event that the information is considered to be of a confidential nature, then the nature of this information, and the reasons why it is considered confidential (with reference to the "Access to Information on the Environment" Regulations) should be stated in the submission and the 'Application Form', where relevant.

Attachment format and file size

All files attached to this 'Application Form' should be submitted in searchable PDF format and be no larger than 10MB each in size.

The information you provide in this 'Application Form' will be used by the EPA to assess your application and may be used for other EPA purposes.

Please note that the EPA is subject to Freedom of Information Act 2014 and the Access to Environmental Information Regulations 2007 as amended. Any information that you save to EDEN at any time will be stored on the EPA's IT system and will be made available as required under law, including the above legislation.

The system generated Application ID for this licence application/review is: **LA001712**

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1. Introduction

1.1. New/Review Authorisation Application

Is this a new or existing activity?

New

1.2. Non-Technical Summary

Upload a copy of the non-technical summary, in accordance with the guidance.

Document Type	Document Name
Non Technical Summary	Attachment 1.2 Non Technical Summary

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2. Organisation

2.1 Organisation Details

Business type

Body Corporate

Company CRO (Registration) number

906838

Organisation Name

AbbVie Ireland NL B.V.

Organisation Address

MANORHAMILTON ROAD
Sligo

Organisation Registered Address**Organisation's Website Address**

Not Provided

Upload a Certificate of Incorporation, in accordance with the guidance, if applicable

Document Type	Document Name
Certificate of Incorporation	certificate of inc

If the applicant is NOT the operator, please upload an attachment that states the name, address and telephone number of the operator and, if the operator is a body corporate, the address of its registered office or principal office (Optional):

Document Type	Document Name
No files uploaded	



Tick to confirm that the above organisation details are correct

NUTS 2 Code	NACE Code
IE041	2120

State the gross capital cost of the activity to which the application relates

€ 113,000,000.00

2.2 Primary Contact for Correspondence on this Application

Primary Contact

Ms. Breda Rafter

Address of Primary Contact

AbbVie Ireland NL.BV

Ballytivnan

Sligo

Sligo

Position in Organisation

Administrator

Business Mobile Number

087 2665146

Landline Number

071 9155679

Email Address

breda.rafter@abbvie.com

2.3 Primary Contact for Correspondence – Post Determination

Primary Contact

Ms. Breda Rafter

Address of Primary Contact

AbbVie Ireland NL.BV

Ballytivnan

Sligo

Sligo

Position in Organisation

Administrator

Business Mobile Number

087 2665146

Landline Number

071 9155679

Email Address

breda.rafter@abbvie.com

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2.4 Holding (Parent) Company

Does the organisation have a holding (parent) company?

No

2.5 Fit and Proper Person

Convictions and Financial Commitment

Has the applicant or other relevant person been convicted as per guidance?

No

Indicate whether the applicant or other relevant person has current or past bankruptcy or other insolvency proceedings against them or has entered into an arrangement with its creditors or suspended its business activities

No

- Please confirm that the applicant, or other relevant persons, will 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

Financial Commitments Declaration

Please download the attached declaration form, sign and upload the signed copy as a PDF document

Document Type	Document Name
Fit and Proper Declaration	Attachment-2-5 Financial-Commitments-Declaration

Technical Knowledge

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

Document Type	Document Name
Technical Knowledge	Attachment 2-5-3 Technical Knowledge

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3. Site

3.1 Site Name and Address

State the site name (update if necessary)

AbbVie Ireland NL B.V.

Site Address

Old Bundoran Road

Ballytivnan

Sligo

F91 K735

NUTS 2 Code

IE01

NUTS 3 Code

IE011

NACE Code

2120

Site Telephone Number

Not Provided

3.2 Site Geographical Location

Site Centre Point – Easting

(Irish Grid Reference – 6 digits)

569801

Site Centre Point – Northing

(Irish Grid Reference – 6 digits)

837545

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Does the site cover multiple townlands?

