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Ireland

INTEGRATED POLLUTION PREVENTION & CONTROL LICENCE
Recommended Determination

Licence Register Number:	P0828-01
Applicant:	Topchem Pharmaceuticals Limited
Location of Installation:	Ballymote Business Park Carrownanty Ballymote County Sligo

INTRODUCTION

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

Topchem Pharmaceuticals Limited proposes to develop a pharmaceutical production facility in Ballymote Business Park, Ballymote Co Sligo. The company will be involved in the manufacture of low volume active pharmaceutical ingredients. The first active ingredient to be manufactured will be "Malathion" which will then be formulated by their customer, at another site, for the treatment of head lice infestation.

The manufacture process proposed will be performed on a laboratory scale within fume hoods.

The licence sets out in detail the conditions under which Topchem Pharmaceutical Limited will operate and manage this installation.

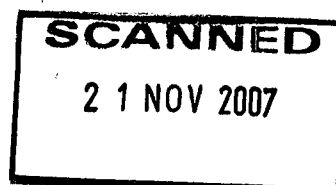


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Glossary of Terms

All terms in this licence should be interpreted in accordance with the definitions in the Environmental Protection Agency Acts 1992 and 2003/Waste Management Acts 1996 to 2007, unless otherwise defined in this section.

Adequate lighting	20 lux measured at ground level.
AER	Annual Environmental Report.
Agreement	Agreement in writing.
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, 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.
Biannually	All or part of a period of six consecutive months.
Biennially	Once every two years.
BOD	5 day Biochemical Oxygen Demand.
CEN	Comité Européen De Normalisation – European Committee for Standardisation.
COD	Chemical Oxygen Demand.
Construction and demolition (C & D) waste	Wastes that arise from construction, renovation and demolition activities: Chapter 17 of the EWC or as otherwise may be agreed.
Containment boom	A boom that can contain spillages and prevent them from entering drains or watercourses or from further contaminating watercourses.
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	0800 hrs to 2200 hrs.
dB(A)	Decibels (A weighted).

DO	Dissolved oxygen.
Documentation	Any report, record, result, 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.
EMP	Environmental Management Programme.
Emission limits	Those limits, including concentration limits and deposition rates, established in <i>Schedule B</i> of this licence.
Environmental damage	Has the meaning given it in Directive 2004/35/EC.
EPA	Environmental Protection Agency.
European Waste Catalogue (EWC)	A harmonised, non-exhaustive list of wastes drawn up by the European Commission and published as Commission Decision 2000/532/EC and any subsequent amendment published in the Official Journal of the European Community.
Facility	Any site or premises used for the purposes of the recovery or disposal of waste.
Fortnightly	A minimum of 24 times per year, at approximately two week intervals.
GC/MS	Gas chromatography/mass spectroscopy.
Green waste	Waste wood (excluding timber), plant matter such as grass cuttings, and other vegetation.
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.
HFO	Heavy fuel oil.
Hours of operation	The hours during which the installation is authorised to be operational.
ICP	Inductively coupled plasma spectroscopy.

Incident	<p>The following shall constitute an incident for the purposes of this licence:</p> <ul style="list-style-type: none">(i) an emergency;(ii) any emission which does not comply with the requirements of this licence;(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.
Installation	<p>A stationary technical unit or plant where the activity concerned referred to in the First Schedule of EPA Acts 1992 and 2003 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.</p>
IPPC	<p>Integrated Pollution Prevention & Control.</p>
K	<p>Kelvin.</p>
kPa	<p>Kilopascals.</p>
Leq	<p>Equivalent continuous sound level.</p>
Licensee	<p>Topchem Pharmaceuticals Limited, Ballymote business Park, Carrownanty, Ballymote, Co. Sligo.</p>
List I	<p>As listed in the EC Directives 76/464/EEC and 80/68/EEC and amendments.</p>
List II	<p>As listed in the EC Directives 76/464/EEC and 80/68/EEC and amendments.</p>
Local Authority	<p>Sligo County Council.</p>
Maintain	<p>Keep in a fit state, including such regular inspection, servicing, calibration and repair as may be necessary to adequately perform its function.</p>
Mass flow limit	<p>An emission limit value which is expressed as the maximum mass of a substance that can be emitted per unit time.</p>
Mass flow threshold	<p>A mass flow rate above which a concentration limit applies.</p>
Monthly	<p>A minimum of 12 times per year, at intervals of approximately one month.</p>
Night-time	<p>2200 hrs to 0800 hrs.</p>

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.
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.
Regional Fisheries Board	North Western Regional Fisheries Board.
Water Services Authority	Sligo County Council.
Sanitary effluent	Wastewater from installation toilet, washroom and canteen facilities
Sample(s)	Unless the context of this licence indicates to the contrary, samples shall include measurements by electronic instruments.
Solvent Regulations	Emissions of Volatile Organic Compounds from Organic Solvents Regulations, 2002 (S.I. No. 253 of 2002) as amended by S. I. No. 199 of 2007.
SOP	Standard operating procedure.
Specified emissions	Those emissions listed in <i>Schedule B: Emission Limits</i> of this licence.
Standard method	A National, European or internationally recognised procedure (eg, 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.
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 Pollution Acts 1977 and 1990.

Trigger level	A parameter value, the achievement or exceedance of which requires certain actions to be taken by the licensee.
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.

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 Acts 1992 and 2003.

