Headquarters
P.O. Box 3000
Johnstown Castle Estate
County Wexford
Ireland

INDUSTRIAL EMISSIONS LICENCE
Recommended Determination

Licence Register Number:	**P1087-01**
Company Register Number:	**906838**
Applicant:	**AbbVie Ireland NL B.V.**
Location of Installation:	**Old Bundoran Road, Ballytivnan, Sligo**

INTRODUCTION

This introduction is not part of the licence and does not purport to be a legal interpretation of the licence.

AbbVie Ireland NL B.V proposes to operate an integrated biochemical installation located on the outskirts of Sligo Town, at Old Bundoran Road, Sligo. The new integrated biochemical manufacturing operation replaces a redundant manufacturing facility at the site. The main process includes linking of a bio-pharmaceutical molecule to a cytotoxic molecule providing effective delivery of the medicine within the patient. No Genetically Modified Organisms are used on-site and therefore no EPA GMO permit is required. There is also an existing separate Abbvie manufacturing operation within the installation boundary, which is not a licensable activity in its own right, manufacturing drug delivery devices such as auto injector pens. This existing operation uses common utilities and is part of the installation.

The installation will operate 7 days per week, 24 hours per day. The total number of staff expected on site may be up to 100 individuals once the plant is fully operational. The installation has been designed to manufacture special medicine for treating illnesses (like cancer) in a highly controlled and contained environment.

The licensed activity falls under the following category of Annex I of the Industrial Emissions Directive:

4.5 The production of pharmaceutical products including intermediates.

The licence sets out in detail the conditions under which **AbbVie Ireland NL B.V**. will operate and manage this installation.

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Glossary of Terms

All terms in this licence should be interpreted in accordance with the definitions in the Environmental Protection Agency Act 1992 as amended, unless otherwise defined in the section.

Adequate lighting	20 lux measured at ground level.
AER	Annual Environmental Report.
Approval	Approval in writing/electronically.
Annually	All or part of a period of twelve consecutive months.
Application	The application by the licensee for this licence.
Appropriate Facility	A waste management facility or installation, duly authorised under relevant law and technically suitable.
Attachment	Any reference to Attachments in this licence refers to attachments submitted as part of this licence application.
BAT	Best Available Techniques.
BAT conclusions	A document containing the parts of a BAT reference document laying down the conclusions on best available techniques, their description, information to assess their applicability, the emission levels associated with the best available techniques, associated monitoring, associated consumption levels and, where appropriate, relevant site remediation measures.
BAT reference document	A document drawn up by the Commission of the European Union in accordance with Article 13 of the Industrial Emissions Directive, resulting from the exchange of information in accordance with that Article of that Directive and describing, in particular, applied techniques, present emissions and consumption levels, techniques considered for the determination of best available techniques as well as BAT conclusions and any emerging techniques.
Biannually	At approximately six – monthly intervals.
Biennially	Once every two years.
BOD	5 day Biochemical Oxygen Demand (without nitrification suppression).
CEN	Comité Européen De Normalisation – European Committee for Standardisation.

COD	Chemical Oxygen Demand.
Containment boom	A boom that can contain spillages and prevent them from entering drains or watercourses or from further contaminating watercourses.
CRO Number	Company Register Number.
CWW CID	**COMMISSION IMPLEMENTING DECISION (EU) 2016/902 of 30 May 2016 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for common waste water and waste gas treatment/ management systems in the chemical sector.**
Daily	During all days of plant operation and, in the case of emissions, when emissions are taking place; with at least one measurement on any one day.
Day	Any 24 hour period.
Daytime	0700 hrs to 1900 hrs.
dB(A)	Decibels (A weighted).
Diffuse Emissions	Non-channelled emissions which can result from 'area' sources (e.g. tanks) or 'point' sources (e.g. pipe flanges).
DO	Dissolved oxygen.
Documentation	Any report, record, results, data, drawing, proposal, interpretation or other document in written or electronic form which is required by this licence.
Drawing	Any reference to a drawing or drawing number means a drawing or drawing number contained in the application, unless otherwise specified in this licence.
Emission limits	Those limits, including concentration limits and deposition rates, established in *Schedule B: Emission Limits*, of this licence.
EMP	Environmental Management Programme.
Environmental damage	As defined in Directive 2004/35/EC.
EPA	Environmental Protection Agency.
Evening Time	1900hrs to 2300hrs

Facility	Any site or premises used for the purpose of the recovery or disposal of waste.
Fortnightly	A minimum of 24 times per year, at approximately two week intervals.
Gas Oil	Gas oil as defined in DIRECTIVE (EU) 2016/802 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 relating to a reduction in the sulphur content of certain liquid fuels.
GC/MS	Gas chromatography/mass spectroscopy.
Groundwater	Has the meaning assigned to it by Regulation 3 of the European Communities Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010), as amended.
ha	Hectare.
Hazardous Substances	Substances or mixtures as defined in Article 3 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.
Heavy metals	This term is to be interpreted as set out in "Parameters of Water Quality, Interpretation and Standards" published by the Agency in 2001. ISBN 1-84095-015-3.
Hours of operation	The hours during which the installation is authorised to be operational.
ICP	Inductively coupled plasma spectroscopy.
IE	Industrial Emissions.
Incident	The following shall constitute as incident for the purposes of this licence: (i) an emergency; (ii) any emission which does not comply with the requirements of this licence; (iii) any malfunction or breakdown of key environmental abatement, control or monitoring equipment (iv) any trigger level specified in this licence which is attained or exceeded; and, (v) any indication that environmental pollution has, or may have, taken place.

Industrial Emissions Directive	Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast).
Installation	A stationary technical unit or plant where the activity concerned referred to in the First Schedule of EPA Act 1992 as amended is or will be carried on, and shall be deemed to include any directly associated activity, which has a technical connection with the activity and is carried out on the site of the activity.
Irish Water	Irish Water, Colvill House, 24/26 Talbot Street, Dublin 1.
K	Kelvin.
kPa	Kilopascals.
$L_{Aeq,T}$	This is the equivalent continuous sound level. It is a type of average and is used to describe a fluctuating noise in terms of a single noise level over the sample period (T).
$L_{Ar,T}$	The Rated Noise Level, equal to the L_{Aeq} during a specified time interval (T), plus specified adjustments for tonal character and/or impulsiveness of the sound.
Licensee	**AbbVie Ireland NL B.V., MANORHAMILTON ROAD, Sligo, CRO Number: 906838.**
List of Waste (LoW)	A harmonised, non-exhaustive list of wastes drawn up by the European Commission and published as Commission Decision 2000/532/EC, as amended by Commission Decision 2014/955/EU and any subsequent amendment published in the Official Journal of the European Community.
Local Authority	Sligo County Council.
Maintain	Keep in a fit state, including such regular inspection, servicing, calibration and repair as may be necessary to perform its function adequately.
Mass flow limit	An emission limit value expressed as the maximum mass of a substance that can be emitted per unit time.
Mass flow threshold	A mass flow rate above which a concentration limit applies.
Monthly	A minimum of 12 times per year, at intervals of approximately one month.