No

Upload a copy of the site plan(s) in accordance with the guidance:

Document Type	Document Name
Site Plan	Drawing 010 - Site Notice Locations
Site Plan	Drawing 008 - Site Drainage Drawing
Site Plan	Drawing 004 - Major Emission Points
Site Plan	Drawing 007 - Chemical and waste storage
Site Plan	Drawing 002 - Site Layout
Site Plan	Drawing 003 - Site Services
Site Plan	Drawing 005 - Minor and Potential Emission Points
Site Plan	Drawing 011 - Site Noise Source Locations

Site Plan	Drawing 006 - Site Monitoring Points
Site Plan	Drawing 009 - Ground Well Locations

Upload a copy of the location map in accordance with the guidance:

Document Type	Document Name
Site Map	Drawing 001 - Site Location

3.3 Site Contact

Primary Contact

Ms. Breda Rafter

Position in Organisation

Administrator

Business Mobile Number

087 2665146

Landline Number

071 9155679

Email Address

breda.rafter@abbvie.com

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3.4 Site and Building Ownership

Is the applicant (or will the applicant be, in the case of a new activity) the owner of the site where the proposed activity is to take place?

Yes

Is the applicant (or will the applicant be, in the case of a new activity) the owner of the building where the proposed activity is to take place?

Yes

4. Activity and Capacity

4.1 Sectors and Classes of Activity

Add sectors and corresponding Classes of Activity relevant to the operation. Then select one Main Class of Activity using the radio buttons.

Sector	Activity and Description	IED Category of Activity	Main Class of Activity
Chemicals	5.16 – The production of pharmaceutical products including intermediates (production means the production on an industrial scale by chemical or biological processing)	4.5	Yes

4.2 Application Type Confirmation

Based on the activities selected above the application type has been determined as:

Industrial Emissions Licence

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4.3 Waste Activities

Section Not Required - based on applicant's response

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4.4 Capacity

Other Capacity

Do you have to provide capacity information as per the guidance?

Yes

Upload details of the capacity and how the capacity was calculated:

Document Type	Document Name
Activity Capacity Information	Attachment 4-4-1 Capacity

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4.5 Other Regulations or Directives

Select all other regulations and directives that are relevant for activities carried out or proposed to be carried out at the installation or facility

1 **EC (Control of Major Accident Hazards involving Dangerous Substances) Regulations (S.I. No. 74 of 2006)**

No

2 **Greenhouse gas emissions regulations permit**

No

3 **GMO regulations permit**

No

4 **Waste authorisation (certificate of registration, waste facility permit) regulations**

No

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

No

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

Yes

Authorisation Number(where relevant)

Status (where relevant)

Apex Controls Ltd. is the certified contractor

Active

7 **European Communities Mercury (Export Ban and Safe Storage) Regulations (S.I. No. 27 of 2012)**

No

- 8 **S.I. No 564 of 2012: European Union (Paints, Varnishes, Vehicle Refinishing Products and Activities) Regulations 2012**
- No
- 9 **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**
- No
- 10 **Operator of an agro-food processing plant where Article 13 of the Council Directive 91/271/EEC concerning urban waste water treatment (> 4,000p.e WWTP discharging to surface water) applies**
- No
- 11 **Local Government (Water Pollution) Act, 1977 (Control of Cadmium Discharges) Regulations 1985 (S.I. No. 294 of 1985);**
- No
- 12 **Local Government (Water Pollution) Act, 1977 (Control of Hexachlorocyclohexane and Mercury Discharges) Regulations 1986 (S.I. No. 55 of 1986)**
- No
- 13 **Local Government (Water Pollution) Acts, 1977 and 1990 (Control of Carbon Tetrachloride, DDT and Pentachlorophenol Discharges) Regulations 1994 (S.I. No. 43 of 1994)**
- No
- 14 **Medium Combustion Plant Directive (EU) 2015/2193 on the limitation of emissions of certain pollutants into the air from medium combustion plants.**
- Yes

Authorisation Number(where relevant)

Status (where relevant)

Not yet operational. Will apply for Authorisation.

Pending

Uploaded a document that describes how each selected regulation or directive is applicable to the activities

Document Type	Document Name
Applicable Regulations	Attachment 4-5-1 Applicable Regulations

Extractive Waste Regulations

Do the Extractive Waste Regulations (Waste Management (Management of Waste from the Extractive Industries) Regulations) apply to your activities?

No

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4.6 Resource and Energy Usage

Water Usage

Do you or do you propose to abstract groundwater for use at the installation or facility?

No

Do you or do you propose to abstract surface water for use at the installation or facility?

No

Do you or do you propose to use water from the public supply for use at the installation or facility?

Yes

Do you or do you propose to use water from another source for use at the installation or facility?

No

Electricity Usage

Do you or do you propose to generate renewable electricity at the installation or facility?

No

Do you or do you propose to generate non-renewable electricity at the installation or facility?

No

Water and Energy Usage

Upload tabulated details of water and energy used or generated on the site.

Document Type	Document Name
Water and Energy Usage	Attachment-4-6-1-Water-Energy-Usage

Raw Materials, Intermediates and Products

Upload tabulated details of process related raw and ancillary materials, substances, preparations, intermediates, products etc., which will be produced by or utilised in the activity

Document Type	Document Name
Materials Used or Generated	Attachment-4-6-2-Raw-Material-Interm-Products

4.7 BAT (Best Available Techniques)

BAT Conclusions

Licence BAT Assessment		
CID 2016/902/EU	Best available techniques (BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, for common waste water and waste gas treatment/ management systems in the chemical sector	
Common Waste Water...		
BATC No.	Objective / Licensee Response / Attachment	Applicability
1	<p>In order to improve the overall environmental performance, BAT is to implement and adhere to an environmental management system (EMS) that incorporates all of the following features:</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : The facility has an existing Environmental Management System (EMS) that will be upgraded to incorporate the new bio-chemical suite. The EMS is accredited to ISO 14001 standard.</p> <p>The EMS incorporates the requirements as outlined in BAT and is available for review by the Environmental Protection Agency (EPA) as required.</p> <p>AbbVie also maintain an EHS & Energy Sustainability Long Range Plan which sets out targets for energy efficiency and persons responsible for monitoring and measuring those targets and documenting successes. This document includes short term and long-term targets.</p> <p>AbbVie has also established Environmental Health & Safety (EHS) management requirements that conform to the ISO 50001, ISO 55001 and OHSAS18001 management system standards.</p>	Yes

2	<p>In order to facilitate the reduction of emissions to water and air and the reduction of water usage, BAT is to establish and to maintain an inventory of waste water and waste gas streams, as part of the environmental management system (see BAT 1), that incorporates all of the following features:</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Low strength wastewater will be collected via a separate wastewater collection system to high high strength wastewater.</p> <p>High high strength wastewater from areas containing cytotoxic materials will be collected in a closed collection system and diverted to a sunken bulk storage tank which will be emptied via road tanker for offsite disposal (incineration).</p> <p>Low strength wastewater from secondary equipment wash and misc. process use and non-drug contact wastewater will be pumped to a separate sunken bulk storage tank and will undergo pH and temperature adjustment as required before being pumped to the municipal sewer outlet. Low strength water can also contain boiler blow-down and cooling tower water.</p> <p>Continuous sampling and grab sampling will be completed for wastewater composition in accordance with the IE licence requirements. Information from sample analysis to be retained as part of on-site inventory.</p> <p>Other foul water sources are domestic foul only.</p> <p>No waste gas emissions</p>	Yes
3	For relevant emissions to water as identified by the inventory of waste water streams (see BAT 2), BAT is to	Yes