Night-time	2300 hrs to 0700 hrs.
Noise-sensitive location (NSL)	Any dwelling house, hotel or hostel, health building, educational establishment, place of worship or entertainment, or any other installation or area of high amenity which for its proper enjoyment requires the absence of noise at nuisance levels.
Odour-sensitive location	Any dwelling house, hotel or hostel, health building, educational establishment, place of worship or entertainment, or any other premises or area of high amenity which for its proper enjoyment requires the absence of odour at nuisance levels.
Oil separator	Device installed according to the International Standard I.S. EN 858-2:2003 (Separator system for light liquids, (e.g. oil and petrol) – Part 2: Selection of normal size, installation, operation and maintenance).
PRTR	Pollutant Release and Transfer Register.
Quarterly	All or part of a period of three consecutive months beginning on the first day of January, April, July or October.
Relevant Hazardous Substances	Those substances or mixtures defined within Article 3 of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) which, as a result of their hazardousness, mobility, persistence and biodegradability (as well as other characteristics), are capable of contaminating soil or groundwater and are used, produced and/or released by the installation.
SAC	Special Area of Conservation designated under the *Habitats Directive*, Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora.
Sample(s)	Unless the context of this licence indicates to the contrary, the term samples shall include measurements taken by electronic instruments.
Sanitary effluent	Wastewater from installation toilet, washroom and canteen facilities.
Soil	The top layer of the Earth's crust situated between the bedrock and the surface. The soil is composed of mineral particles, organic matter, water, air and living organisms.
SOP	Standard operating procedure.
SPA	Special Protection Area designated under the Birds Directive, Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds
Specified emissions	Those emissions listed in *Schedule B: Emission Limits,* of this licence.
Standard method	A National, European or internationally recognised procedure (e.g. I.S. EN, ISO, CEN, BS or equivalent); or an in-house documented procedure based on the above references; a procedure as detailed in the current

	edition of "Standard Methods for the Examination of Water and Wastewater" (prepared and published jointly by A.P.H.A., A.W.W.A. & W.E.F.), American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005, USA; or an alternative method as may be agreed by the Agency.
Storage	Includes holding of waste.
Storm water	Rain water run-off from roof and non-process areas.
The Agency	Environmental Protection Agency.
TOC	Total organic carbon.
Trade effluent	Trade effluent has the meaning given in the Water Services Act, 2007.
Trigger level	A parameter value, the achievement or exceedance of which requires certain actions to be taken by the licensee.
Waste	Any substance or object which the holder discards or intends or is required to discard.
Water Services Authority	Sligo County Council.
Weekly	During all weeks of plant operation and, in the case of emissions, when emissions are taking place; with at least one measurement in any one week.
WWTP	Waste water treatment plant.

Decision & Reasons for the Decision

The Environmental Protection Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of this licence, any emissions from the activity will comply with and will not contravene any of the requirements of Section 83(5) of the Environmental Protection Agency Act 1992 as amended.

The Agency also considers that the activity will not adversely affect the integrity of any European Site, and has decided to impose conditions for the purposes of ensuring they do not do so. It has determined that the activity, if managed, operated and controlled in accordance with the licence, will not have any adverse effect on the integrity of any of those sites.

The Agency has applied the Commission Implementing Decision (**EU) 2016/902** of 30 May 2016 establishing Best Available Techniques (BAT) Conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for **common waste water and waste gas treatment/management systems in the chemical sector** as a reference when setting licence conditions.

The Agency accordingly proposes to grant a licence to **AbbVie Ireland NL B.V**. to carry on the activity listed in *Part I, Schedule of Activities Licensed*, subject to the conditions set out in *Part III, Conditions*.

In reaching this decision the Agency has considered the documentation relating to the application, Register **Number: P1087-01** and the supporting documentation received from the applicant; the submissions received; the Inspector's Report dated **19 November 2019;** and has carried out an Environmental Impact Assessment (EIA) and an Appropriate Assessment of the likely significant effects of the activity on European Sites.

It is considered that the Inspector's Report contains a fair and reasonable examination, evaluation and analysis of the likely significant effects of the activity on the environment, and adequately and accurately identifies, describes and assesses those effects. The assessment as reported in those documents is adopted as the assessment of the Agency. Having regard to this assessment, it is considered that the activity, if managed, operated and controlled in accordance with the licence will not result in the contravention of any relevant environmental quality standards or cause environmental pollution.

Having regard to the examination of environmental information in the Inspector's Report, and in particular to the content of the Environmental Impact Assessment Report (EIAR) and supplementary information provided by the applicant, and the submissions from the planning authority, and the third parties in the course of the application, it is considered that the potential significant direct and indirect effects of the activity on the environment are as follows:

- **Generation of effluent and discharge to sewer.**
- **Emissions to air.**
- **Noise emissions.**
- **Accidental leakages or spills.**

Having assessed those potential effects, the Agency has concluded as follows:

- **Generation of process water and discharge to sewer will be mitigated through: operation of abatement equipment, imposing emission limit values; and implementing monitoring and control measures;**
- **Emissions to air will be mitigated through: imposing emission limit values to comply with ambient air quality standards; and implementing monitoring, maintenance and control measures;**

- **Noise emissions will be mitigated through: imposing daytime, evening-time and night-time noise limits at noise sensitive locations; and implementing monitoring, maintenance and control measures;**
- **Accidental leakages or spills will be mitigated through inspection and maintenance of bunds and tanks and accident and emergency requirements specified in the licence.**

Having regard to the effects (and interactions) identified, described and assessed throughout this report, it is considered that the monitoring, mitigation and preventative measures proposed will enable the activity to operate without causing environmental pollution, subject to compliance with the licence. The Conditions of the licence and the mitigation measures proposed will significantly reduce the likelihood of accidental emissions occurring and limit the environmental consequences of an accidental emission should one occur.

A screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the activity, individually or in combination with other plans or projects is likely to have a significant effect on any European Site. In this context, particular attention was paid to the European Site(s) at **Cummeen Strand /Drumcliff bay (Sligo Bay) SAC (000627) and Cummeen Strand SPA (004035).**

The activity is not directly connected with or necessary to the management of any European Site and the Agency considered, for the reasons set out below, that it cannot be excluded, on the basis of objective information, that the activity, individually or in combination with other plans or projects, will have a significant effect on any European Site and accordingly determined that an Appropriate Assessment of the activity was required, and for this reason determined to require the applicant to submit a Natura Impact Statement. **This determination has been made based on the project's hydrological connectivity with, and the distance to, European sites.**

The Agency has completed the Appropriate Assessment of potential impacts on these sites and has made certain, based on best scientific knowledge in the field and in accordance with the European Communities (Birds and Natural Habitats) Regulations 2011 as amended, pursuant to Article 6(3) of the Habitats Directive, that the activity, individually or in combination with other plans or projects, will not adversely affect the integrity of any European Site, in particular **Cummeen Strand /Drumcliff bay (Sligo Bay) SAC (000627) and Cummeen Strand SPA (004035)**, having regard to their conservation objectives and will not affect the preservation of these sites at favourable conservation status if carried out in accordance with this licence and the conditions attached hereto for the following reasons:

- **Air dispersion modelling has demonstrated that the impact of air emissions from the installation on qualifying interests of any European site is low.**
- **All process effluent from the installation is discharged to sewer and ultimately treated in Sligo WWTP in accordance with an EPA waste water discharge licence.**
- **The licence specifies noise emission limit values at any noise sensitive locations, and the noise modelling assessment demonstrated that these limits can be complied with to avoid disturbance of qualifying interest species.**
- **While there is potential for accidents and unplanned releases from the installation, it is considered that the conditions of the licence in relation to bunding and the protection of surface water and groundwater, are sufficient to ensure that accidental emissions from the activity will not impact on the qualifying interests of any of the European sites identified above, particularly in light of the nature of the potential accidental emissions.**

The Agency is satisfied that no reasonable scientific doubt remains as to the absence of adverse effects on the integrity of those European Sites **Cummeen Strand /Drumcliff bay (Sligo Bay) SAC (000627) and Cummeen Strand SPA (004035).**

Part I Schedule of Activities Licensed

In pursuance of the powers conferred on it by the Environmental Protection Agency Act 1992 as amended, the Agency proposes to grant this Industrial Emissions licence to:

AbbVie Ireland NL B.V., Manorhamilton Road, Sligo, and CRO Number 906838

under Section 83(1) of the said Act to carry on the following activity:

The production of pharmaceutical products including intermediates

at Old Bundoran Road, Ballytivnan, Sligo, subject to the following twelve Conditions, with the reasons therefor and associated schedules attached thereto.

Part II Schedule of Activities Refused

None of the proposed activities as set out in the licence application have been refused.

Part III Conditions

Condition 1. Scope

1.1 Industrial Emissions Directive activities at this installation shall be restricted to those listed and described in *Part I Schedule of Activities Licensed*, and shall be as set out in the licence application or as modified under Condition 1.4 of this licence and subject to the conditions of this licence.

1.2 The licensee shall carry on the licensed activity in accordance with the limitations set out in *Schedule A: Limitations*, of this licence.

1.3 For the purposes of this licence, the installation is the area of land outlined in **red** on Drawing No. **99/B.04P/0001** of the application. Any reference in this licence to "installation" shall mean the area thus outlined in **red**. The licensed activity shall be carried on only within the area outlined.

1.4 All activities which are directly associated with, and technically connected to the licensed activity, whether operated by the licensee or by another party, shall be subject to the conditions of this licence, and the licensee shall bear full responsibility for any breach of these conditions.

1.5 No alteration to, or reconstruction in respect of, the activity, or any part thereof, that would, or is likely to, result in

(i) a material change or increase in:

- the nature or quantity of any emission;
- the abatement/treatment or recovery systems;
- the range of processes to be carried out;
- the fuels, raw materials, intermediates, products or wastes generated, or

(ii) any changes in:

- site management, infrastructure or control with adverse environmental significance;

shall be carried out or commenced without prior notice to, and without the approval of, the Agency.

1.6 The installation shall be controlled, operated and maintained, and emissions shall take place as set out in the licence. All programmes required to be carried out under the terms of this licence become part of this licence.

1.7 This licence is for the purpose of licensing under the EPA Act 1992 as amended only and nothing in this licence shall be construed as negating the licensee's statutory obligations or requirements under any other enactments or regulations.

1.8 Having regard to the nature of the activity and arrangements necessary to be made or made in connection with the carrying on of the activity, the specified period for the purposes of Section 92(2)(a) of the EPA Act 1992 as amended **is 5 years**.

Reason: To clarify the scope of this licence.

Condition 2. Management of the Installation

2.1 Installation Management

2.1.1 The licensee shall employ a suitably qualified and experienced installation manager who shall be designated as the person in charge. The installation manager or a nominated, suitably qualified and experienced deputy shall be present on the installation at all times during its operation or as otherwise required by the Agency.

2.1.2 The licensee shall ensure that personnel performing specifically assigned tasks shall be qualified on the basis of appropriate education, training and experience as required and shall be aware of the requirements of this licence.

2.2 Environmental Management System (EMS)

2.2.1 The licensee shall **establish, maintain and implement** an Environmental Management System (EMS), which shall incorporate energy efficiency management, **a waste management plan and a noise management plan, in advance of the commencement of the licensed activity.** The EMS shall be reviewed by senior management for suitability, adequacy and effectiveness and updated on an annual basis.

2.2.2 The EMS shall include, as a minimum, the following elements:

2.2.2.1 Commitment of management, including senior management.

2.2.2.2 An environmental policy defined for the installation that includes the continuous improvement for the installation by the management.

2.2.2.3 Management and Reporting Structure and responsibility.

2.2.2.4 The necessary procedures, objectives and targets, in conjunction with financial planning and investment.

2.2.2.5 Procedures that ensure employee involvement in ensuring compliance with environmental legislation.

2.2.2.6 A procedure for checking performance by sectoral benchmarking on a regular basis including energy efficiency.

2.2.2.7 Schedule of Environmental Objectives and Targets.

The licensee shall prepare, maintain and implement a Schedule of Environmental Objectives and Targets. The Schedule shall, as a minimum, provide for a review of all operations and processes, including an evaluation of practicable options, for energy and resource efficiency, reduction in water consumption, reduction in effluent generation, optimisation of Cleaning in Place (CIP) system, the use of cleaner technology, cleaner production, **inventory of waste water, materials substitution,** odour and noise management, and the prevention, reduction and minimisation of waste and shall include waste reduction targets**.** The Schedule shall include time frames for the achievement of set targets and shall address a five-year period as a minimum. The Schedule shall be reviewed annually.

2.2.2.8 Environmental Management Programme (EMP)

The licensee shall **prepare, maintain and implement** an EMP, including a time schedule, for achieving the Environmental Objectives and Targets prepared under Condition 2.2.2.7. The EMP shall include:

- designation of responsibility for targets;
- the means by which they may be achieved;
- the time within which they may be achieved.

The EMP shall be reviewed annually.

A report on the programme, including the success in meeting agreed targets, shall be prepared and submitted to the Agency as part of the AER. Such reports shall be retained on-site for a period of not less than seven years and shall be available for inspection by authorised persons of the Agency.

2.2.2.9 Documentation

(i) The licensee shall establish, maintain and implement an environmental management documentation system.

(ii) The licensee shall issue a copy of this licence to all relevant personnel whose duties relate to any condition of this licence.

2.2.2.10 Corrective and Preventative Action

(i) The licensee shall establish, maintain and implement procedures to ensure that corrective and preventative action is taken should the specified requirements of this licence not be fulfilled. The responsibility and authority for persons initiating further investigation and corrective and preventative action in the event of a reported non-conformity with this licence shall be defined.

(ii) Where a breach of one or more of the conditions of this licence occurs, the licensee shall without delay take measures to restore compliance with the conditions of this licence in the shortest possible time and initiate any feasible preventative actions to prevent recurrence of the breach.

(iii) All corrective and preventative actions shall be documented

2.2.2.11 Internal Audits

The licensee shall establish, maintain and implement a programme for independent internal audits of the EMS. Such audits shall be carried out at least once every three years. The audit programme shall determine whether or not the EMS is being implemented and maintained properly, and in accordance with the requirements of the licence. Audit reports and records of the resultant corrective and preventative actions shall be maintained as part of the EMS in accordance with condition 2.2.2.9.

2.2.2.12 Awareness, Training and Competence

The licensee shall establish, maintain and implement procedures for identifying training needs, and for providing appropriate training, for all personnel whose work can have a significant effect upon the environment to ensure awareness and competence in their work area. Appropriate records of training shall be maintained.

2.2.2.13 Communications Programme

The licensee shall establish, maintain and implement a Public Awareness and Communications Programme to ensure that members of the public can obtain information at the installation, at all reasonable times, concerning the environmental performance of the installation.

2.2.2.14 Maintenance Programme

The licensee shall establish, maintain and implement a programme for maintenance of all plant and equipment based on the instructions issued by the manufacturer/supplier or installer of the equipment. Appropriate record keeping and diagnostic testing shall support this maintenance programme. The licensee shall clearly allocate responsibility for the planning, management and execution of all aspects of this programme to appropriate personnel (see Condition 2.1

above). The maintenance programme shall use appropriate techniques and measures to ensure the optimisation of energy efficiency in plant and equipment.