	<p>monitor key process parameters (including continuous monitoring of waste water flow, pH and temperature) at key locations (e.g. influent to pretreatment and influent to final treatment).</p> <p>Response : Emissions of industrial effluent to the public sewer will be monitored at the licenced emission point in accordance with the requirements of IE licence for the facility.</p> <p>Continuous monitoring of pH, temperature and flow proposed. Other parameters to be sampled by composite sampler and reported monthly for daily, weekly and monthly averages. Information from sample analysis to be retained as part of on-site inventory.</p>	
4	<p>BAT is to monitor emissions to water in accordance with EN standards with at least the minimum frequency given below. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : There are no wastewater emissions to surface water. Emissions of wastewater will be to the public sewer which will be treated offsite.</p> <p>Monitoring of the low strength wastewater emissions from the facility will be at the licenced monitoring points (SE1a, SE1b) in accordance with the requirements of IE licence for the facility.</p> <p>Monitoring and analysis will be in accordance with the relevant EN standards indicated on the table. For Chemical Oxygen Demand (COD), Total Phosphorous, chlorides, sulphates, Oils, Fats and Greases, detergents the relevant ISO or national standard will be applied as agreed with the EPA.</p>	Not Applicable
5	<p>BAT is to periodically monitor diffuse VOC emissions to air</p>	Not Applicable

	<p>from relevant sources by using an appropriate combination of the techniques I-III or, where large amounts of VOC are handled, all of the techniques I-III.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Not Applicable – potential diffuse Volatile Organic Compounds (VOCs) sources are carefully controlled and as such there will be limited diffuse VOC sources (I.e. Isopropyl Alcohol (IPA) from pre-wetted wipes and spray bottles, solvents from printing).</p> <p>Monitoring of VOC emissions will not be required as there are no proposed emissions to air from the processes.</p>	
6	<p>BAT is to periodically monitor odour emissions from relevant sources in accordance with EN standards.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Not applicable – No odours are expected from the plant.</p> <p>Vaporised hydrogen peroxide (used for decontamination) will be emitted to air via a catalytic converted unit which neutralises any waste gas including odours. No monitoring is required however certification of the unit's compliance will be provided to the EPA as required.</p>	Not Applicable
7	<p>In order to reduce the usage of water and the generation of waste water, BAT is to reduce the volume and/or pollutant load of waste water streams, to enhance the reuse of waste water within the production process and to recover and reuse raw materials.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Applicable - Process is constrained by Good Management Practice (GMP) regulations and as such there is limited opportunity for recovery and recycling of waste streams. Clean in Place (CIP) rinses will be once through</p>	Yes

	<p>only due to the exposure to cytotoxic material.</p> <p>Water used for cleaning is set based on validated cleaning cycles and therefore no potential for reductions in water use. Water reduction targets are in place for the remainder of the site in accordance with the company's environmental policies.</p> <p>No trade wastewater produced from existing medical devices facility.</p> <p>Boiler and cooling tower water recirculated and blow down discharged to sewer only as necessary.</p>	
8	<p>In order to prevent the contamination of uncontaminated water and to reduce emissions to water, BAT is to segregate uncontaminated waste water streams from waste water streams that require treatment.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Applicable – Stormwater drains and wastewater drains are segregated. Uncontaminated rainwater is collected and discharged to the land drain adjacent to the site rather than to foul sewer.</p> <p>Wastewater will be segregated into low strength and high high strength wastewater streams with only low strength wastewater to be discharged to sewer.</p>	Yes
9	<p>In order to prevent uncontrolled emissions to water, BAT is to provide an appropriate buffer storage capacity for waste water incurred during other than normal operating conditions based on a risk assessment (taking into account e.g. the nature of the pollutant, the effects on further treatment, and the receiving environment), and to take appropriate further measures (e.g. control, treat, reuse).</p> <p>See linked document for the full text of the BAT</p>	Yes