2.2.2.15 Efficient Process Control

The licensee shall establish, maintain and implement a programme to ensure there is adequate control of processes under all modes of operation. The programme shall identify the key indicator parameters for process control performance, as well as identifying methods for measuring and controlling these parameters. Abnormal process operating conditions shall be documented, and analysed to identify any necessary corrective action.

Reason: ***To make provision for management of the activity on a planned basis having regard to the desirability of ongoing assessment, recording and reporting of matters affecting the environment.***

Condition 3. Infrastructure and Operation

3.1 The licensee shall ensure, at all times after commencement of the **licensed** activity, that all infrastructure and all equipment required under this licence has been and is:

(i) installed,
(ii) commissioned,
(iii) present on site, and
(iv) maintained in full working order.

3.2 Where any condition / schedule of this licence specifies any later deadline for installation of any piece of infrastructure or equipment, condition number 3.1 shall apply as and from the deadline specified.

3.3 The licensee shall establish and maintain, for each component of the installation, all infrastructure referred to in this licence in advance of the commencement of the **licensed** activity in that component, or as required by the conditions of this licence. Infrastructure specified in the application that relates to the environmental performance of the installation and is not specified in the licence, shall be installed in accordance with the schedule submitted in the application.

3.4 The licensee shall have regard to the following when choosing and/or designing any new plant/infrastructure:

(i) Energy efficiency, and

(ii) The environmental impact of eventual decommissioning.

3.5 Installation Notice Board

(i) The licensee shall, within one month of the date of grant of this licence, provide an Installation Notice Board on the installation so that it is legible to persons outside the main entrance to the installation. The minimum dimensions of the board shall be 1200 mm by 750 mm. The notice board shall be maintained thereafter.

(ii) The board shall clearly show:

(i) the name and telephone number of the installation;
(ii) the normal hours of operation;
(iii) the name of the licence holder;
(iv) an emergency out of hours contact telephone number;
(v) the licence reference number; and

(vi) where environmental information relating to the installation can be obtained.

3.6 The licensee shall install on all emission points such sampling points or equipment, including any data-logging or other electronic communication equipment, as may be required by the Agency. All such equipment shall be consistent with the safe operation of all sampling and monitoring systems.

3.7 In the case of composite sampling of aqueous emissions from the operation of the installation, a separate composite sample or homogeneous sub-sample (of sufficient volume as advised) shall be refrigerated immediately after collection and retained as required for EPA use.

3.8 The licensee shall clearly label and provide safe and permanent access to all on-site sampling and monitoring points and to off-site points as required by the Agency. The requirement with regard to off-site points is subject to the prior agreement of the landowner(s) concerned.

3.9 Tank, Container and Drum Storage Areas

3.9.1 All tank, container and drum storage areas shall be rendered impervious to the materials stored therein. Bunds shall be designed having regard to Agency guidelines 'Storage and Transfer of Materials for Scheduled Activities' (2004).

3.9.2 All tank and drum storage areas shall, as a minimum, be bunded, either locally or remotely, to a volume not less than the greater of the following:

(i) 110% of the capacity of the largest tank or drum within the bunded area; or

(ii) 25% of the total volume of substance that could be stored within the bunded area

3.9.3 All drainage from bunded areas shall be treated as contaminated unless it can be demonstrated to be otherwise. All drainage from bunded areas shall be diverted for collection and safe disposal, unless it can be deemed uncontaminated and does not exceed the trigger levels set for storm water emissions under Condition 6.12.

3.9.4 All inlets, outlets, vent pipes, valves and gauges must be within the bunded area.

3.9.5 All tanks, containers and drums shall be labelled to clearly indicate their contents.

3.9.6 All bunds shall be uniquely identified and labelled at the bund.

3.10 The licensee shall have in storage an adequate supply of containment booms and/or suitable absorbent material to contain and absorb any spillage at the installation. Once used, the absorbent material shall be disposed of at an appropriate facility.

3.11 Oil Separators

The licensee shall, **in advance of the commencement of the licensed activity**, install and maintain oil separators at the installation:

(i) Class I by-pass separators from low risk areas including car parks, and

(ii) Class 1 full retention separator at the loading bay.

The separator shall be in accordance with I.S. EN-858-2: 2003 (separator systems for light liquids).

3.12 Fire-water Retention

3.12.1 The licensee shall carry out a risk assessment to determine if the activity should have a fire-water retention facility. The licensee shall submit a report to the Agency for approval on the findings and recommendations of the assessment within **six** months of the date of grant of this licence.

3.12.2 In the event that a significant risk exists for the release of contaminated fire-water, the licensee shall, based on the findings of the risk assessment, prepare and implement, with the approval of the Agency, a suitable risk management programme. The risk management programme shall be fully implemented within t**hree** months of date of **approval** by the Agency.

3.12.3 In the event of a fire or a spillage to storm water, the site storm water shall be diverted for collection.

3.12.4 The licensee shall examine (based upon the findings of the risk assessment in Condition 3.12.1) as part of the response programme in Condition 3.12.2 the need to provide automatic diversion of storm water for collection.

3.12.5 The licensee shall have regard to relevant Environmental Protection Agency Guidance when implementing Conditions 3.12.1 and 3.12.2 above.

3.13 All pump sumps, storage tanks or other treatment plant chambers from which spillage of environmentally significant materials might occur in such quantities as are likely to breach local or remote containment or separators, shall be fitted with high liquid level alarms (or oil detectors as appropriate) **in advance of the commencement of the licensed activity.**

3.14 The provision of a catchment system to collect any leaks from flanges and valves of all over-ground pipes used to transport material other than water shall be examined. This shall be incorporated into a Schedule of Environmental Objectives and Targets set out in Condition 2 of this licence for the reduction in fugitive emissions.

3.15 All installed wellheads at the installation shall be adequately protected to prevent contamination or physical damage.

3.16 The licensee shall, **in advance of the commencement of the licensed activity**, install in a prominent location on the site a wind sock, or other wind direction indicator, which shall be visible from the public roadway outside the site.

3.17 **Liquefied Petroleum Gas (LPG) s**hall be used in the boilers on site. In the event of an interruption to the supply of **LPG**, an alternative fuel such as gas oil may be used with the prior approval of the Agency.

3.18 The hours of operation of the emergency diesel generator (A1-4) shall not exceed 500 hours annually, as a rolling average over a five-year period. The licensee shall record the hours of operation to the satisfaction of the Agency.

3.19 The licensee shall use a combination of techniques listed in BAT 19 of the CWW CID in order to prevent or, where that is not practicable, to reduce diffuse VOC emissions to air.

Reason: ***To provide for appropriate operation of the installation to ensure protection of the environment.***

Condition 4. Interpretation

4.1 Emission limit values for emissions to atmosphere in this licence shall be interpreted in the following way:

4.1.1 Continuous Monitoring

(i) No 24 hour mean value shall exceed the emission limit value.

(ii) 97% of all 30 minute mean values taken continuously over an annual period shall not exceed 1.2 times the emission limit value.

(iii) No 30 minute mean value shall exceed twice the emission limit value.

4.1.2 Non-Continuous Monitoring

(i) For any parameter where, due to sampling/analytical limitations, a 30 minute sample is inappropriate, a suitable sampling period should be employed and the value obtained therein shall not exceed the emission limit value.

(ii) For flow, no hourly or daily mean value, calculated on the basis of appropriate spot readings, shall exceed the relevant limit value.

(iii) For all other parameters, no 30 minute mean value shall exceed the emission limit value.

4.2 The concentration and volume flow limits for emissions to atmosphere specified in this licence shall be achieved without the introduction of dilution air and shall be based on gas volumes under standard conditions of:

4.2.1 From non-combustion sources:

Temperature 273K, Pressure 101.3 kPa (no correction for oxygen or water content).

4.2.2 From combustion sources:

Temperature 273K, Pressure 101.3 kPa, dry gas; 3% oxygen for liquid and gas fuels.

4.3 Emission limit values for emissions to sewer/waters in this licence shall be achieved without the introduction of aqueous dilution, and shall be interpreted in the following way:

4.3.1 Continuous Monitoring

(i) No flow value shall exceed the specific limit.

(ii) No pH value shall deviate from the specified range.

(iii) No temperature value shall exceed the limit value.

4.3.2 Composite Sampling

(i) No pH value shall deviate from the specified range.

(ii) For parameters other than pH and flow, eight out of ten consecutive composite results, based on flow proportional composite sampling, shall not exceed the emission limit value. No individual results similarly calculated shall exceed 1.2 times the emission limit value.

4.3.3 Discrete Sampling

For parameters other than pH and temperature, no grab sample value shall exceed 1.2 times the emission limit value.

4.4 Where the ability to measure a parameter is affected by mixing before emission, then, with **approval** from the Agency, the parameter may be assessed before mixing takes place.

4.5 Noise

Noise from the installation shall not give rise to sound pressure levels measured at **the NSLs** which exceed the limit value(s).

Reason: To clarify the interpretation of limit values fixed under the licence.

Condition 5. Emissions

5.1 Emissions may be made from the specified emission points set out in *Schedule B: Emission Limits,* of this licence subject to compliance with the Emission Limit Values specified in that Schedule.

5.1.1 Uncontaminated storm water may be discharged to surface water.

5.1.2 Uncontaminated storm water may be emitted to groundwater or to soil.

5.1.3 Minor, diffuse and potential emissions may be emitted to air as specified in the application, or as approved by the Agency under Condition 1 of this licence.

5.2 Notwithstanding the requirements of condition 5.1, there shall be no other emissions from the installation.

5.3 No emissions, including odours, from the activities carried on at the site shall result in an impairment of, or an interference with amenities or the environment beyond the installation boundary or any other legitimate uses of the environment beyond the installation boundary.

5.4 No substance shall be discharged in a manner, or at a concentration, that, following initial dilution, causes tainting of fish or shellfish.

5.5 Emissions to Sewer

5.5.1 Other than the trade effluent authorised to be discharged under this licence, the licensee shall at no time discharge or cause or permit to be discharged into the sewer, trade effluent or any other matter unless authorised in writing by Irish Water.

5.5.2 The licensee shall ensure that any trade effluent generated from canteen activities shall pass through appropriate grease removal equipment prior to discharge to sewer.

5.5.3 A summary report of volumes of trade effluent and other matter discharged to the sewer along with monitoring and analysis data as specified in *Schedule B: Emission Limits to Sewer*, of this licence and *Schedule C: Control & Monitoring*, of this licence shall be forwarded to both Irish Water and the Local Authority in a manner and timeframe as may be specified by Irish Water.

Reason: ***To provide for the protection of the environment by way of control and limitation of emissions and to provide for the requirements of Irish Water in accordance with Section 99E of the EPA Act 1992 as amended.***

Condition 6. Control and Monitoring

6.1 The licensee shall carry out such sampling, analyses, measurements, examinations, maintenance and calibrations as set out below and as in accordance with *Schedule C: Control & Monitoring*, of this licence.

6.1.1 Sampling and analysis shall be undertaken by competent staff in accordance with documented operating procedures. Unless otherwise approved by the Agency, sampling and analysis of emissions to atmosphere shall be carried out by ISO 17025 accredited persons/organisations, with accreditation for the relevant scope of sampling and analysis, and in accordance with the Agency's air monitoring policy.

6.1.2 Such procedures shall be assessed for their suitability for the test matrix and performance characteristics shall be determined.

6.1.3 Such procedures shall be subject to a programme of Analytical Quality Control using appropriate control standards with evaluation of test responses.

6.1.4 Where any analysis is sub-contracted it shall be outsourced to a competent laboratory.

6.2 The licensee shall ensure that:

(i) sampling and analysis for all parameters listed in the schedules to this licence; and

(ii) any reference measurements for the calibration of automated measurement systems

shall be carried out in accordance with CEN-standards. If CEN standards are not available, ISO, national or international standards that will ensure the provision of data of an equivalent scientific quality shall apply.

The automated measuring systems shall be subject to parallel measurements with the reference methods at least once per year. The licensee shall submit to the Agency an air monitoring report with the results of the parallel measurements.

6.3 All automatic monitors and samplers shall be functioning at all times (except during maintenance and calibration) when the activity is being carried on unless alternative sampling or monitoring has been **approved** in writing by the Agency for a limited period. In the event of the malfunction of any continuous monitor, the licensee shall contact the Agency as soon as practicable, and alternative sampling and monitoring facilities shall be put in place. The use of alternative equipment, other than in emergency situations, shall be as **approved** by the Agency.

6.4 Monitoring and analysis equipment shall be installed, operated and maintained as necessary so that all monitoring accurately reflects the emission/discharge.

6.5 The licensee shall ensure that groundwater monitoring well sampling equipment is available or installed on-site at the installation and is fit for purpose at all times. The sampling equipment shall be to Agency specifications.

6.6 All treatment/abatement and emission control equipment shall be calibrated and maintained in accordance with the instructions issued by the manufacturer/supplier or installer.

6.7 The frequency, methods and scope of monitoring, sampling and analyses, as set out in this licence, may be amended as required or approved by the Agency following evaluation of test results.

6.8 The licensee shall prepare a programme, to the satisfaction of the Agency, for the identification and reduction of fugitive emissions using an appropriate combination of best available techniques. This programme shall be included in the Environmental Management Programme.

6.9 The integrity and water tightness of all tanks, bunding structures, containers and underground pipes and their resistance to penetration by water or other materials carried or stored therein shall be tested and demonstrated by the licensee **within three months of the date of the grant of this licence**. This testing shall be carried out by the licensee at least once every three years thereafter and reported to the Agency on each occasion. This testing shall be carried out in accordance with any guidance published by the Agency. A written record of all integrity tests and any maintenance or remedial work arising from them shall be maintained by the licensee.

6.10 The stormwater drainage system (i.e., gullies, manholes, any visible drainage conduits and such other aspects as may be agreed), **bunds, oil separators** shall be inspected weekly, and **properly maintained including** desludged as necessary. All sludge and drainage from these operations shall be collected for safe disposal. The licensee shall maintain a drainage map on site. The drainage map shall be reviewed annually and updated as necessary.

6.11 An inspection system for the detection of leaks on all flanges and valves on over-ground pipes used to transport materials other than water shall be developed and maintained prior to the commencement of the **licensed** activity.

6.12 Storm Water

6.12.1 A visual examination of the storm water discharges shall be carried out **weekly**. A log of such inspections, shall be maintained.

6.12.2 The licensee shall, within six months of commencement of the **licensed** activity, establish suitable trigger levels for **pH, TOC** in storm water discharges, such that storm waters exceeding these levels will be diverted for retention and suitable disposal. The licensee shall have regard to the Environmental Protection Agency "Guidance on the setting of trigger values for storm water discharges to off-site surface waters at EPA IPPC and Waste licensed facilities" when establishing the suitable trigger levels

6.13 Noise

The licensee shall carry out a noise survey of the site operations annually. The survey programme shall be undertaken in accordance with the methodology specified in the 'Guidance Note for Noise:

Licence Applications, Surveys and Assessments in Relation to Scheduled Activities (NG4)' as published by the Agency.