	<p>conclusion</p> <p>Response : Low strength wastewater will be diverted to a bunded 10m³ sunken sump tank where it will be pumped to a bunded 30m³ GRP sunken bulk tank to smooth out peaks and troughs in the effluent. The bund will be chemical resistant coating lined concrete and is equipped with level detection i.e. in the unlikely event of a spillage, the wastewater will be pumped to the appropriate storage tank and tested.</p> <p>The wastewater stream will undergo pH and temperature adjustment as required before being pumped to the municipal sewer outlet. It will be measured for flow/temperature/pH at point of discharge. The wastewater will then be combines with the foul sewer.</p>	
10	<p>In order to reduce emissions to water, BAT is to use an integrated waste water management and treatment strategy that includes an appropriate combination of the techniques in the priority order given below.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Process integrated techniques and wastewater pre-treatment (pH and temperature adjustment) have been utilised. Final wastewater treatment is via local Sligo Wastewater Treatment Plant (WWTP).</p> <p>Contaminant recovery not possible (cytotoxic material).</p> <p>Wastewater will be collected via separated wastewater collection systems (high high strength and low strength). Wastewater from areas containing cytotoxic materials will be collected in a closed collection system and the commissioned Process Automatic System and site SOPs will prevent cross contamination of low strength waste with high high strength waste. The process areas only contain high high strength drains.</p>	Yes

	<p>Wastewater that has not been contaminated by cytotoxic materials will be diverted to the low strength wastewater system for pH and temperature adjustment and controlled disposal to sewer.</p>	
11	<p>In order to reduce emissions to water, BAT is to pretreat waste water that contains pollutants that cannot be dealt with adequately during final waste water treatment by using appropriate techniques.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Wastewater that has been in contact with cytotoxic material will not be treated onsite and will not be discharged to sewer. This waste stream will require removal offsite for incineration.</p> <p>Low strength wastewater contains very low levels of contaminants and will not require pre-treatment onsite before discharging to sewer. Attenuation and pH and temperature adjustment will be provided prior to discharge to sewer.</p> <p>Certain lab chemicals and liquid wastes are also not suitable for discharge to the sewer and will be collected in suitable plastic drums, labelled as hazardous waste, and transferred to a designated waste chemical storage area. This will be managed by the facility's SOPs.</p> <p>Diesel and other fuel will be excluded from effluent by site management and control. There are 3 no. stormwater discharge points to the south and east of the site and 4 no. hydrocarbon interceptors within the drainage network and these are cleaned out as needed.</p>	Yes
12	<p>In order to reduce emissions to water, BAT is to use an appropriate combination of final waste water treatment techniques.</p> <p>See linked document for the full text of the BAT</p>	Yes

	<p>conclusion</p> <p>Response : Waste water will contain very low levels of contaminants and will not require preliminary or primary treatment (pH and temperature adjustment only) to ensure discharges from site meet the required quality standards thereby ensuring no damage to the downstream treatment facility.</p> <p>No anticipated issues with Total Nitrogen, Total P, Biochemical Oxygen Demand (BOD), COD, sulphates, chlorides, suspended solids, etc.</p> <p>Further details on the final wastewater treatment is provided in Attachment 7.3.2. Equivalent Levels of Protection.</p>	
13	<p>In order to prevent or, where this is not practicable, to reduce the quantity of waste being sent for disposal, BAT is to set up and implement a waste management plan as part of the environmental management system (see BAT 1) that, in order of priority, ensures that waste is prevented, prepared for reuse, recycled or otherwise recovered.</p> <p>Response : There is a waste management plan and EMS in place for the existing facility. This will be updated to reflect the site changes associated with the new bio-chemical suite. The EMS includes a requirement for the site to manage wastes in accordance with Waste Hierarchy.</p> <p>All waste management to be carried out in accordance with the IE licence and relevant legislation, is overseen by the EHS and Supply Chain. The EHS Department regularly audit the onsite waste storage facilities and infrastructure and provide advice on waste segregation requirements. EHS support Operations and Supply Chain in preparing and updating documented procedures for waste management, managing the waste contractors, auditing and maintaining a full paper trail of waste documentation for all waste</p>	Yes