6.14 Pollutant Release and Transfer Register (PRTR)

The licensee shall submit a PRTR data report for the site. The pollutants and/or wastes to be included in the PRTR shall be determined by reference to EC Regulations No. 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register. The PRTR shall be prepared in accordance with any relevant Agency guidance and shall be submitted electronically in the format specified by the Agency.

6.15 Groundwater and Soil Monitoring

6.15.1 The licensee shall assess groundwater monitoring data to determine compliance with the *Environmental Objectives (Groundwater) Regulations 2010 as amended.* The assessment shall be submitted to the Agency. Monitoring shall be carried out in accordance with S*chedule C.6 Groundwater Monitoring*.

6.15.2 The licensee shall, within twelve months of the date of grant of this licence, arrange for the carrying out, by an appropriately qualified consultant/professional, of a comprehensive hydrogeological investigation of the site. The scope, detail and programme, including report structure and reporting schedule for this investigation must be approved by the Agency prior to implementation. Any recommendations arising from a report or reports on this investigation must be implemented within such a period to be approved by the Agency.

6.15.3 The licensee shall carry out monitoring for relevant hazardous substances in soil and groundwater at the site of the installation. The substances for monitoring shall be identified by the licensee by undertaking a risk based assessment. The risk assessment, sampling and monitoring shall be carried out in accordance with any guidance published by the Agency. The licensee shall have regard to the '*Classification of Hazardous and Non-Hazardous Substances in Groundwater'* as published by the Agency.

6.15.4 Groundwater monitoring shall be carried out **for relevant hazardous substances** at least once every five years. Monitoring shall be carried out in accordance with S*chedule C.6 Groundwater Monitoring*.

6.15.5 Soil monitoring shall be carried out at the site of the installation at least once every ten years. Monitoring shall be carried out in accordance with S*chedule C.6 Soil Monitoring.*

Reason: ***To provide for the protection of the environment by way of treatment and monitoring of emissions and to provide for the requirements of Irish Water in accordance with Section 99E of the EPA Act 1992 as amended.***

Condition 7. Resource Use and Energy Efficiency

7.1 The licensee shall carry out an audit of the energy efficiency of the site within **one year of the date of commencement of the licensed activity**. The audit shall be carried out in accordance with the guidance published by the Agency, "Guidance Note on Energy Efficiency Auditing". The energy efficiency audit shall be repeated at intervals as required by the Agency.

7.2 The audit shall identify all practicable opportunities for energy use reduction and efficiency and the recommendations of the audit will be incorporated into the Schedule of Environmental Objectives and Targets under Condition 2 above.

7.3 The licensee shall identify opportunities for reduction in the quantity of water used on site including recycling and reuse initiatives, wherever possible. Reductions in water usage shall be incorporated into Schedule of Environmental Objectives and Targets.

7.4 The licensee shall undertake an assessment of the efficiency of use of raw materials in all processes, having particular regard to the reduction in waste generated. The assessment should take account of best international practice for this type of activity. Where improvements are identified, these shall be incorporated into the Schedule of Environmental Objectives and Targets.

Reason: To provide for the efficient use of resources and energy in all site operations.

Condition 8. Materials Handling

8.1 The licensee shall ensure that waste generated in the carrying on of the activity shall be prepared for re-use, recycling or 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.

8.2 Waste sent off-site for recovery or disposal

8.2.1 Waste sent off-site for recovery or disposal shall be transported only by an authorised waste contractor. The waste shall be transported from the site of the activity to the site of recovery/disposal only in a manner that will not adversely affect the environment and in accordance with the appropriate National and European legislation and protocols.

8.2.2 Waste sent off-site for recovery or disposal shall be transferred only to an appropriate facility.

8.3 The licensee shall ensure that, in advance of transfer to another person, waste shall be classified, packaged and labelled in accordance with National, European and any other standards which are in force in relation to such labelling.

8.4 The loading and unloading of materials shall be carried out in designated areas protected against spillage and leachate run-off.

8.5 Waste and materials shall be stored in designated areas, protected as may be appropriate against spillage and leachate run-off. The waste and materials shall be clearly labelled and appropriately segregated.

8.6 Waste for disposal/recovery off-site shall be analysed in accordance with *Schedule C: Control & Monitoring*, of this licence.

8.7 Unless approved in writing, in advance, by the Agency the licensee is prohibited from mixing a hazardous waste of one category with a hazardous waste of another category or with any other non-hazardous waste.

8.8 The licensee shall neither import waste into the State nor export waste out of the State except in accordance with the relevant provisions of Regulation (EC) No 1013/2006 of the European Parliament and of the Council of 14th June 2006 on shipments of waste and associated national regulations.

Reason: To provide for the appropriate handling of material and the protection of the environment.

Condition 9. Accident Prevention and Emergency Response

9.1 The licensee shall**, in advance of the commencement of the licensed activity,** ensure that a documented Accident Prevention Procedure is in place that addresses the hazards on-site, particularly in relation to the prevention of accidents with a possible impact on the environment. This procedure shall be reviewed annually and updated as necessary.

9.2 The licensee shall**, in advance of the commencement of the licensed activity**, ensure that a documented Emergency Response Procedure is in place, that addresses any emergency situation which may originate on-site. This procedure shall include provision for minimising the effects of any emergency on the environment. This procedure shall be reviewed annually and updated as necessary.

9.3 Incidents

9.3.1 In the event of an incident the licensee shall immediately:

(i) carry out an investigation to identify the nature, source and cause of the incident and any emission arising therefrom;

(ii) isolate the source of any such emission;

(iii) evaluate the environmental pollution, if any, caused by the incident;

(iv) identify and execute measures to minimise the emissions/malfunction and the effects thereof;

(v) identify the date, time and place of the incident;

(vi) notify the Agency as required by Condition 11.4 of this licence.

9.3.2 Where an incident or accident that significantly affects the environment occurs, the licensee shall, without delay take measures to limit the environmental consequences of the incident or accident and to prevent further incident or accident.

Reason: To provide for the protection of the environment.

Condition 10. Closure, Restoration and Aftercare Management

10.1 Following termination, or planned cessation for a period greater than six months, of use or involvement of all or part of the site in the licensed activity, the licensee shall, to the satisfaction of the Agency, decommission, render safe or remove for disposal/recovery any soil, subsoil, buildings, plant or equipment, or any waste, materials or substances or other matter contained therein or thereon, that may result in environmental pollution. A final validation report to include a certificate of completion to demonstrate there is no continuing risk to the environment shall be submitted to the Agency within three months of termination or planned cessation of the activity.

Reason: To make provision for the proper closure of the activity ensuring protection of the environment.

Condition 11. Notification, Records and Reports

11.1 The licensee shall submit the reports, proposals and submissions required by this licence by the deadlines specified. The licensee shall not be in compliance with the requirements of this condition unless and until it has submitted every report, proposal and submission, the deadline for which has passed.

11.2 The licensee shall carry out every action required by the Agency, and arising out of such reports, proposals or submission, by such deadline as the Agency may specify. The licensee shall not be in compliance with the requirements of this condition unless and until it has carried out every such action.

11.3 The licensee shall notify the Agency, in a format as may be specified by the Agency, one month in advance of the intended date of commencement of the Scheduled Activity.

11.4 The licensee shall notify the Agency by both telephone and either email or webform, to the Agency's headquarters in Wexford, or to such other Agency office as may be specified by the Agency, as soon as practicable after the occurrence of any of the following:

(i) an incident or accident as defined by the glossary;

(ii) any release of environmental significance to atmosphere from any potential emissions point including bypasses;

(iii) any breach of one or more of the conditions attached to this licence;

(iv) any malfunction or breakdown of key environmental abatement, control or monitoring equipment; and

(v) any incident or accident as defined in the glossary requiring an emergency response by the Local Authority.

The licensee shall include as part of the notification, date and time of the incident, summary details of the occurrence, and where available, the steps taken to minimise any emissions. All details required to be communicated must be in accordance with any Guidance provided by the Agency.

11.5 In the event of any incident which relates to discharges to sewer having taken place, the licensee shall notify Irish Water and the Local Authority in a manner prescribed by Irish Water, as soon as practicable after such an incident.

11.6 The following shall be notified, as soon as practicable after the occurrence of any incident which relates to a discharge to water:

(i) Inland Fisheries Ireland in the case of discharges to receiving waters.

(ii) The local authority, in the case of discharges to designated bathing waters.

11.7 The licensee shall make a record of any notification made under Condition 11.4. This record shall include details of the nature, extent, and impact of, and circumstances giving rise to, the incident or accident. The record shall include all corrective actions taken to manage the incident or accident, minimise wastes generated and the effect on the environment, and avoid recurrence. In the case of a breach of a condition, the record shall include measures to restore compliance.

11.8 The licensee shall record all complaints of an environmental nature related to the operation of the activity. Each such record shall give details of the date and time of the complaint, the name of the complainant (if provided), and give details of the nature of the complaint. A record shall also be kept of the response made in the case of each complaint.

11.9 The licensee shall record all sampling, analyses, measurements, examinations, calibrations and maintenance carried out in accordance with the requirements of this licence and all other such monitoring which relates to the environmental performance of the installation.

11.10 The licensee shall as a minimum ensure that the following documents are accessible at the site:

(i) the licences relating to the installation;

(ii) the current EMS for the installation including all associated procedures, reports, records and other documents;

(iii) the previous year's AER for the installation;

(iv) records of all sampling, analyses, measurements, examinations, calibrations and maintenance carried out in accordance with the requirements of this licence and all other such monitoring which relates to the environmental performance of the installation;

(v) relevant correspondence with the Agency;

(vi) up-to-date site drawings/plans showing the location of key process and environmental infrastructure, including monitoring locations and emission points;

(vii) up-to-date Standard Operational Procedures for all processes, plant and equipment necessary to give effect to this licence or otherwise to ensure that standard operation of such processes, plant or equipment does not result in unauthorised emissions to the environment;

(viii) any elements of the licence application or EIA documentation referenced in this licence.

This documentation shall be available to the Agency for inspection at all reasonable times.

11.11 The licensee shall submit to the Agency, by the 31st March of each year, an AER covering the previous calendar year. This report, which shall be to the satisfaction of the Agency, shall include as a minimum the information specified in *Schedule D: Annual Environmental Report*, of this licence and shall be prepared in accordance with any relevant guidelines issued by the Agency.

11.12 A full record, which shall be open to inspection by authorised persons of the Agency at all times, shall be kept by the licensee on matters relating to the waste management operations and practices at this site. This record shall be as a minimum contain details of the following:

(i) the tonnages and LoW Code for the waste materials sent off-site for disposal/recovery;

(ii) the names of the agent and carrier of the waste, and their waste collection permit details, if required (to include issuing authority and vehicle registration number);

(iii) details of the ultimate disposal/recovery destination facility for the waste and its appropriateness to accept the consigned waste stream, to include its permit/licence details and issuing authority, if required;

(iv) written confirmation of the acceptance and disposal/recovery of any hazardous waste consignments sent off-site;

(v) details of all waste consigned abroad for Recovery and classified as 'Green' in accordance with the EU Shipment of Waste Regulations (Council Regulation EEC No. 1013/2006, as may be amended). The rationale for the classification must form part of the record;

(vi) details of any rejected consignments;

(vii) details of any approved waste mixing;

(viii) the results of any waste analyses required under *Schedule C: Control & Monitoring*, of this licence; and

(ix) the tonnage and LoW Code for the waste materials recovered/disposed on-site.

11.13 The licensee shall submit report(s) **electronically** as required by the conditions of this licence to the Agency.

11.14 All reports shall be certified accurate and representative by the installation manager or a nominated, suitably qualified and experienced deputy.

Reason: To provide for the collection and reporting of adequate information on the activity.

Condition 12. Financial Charges and Provisions

12.1 Agency Charges

12.1.1 The licensee shall pay to the Agency an annual contribution of €**13,773**, or such sum as the Agency from time to time determines, having regard to variations in the extent of reporting, auditing, inspection, sampling and analysis or other functions carried out by the Agency, towards the cost of monitoring the activity as the Agency considers necessary for the performance of its functions under the Environmental Protection Agency Act 1992 as amended. The first payment shall be a pro-rata amount for the period from **date of commencement of enforcement to the** 31st day of December and shall be paid to the Agency within one month from the date of grant of the licence. In subsequent years the licensee shall pay to the Agency such revised annual contribution as the Agency shall from time to time consider necessary to enable performance by the Agency of its relevant functions under the Environmental Protection Agency Act 1992 as amended, and all such payments shall be made within one month of the date upon which demanded by the Agency.

12.1.2 In the event that the frequency or extent of monitoring or other functions carried out by the Agency needs to be increased, the licensee shall contribute such sums as determined by the Agency to defray its costs in regard to items not covered by the said annual contribution.

12.2 Irish Water Charges

The licensee shall pay to Irish Water such sum as may be determined from time to time, having regard to the variations in the cost of providing drainage and the variation in effluent reception, treatment, monitoring, sampling and analysis costs. Payment to be made on demand from Irish Water.

12.3 Environmental Liabilities

12.3.1 The Agency may amend this licence at any time in certain circumstances in accordance with section 96 of the Environmental Protection Agency Act 1992 as amended, to require, or not require as the case may be, the putting in place of a financial provision to incorporate costings for CRAMP and/or Environmental Liabilities Risk Assessment. This amendment may be implemented by the Agency in the event of an incident that creates a significant residual environmental liability or where the environmental risk profile changes on site.

Reason: ***To provide for adequate financing for monitoring and financial provisions for measures to protect the environment and to provide for the requirements of Irish Water in accordance with Section 99E of the EPA Act 1992 as amended.***

SCHEDULE A: Limitations

Organic solvent consumption in the manufacture of pharmaceutical products shall not exceed 50 tonnes per year.

SCHEDULE B: Emission Limits

B.1 Emissions to Air

Emission Point Reference No:	A1-1, A1-2	
Location:	Boiler House	
Volume to be emitted:	Maximum in any one day:	**20,100 m^3**
	Maximum rate per hour:	**840 m^3**
Minimum discharges height:	17.4 m above ground	

Parameter	Emission Limit Value **mg/m^3**
Sulphur dioxide	**35**
Nitrogen oxides (as NO_2)	**200**

B.2 Emissions to Water

There shall be no emissions to water of environmental significance.