	movements from the site.	
14	<p>In order to reduce the volume of waste water sludge requiring further treatment or disposal, and to reduce its potential environmental impact, BAT is to use one or a combination of the techniques given below.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : No waste water sludge generated.</p>	Not Applicable
15	<p>In order to facilitate the recovery of compounds and the reduction of emissions to air, BAT is to enclose the emission sources and to treat the emissions, where possible.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Hydrogen peroxide to be used for sterilisation in the new bio-chemical suite. Waste VHP gases collected in dedicated extract and treated using catalytic converter.</p> <p>No waste gases from the existing facility.</p>	Yes
16	<p>In order to reduce emissions to air, BAT is to use an integrated waste gas management and treatment strategy that includes process-integrated and waste gas treatment techniques.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Hydrogen peroxide to be used for Isolator sterilisation in the new bio-chemical suite. Waste Vaporised Hydrogen Peroxide (VHP) gases collected in dedicated extract and treated using 2 no. catalytic converters in series on the exhaust line.</p> <p>The use of VHP is within a single fill/finish suite onsite and therefore is not relevant to the entire process as a whole. Integrated techniques to not apply.</p>	Yes
17	In order to prevent emissions to air from flares, BAT is to	Not Applicable

	<p>use flaring only for safety reasons or non-routine operational conditions (e.g. start-ups, shutdowns) by using one or both of the techniques given below.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Not Applicable – no flaring</p>	
18	<p>In order to reduce emissions to air from flares when flaring is unavoidable, BAT is to use one or both of the techniques given below.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Not Applicable – no flaring</p>	Not Applicable
19	<p>In order to prevent or, where that is not practicable, to reduce diffuse VOC emissions to air, BAT is to use a combination of the techniques given below.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : As part of the design of the facility the project engineers have identified a number of measures designed to limit emission sources, improve integrity of process equipment and connections etc. Commissioning will be completed by vendors as part of the project – this will be overseen by suitably qualified engineers to ensure the required performance criteria are achieved.</p> <p>Details on the IPA, DMSO/DMA, and Acetic Acid use and minimisation of diffuse emissions is provided in Attachment 4-7-1.</p> <p>Within the existing processes, the anticipated solvent usage will include solvents used in printing onto medical devices. Solvents used in printing are stored in sealed containers in locked cabinets until use. The volumes used are not significant and there are no significant fugitive emissions requiring abatement.</p>	Yes

20	<p>In order to prevent or, where that is not practicable, to reduce odour emissions, BAT is to set up, implement and regularly review an odour management plan, as part of the environmental management system (see BAT 1), that includes all of the following elements:</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Not applicable – No odours are expected from the plant.</p>	Not Applicable
21	<p>In order to prevent or, where that is not practicable, to reduce odour emissions from waste water collection and treatment and from sludge treatment, BAT is to use one or a combination of the techniques given below.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Not applicable – No odours are expected from the plant.</p>	Not Applicable
22	<p>In order to prevent or, where that is not practicable, to reduce noise emissions, BAT is to set up and implement a noise management plan, as part of the environmental management system (see BAT 1), that includes all of the following elements:</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : A noise management plan including noise monitoring will be outlined in the facility's EMS.</p> <p>The impact assessment undertaken as part of the Environmental Impact Assessment Report (EIAR) found that predicted noise levels associated with the day to day operations of the site will be compliant with the proposed criteria applicable to a site of this nature. Due consideration as part of the detailed design process will ensure that the new development will operate within the noise limits stipulated in the site IE licence issued by the EPA.</p>	Yes
23	In order to prevent or, where that is not practicable, to	Yes

	<p>reduce noise emissions, BAT is to use one or a combination of the techniques given below.</p> <p>See linked document for the full text of the BAT conclusion</p> <p>Response : Noise from external plant items will be minimised through installation of low noise generating equipment. Through equipment specification, all new internal plant will be below 85dB. No new external plan (other than the generator, which is for emergency situations only).</p> <p>Noise model shows that operational noise will be within the relevant day time and night time limits at the noise receptors.</p>	
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BREF

Select all relevant BAT reference document(s) (BREFs), provide an assessment against each