B.3 Emissions to Sewer

Emission Point Reference No:	SE1	
Name of Sewer:	Irish Water Sewer	
Monitoring Location:	Waste Water Tanks Building Flow meter SE1a (Grid Reference (169843E, 337621N) Composite Sampler SE1b (Grid Reference (169845E, 337620N)	
Discharge Location:	SE1 (Grid Reference (169924E, 337330E)	
Volume to be emitted:	Maximum in any one day:	180 m^3
	Maximum rate per hour:	12.7 m^3

Parameter	**Emission Limit Value**	
Temperature	**35 ºC (max)**	
pH	**6 - 9**	
	mg/1	**kg/day**
BOD	**377**	**61**
COD	**599**	**97**
Suspended Solids	**333**	**54**
Total Nitrogen	**12**	**2**
Chlorides	**6000**	**18**
Sulphates (as SO_4)	**15**	**-**
Oils, Fats and greases	**10**	**-**
Detergents (as MBAS)	**20**	**-**

B.4 Noise Emissions

Daytime dB $L_{Ar,T}$ (30 minutes)	**Evening time dB $L_{Ar,T}$ (30 minutes)**	Note 1 **Night-time dB $L_{Aeq,T}$ (30 minutes)**
55	50	45

Note 1: During night time hours, there shall be no clearly audible tonal component or impulsive component in the noise emission from the activity at any noise-sensitive location.

SCHEDULE C: Control & Monitoring

C.1.1. Control of Emissions to Air

Emission Point Reference No: A1-1, A1-2

Control Parameter	Monitoring	Key Equipment [Note 1]
Boiler Efficiency	Flue Gas Analysis	Flue Gas Analyser

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.

C.1.2. Monitoring of Emissions to Air

Emission Point Reference No: **A1-1, A1-2**

Parameter	Monitoring Frequency	Analysis Method/Technique
Sulphur dioxide	**Every three years**	**Flue gas analyser**
Nitrogen oxides (as NO_2)	**Every three years**	**Flue gas analyser**
Combustion Efficiency (to include carbon monoxide measurement)	**Every three years**	**Flue gas analyser**

Emission Point Reference No: **A1-4**

Parameter	Monitoring Frequency	Analysis Method/Technique
Nitrogen oxides (as NO_2)	**Every 1,500 hours of operation**	**Flue gas analyser**

C.2.1. Control of Emissions to Water

There shall be no emissions to water of environmental significance.

C.2.2. Monitoring of Emissions to Water

There shall be no emissions to water of environmental significance.

C.2.3. Monitoring of Storm Water Emissions

Emission Point Reference No: **SW1, SW2 and SW3**

Parameter	Monitoring Frequency	Analysis Method/Technique
pH	**Weekly**	Standard method
TOC	**Weekly**	Standard method
Visual Inspection	**Weekly**	Sample and examine for colour and odour.

C.3.1. Control of Emissions to Sewer

Emission Point Reference No: SE1
Description of Treatment: Wastewater Treatment

Control Parameter	Monitoring	Key Equipment [Note 1]
Flow	Continuous	Balancing Tank
pH	Continuous	pH dosing
Temperature	Continuous	Temperature probe

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.

Description of Treatment: Removal of Fats, Oils and Grease generated as a result of any canteen activities

Control Parameter	Monitoring	Key Equipment [Note 1]
Fats, oil and grease removal	Fats, oil and grease content in trade effluent as a result of canteen activities	Grease removal equipment

Note 1: Grease removal equipment shall comply with the requirements of European Standards (EN) or Plumbing and Drainage Institute (PDI) standards or as otherwise specified by Irish Water.

C.3.2. Monitoring of Emissions to Sewer

Emission Point Reference No: SE1

Parameter	Monitoring Frequency [Note 1]	Analysis Method /Technique
Flow	Continuous [Note 2]	On-line flow meter with recorder
Temperature	Continuous	On-line temperature probe with recorder
pH	Continuous	pH electrode/meter and recorder
Chemical Oxygen Demand	Weekly [Note 2]	Standard Method
Biochemical Oxygen Demand	Weekly [Note 2]	Standard Method
Suspended Solids	Weekly [Note 2]	Standard Method
Total Phosphorus (as P)	Weekly [Note 2]	Standard method
Total Nitrogen	Weekly [Note 2]	Standard method
Chlorides	Quarterly [Note 2]	Standard method
Sulphates (as SO_4)	Quarterly [Note 2]	Standard method
Oils, Fats and greases	Quarterly [Note 2]	Standard method
Detergents (as MBAS)	Quarterly [Note 2]	Standard method
Total Heavy metals	Annually [Note 2]	Standard method
Volatile Organic Compounds/Semi Volatile Organic Compounds (VOC/SVOC) (according to US EPA Method 542.2 list) [Note 3]	Annually [Note 2]	Standard method
Active Pharmaceuticals	As may be required by the Agency or Irish Water [Note 2]	Standard method
Toxicity	As may be required the Agency or Irish Water [Note 2]	To be agreed by the Agency
Respirometry	Annually [Note 2]	Standard method

Note 1: **Sampling shall take place on alternative week days on a rolling basis to ensure representative samples are obtained for site operations which may vary across the working week.**

Note 2: The licensee shall install a composite sampler **in advance of the commencement of the licensed activity**. All samples shall be collected on a 24 hour flow proportional composite sampling basis.

Note 3: **Analysis shall include those organic solvents in use in the process, which are likely through normal process operations to be present in the waste water discharge.**

C.4 Waste Monitoring

Waste Class	Frequency	Parameter	Method
To be approved by the Agency [Note 1]	**To be approved by the Agency.**	**To be approved by the Agency.**	**To be approved by the Agency.**

Note 1: Analytical requirements to be determined on a case by case basis.

C.5 Noise Monitoring

No additional noise monitoring is required in this schedule.

C.6 Ambient Monitoring

Groundwater Monitoring

Location: Well Nos. MW1, MW2 and MW3 and/or any alternative monitoring location(s) approved by the Agency.

Parameter	Monitoring Frequency	Analysis Method/Techniques
pH	Annually	pH electrode/meter
COD	Annually	Standard Method
Conductivity	Annually	Standard Method
Chloride	Annually	Standard Method
Aluminium	Quarterly	Standard Method
Nickel	Quarterly	Standard Method
Iron	Quarterly	Standard Method
Arsenic	Quarterly	Standard Method
Manganese	Quarterly	Standard Method
Relevant Hazardous Substances Note1	Every five years	Standard Method

Note 1: Groundwater monitoring for relevant hazardous substances shall be in accordance with Condition 6.15.

Soil Monitoring

Monitoring Location: As per the 'Baseline Report' or alternative monitoring location(s) as approved by the Agency [Note 1]

Parameter	Monitoring Frequency	Analysis Method/Techniques
Relevant hazardous Substances [Note 2]	Every ten years	Standard Method

Note 1: Soil monitoring for relevant hazardous substances shall be in accordance with Condition 6.15.

SCHEDULE D: Annual Environmental Report

Annual Environmental Report Content [Note 1]
Emissions from the installation.
Waste management record.
Resource consumption summary.
Complaints summary.
Schedule of Environmental Objectives and Targets.
Environmental management programme – report for previous year.
Environmental management programme – proposal for current year.
Noise monitoring report summary.
Ambient monitoring summary.
Tank and pipeline assessment report.
Reported incidents summary.
Energy efficiency audit report summary.
Report on the assessment of the efficiency of use of raw materials in processes and the reduction in waste generated.
Report on progress made and proposals being developed to minimise water demand and the volume of trade effluent discharges.
Development/Infrastructural works summary (completed in previous year or prepared for current year).
Any other items specified by the Agency.

Note 1: Content may be revised subject to the approval of the Agency.

Signed on behalf of the said Agency _____
On the xx day of xxxxx, 201X xxxxxxxxxxx **Authorised Person**