BREF	Document Type	BREF Document Name
Emissions from Storage	BREF Assessment	Attachment 4-7-4 BAT REF - Emissions from storage
Manufacture of Organic Fine Chemicals	BREF Assessment	Attachment 4-7-2 -BREF- Organic Fine Chemicals
Energy Efficiency	BREF Assessment	Attachment 4-7-3 BAT REF - Energy Efficiency

EPA National BAT

Select all relevant EPA BAT guidance notes and attach the assessments made against them

EPA Bat Guidance Note	Document Type	EPA National BAT Assessment Document Name
<i>No files uploaded</i>		

4.8 Reports

Operational Report

Upload an 'Operational Report' for the activity in accordance with the guidance

Document Type	Document Name
Operational Report	Attachment 4-7-1 -CID -BAT-Common Wastewater
Operational Report	Attachment 4-9-2 Solvent Management
Operational Report	Attachment 4-8-1 Operational Report
Operational Report	Attachment-4-9-4-IED-Art 59(7) Precautions

Baseline Report

Upload a report that addresses sections 1 to 3 of the [European Commission's guidance concerning baseline reports](#)

Document Type	Document Name
Baseline Screening	Attachment 4-8-2 Screening for Baseline

Does the report referred to above specify that a Baseline Report is required?

Yes

Upload the baseline report in accordance with the European Commission's guidance concerning baseline reports

Document Type	Document Name
Baseline Report	Attachment 4-8-3 Appendix B Part 2
Baseline Report	Attachment 4-8-3 Appendix B Part 1
Baseline Report	Attachment 4-8-3 Soil GW Baseline

Site Condition Report

Upload a document that describes the condition of the site of the installation or facility in accordance with the guidance

Document Type	Document Name
Site Condition Report	Attachment 4-8-4 Site Condition Report

4.9 Solvents

Do you or do you intend to use organic solvents at the installation or facility?

Yes

Select all relevant solvent activities with reference to [Schedule 2 of Statutory Instrument No. 565/2012] (Solvent Regulations) (solvent consumption threshold in tonnes/year) and the maximum consumption of solvent when undertaking that activity.

Solvent Activity	Solvent Consumption of Previous Calendar Year (tonnes/annum)	Projected Annual Solvent Consumption Under Licence (tonnes/annum)	Control Measure Proposed to Control Emissions
Manufacturing of pharmaceutical products (> 50)	0	0	
Other rotogravure, flexography, rotary screen printing, laminating or varnishing units (> 15)	1	1	
Other Activity not listed above	0	2	

Applicability of Chapter V of the IED

No

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4.10 Large Combustion Plants

Section Not Required - based on applicant's response

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4.11 Incineration and Co-Incineration

Section Not Required - based on applicant's response

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5. Financial

5.1 Financial Template

Completed template

Document Type	Document Name
Financial Application Section	Attachment-5-1-Financial

5.2 Additional Documents

Upload additional documents referred to in the completed template

Document Type	Document Name
Fee Payment Evidence	Attachment 5-2- Fee Payment Evidence PUBLIC

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6. Stakeholder Engagement

6.1 Stakeholder Engagement Template

Completed template

Document Type	Document Name
Stakeholder Engagement Section	Attachment-6-1-Stakeholder-Engagement FINAL

6.2 Additional Documents

Upload additional documents referred to in the completed template

Document Type	Document Name
AA Screening	Attachment 6-2-1-AA Screening Report May 2018
EIS - Planning	Attachment 6-3-6-EIAR Planning - Appendices
EIS - Planning	Attachment 6-3-6-EIAR Planning - Non-Technical
EIS - Planning	Attachment 6-3-6-EIAR Planning May 2018
Evidence of Notices	Attachment 6-7-1-Evidence of Notices - Site
Evidence of Notices	Attachment 6-7-4- Evidence of Notices - PA
Evidence of Notices	Attachment 6-7-2-Evidence of Notices - Newspaper
Evidence of Notices	Attachment-6-7-3-Evidence of Notices - Map
Planning Decision	Attachment 6-3-1- Planning Decision August 2018

7. Emissions

7.1 Overview

Emissions, Discharges and Landspreading Applicability

With reference to the emissions/discharges from the installation and any associated landspreading activity indicate whether the thematic is applicable by inserting yes or no (Note: If you select 'no' you are indicating that there are no emissions of this type and your application will be considered on this basis)

Emission Type	Applicable
Emissions to Surface Water (not including Storm Water)	No
Emissions to Sewer	Yes
Emissions to Air (including minor, potential and fugitive emissions to air)	Yes
Noise Emissions and Noise Monitoring Points	Yes
Emissions to Ground (including disposal of sanitary effluent and potential emissions to ground) and Landspreading	No
Storm Water Discharges	Yes

Emissions Overview Template

Completed template

Document Type	Document Name
Emissions Overview Section	Attachment-7-1-Emissions-Overview_2018

Additional Documents

Upload additional documents referred to in the completed template

Document Type	Document Name
Emissions Compliance Report	Attachment 7-1-3-1 - Emissions Compliance Report
Emissions Impact Assessment	Attachment 7-1-3-2 - Emissions Impact Assessment
Receiving Environment Report	Attachment 7-1-3-3 - Receiving Environment Report

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7.2 Emissions to Surface Water (not including Storm Water)

Section Not Required – based on applicant's response

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7.3 Emissions to Sewer

Emissions to Sewer Template

Completed template

Document Type	Document Name
Emissions - Sewer Section	Attachment-7-3-1-Emissions-to-Sewer

Additional Documents

Upload additional documents referred to in the completed template

Document Type	Document Name
Equivalent Protection - Sewer	Attachment-7-3-2 Equivalent-Protection-Sewer

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7.4 Emissions to Air (including minor, potential and fugitive emissions to air)

Emissions to Air (including minor, potential and fugitive emissions to air) Template

Completed template

Document Type	Document Name
Emissions - Air Section	Attachment-7-4-1-Emissions-to-Air-Main

Additional Documents

Upload additional documents referred to in the completed template

Document Type	Document Name
Minor - Potential Emissions	Attachment-7-4-2-Emissions-to-Air-Minor-Potential

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7.5 Noise Emissions and Noise Monitoring Points

Noise Emissions and Noise Monitoring Points Template

Completed template

Document Type	Document Name
Emissions - Noise Section	Attachment-7-5-Noise-Emissions

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7.6 Emissions to Ground and Landspreading

Section Not Required – based on applicant's response

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7.7 Storm Water Discharges

Storm Water Discharges Template

Completed template

Document Type	Document Name
Storm Water Section	Attachment-7-7-Storm-Water-Discharges

Additional Documents

Upload additional documents referred to in the completed template

Document Type	Document Name
<i>No files uploaded</i>	

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8. Waste Generated On-Site

8.1 Waste Generated On-Site Template

Completed template

Document Type	Document Name
Waste Generated Section	Attachment-8-1 Waste Generated

8.2 Additional Documents

Upload additional documents referred to in the completed template

Document Type	Document Name
Waste Hierarchy	Attachment-8-1-2 Waste Mgt and Hierarchy

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9. Environmental Management and Techniques

9.1 Environmental Management and Techniques Template

Completed template

Document Type	Document Name
EMT Section	Attachment-9-1-Environmental-Management Techniques

9.2 Additional Documents

Upload additional documents referred to in the completed template

Document Type	Document Name
Site Closure	Attachment 9-2-3 Site Closure Plan

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10. Submit Application

Prior to submitting your completed application, please tick the box below to confirm the following:

- I declare that all the information and particulars given in this application form and all associated attachments are truthful, accurate and complete to the best of my knowledge and belief.
- I give consent to the EPA to copy this application form and all associated attachments for its own use and to make it available for inspection and copying by the public both in paper form and on the EPA's website. This consent relates to the application form itself, all associated attachments 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.

I confirm

First Name

Columba

Surname

McGarvey

Position

Site Director

Upload a copy of scanned signature and company stamp

Document Type	Document Name
Signature and Company Stamp	Attachment-10-1-Signature-Stamp