In reaching this decision the Environmental Protection Agency has considered the application and supporting documentation received from the applicant, and the report of its inspector.

Part I Schedule of Activities Licensed

In pursuance of the powers conferred on it by the Environmental Protection Agency Acts 1992 and 2003, the Agency proposes to grant this Integrated Pollution Prevention & Control licence to:

Topchem Pharmaceuticals Limited, Ballymote Business Park, Carrownanty,
Ballymote, County Sligo,

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

Class 5.16: The use of a chemical or biological process for the production of basic pharmaceutical products

at Topchem Pharmaceuticals Limited, Ballymote Business Park, Carrownanty, Ballymote, County 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 Activities at this installation shall be limited as set out in *Schedule A: Limitations of this licence*.
- 1.2 The installation shall be controlled, operated, and maintained and emissions shall take place as set out in this licence. All programmes required to be carried out under the terms of this licence, become part of this licence.
- 1.3 For the purposes of this licence, the installation is the area of land outlined in red on drawing labelled "Location Map" Attachment B.2 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 No alteration to, or reconstruction in respect of, the activity or any part thereof which 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 agreement of, the Agency.
- 1.5 This licence is for the purposes of IPPC licensing under the EPA Acts 1992 and 2003 only and nothing in this licence shall be construed as negating the licensee's statutory obligations or requirements under any other enactments or regulations.

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 and maintain** an Environmental Management System (EMS) within six months of the date of grant of this licence. The EMS shall be updated on an annual basis.
- 2.2.2 The EMS shall include as a minimum the following elements:

2.2.2.1 Management and Reporting Structure.

2.2.2.2 Schedule of Environmental Objectives and Targets.

The licensee shall **prepare and maintain** 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, the use of cleaner technology, cleaner production, 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 and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER).

2.2.2.3 Environmental Management Programme (EMP)

The licensee shall, **not later than six months from the date of grant of this licence, submit to the Agency for agreement an EMP**, including a time schedule, for achieving the Environmental Objectives and Targets prepared under Condition 2.2.2.2. Once agreed the EMP shall be **established and maintained** by the licensee. It shall include:

- (i) designation of responsibility for targets;
- (ii) the means by which they may be achieved;
- (iii) the time within which they may be achieved.

The EMP shall be reviewed annually and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER) (Condition 11.8).

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.

2.2.3 Documentation

- (i) The licensee shall **establish and maintain** an environmental management documentation system which shall be to the satisfaction of the Agency.
- (ii) The licensee shall issue a copy of this licence to all relevant personnel whose duties relate to any condition of this licence.

2.2.4 Corrective Action

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

2.2.5 Awareness and Training

The licensee shall **establish and maintain** procedures for identifying training needs, and for providing appropriate training, for all personnel whose work can have a significant effect upon the environment. Appropriate records of training shall be maintained.

2.2.6 Communications Programme

The licensee shall **establish and maintain** 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.

2.2.7 Maintenance Programme

The licensee shall **establish and maintain** 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).

2.2.8 Efficient Process Control

The licensee shall **establish and maintain** 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 **establish and maintain** all infrastructure referred to in this licence in advance of the commencement of the licensed activities or as required by the conditions of this licence. Infrastructure specified in the application which 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.

3.2 Installation Notice Board

3.2.1 The licensee shall, within four months of the date of grant of this licence, provide and maintain 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.

3.2.2 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.

3.3 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.

3.4 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.

3.5 Tank, Container and Drum Storage Areas

- 3.5.1 All tank, container and drum storage areas shall be rendered impervious to the materials stored therein. Bunds should be designed having regard to Agency guidelines 'Storage and Transfer of Materials for Scheduled Activities' (2004).
- 3.5.2 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 which could be stored within the bunded area.
- 3.5.3 All drainage from bunded areas shall be treated as hazardous waste unless it can be demonstrated to be otherwise. All drainage from bunded areas shall be diverted for collection and safe disposal.
- 3.5.4 All inlets, outlets, vent pipes, valves and gauges must be within the bunded area.
- 3.5.5 All tanks, containers and drums shall be labelled to clearly indicate their contents.
- 3.6 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.
- 3.7 Fire-Water Retention
- 3.7.1 The licensee shall carry out a risk assessment to determine if the activity should have a fire-water retention facility. The licensee shall submit the assessment and a report to the Agency on the findings and recommendations of the assessment within six months from the date of grant of this licence.
- 3.7.2 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 agreement of the Agency, a suitable risk management programme. The risk management programme shall be fully implemented within three months from date of notification by the Agency.
- 3.7.3 The licensee shall have regard to the Environmental Protection Agency Draft Guidance Note to Industry on the Requirements for Fire-Water Retention Facilities when implementing Conditions 3.7.1 and 3.7.2 above.
- 3.8 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 objectives and targets set out in Condition 2.2 of this licence for the reduction in fugitive emissions.
- 3.9 The licensee shall, within three months of the date of grant of this licence, 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.

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

Condition 4. Interpretation

4.1 Noise

Noise from the installation shall not give rise to sound pressure levels (Leq, T) measured at **the boundary** of the installation which exceed the limit value(s).

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

Condition 5. Emissions

- 5.1 No specified emission from the installation shall exceed the emission limit values set out in *Schedule B: Emission Limits* of this licence. There shall be no other emissions of environmental significance.
- 5.2 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.
- 5.3 The licensee shall not discharge any washings or process wastes to Water Services Authority sewer or surface water.

Reason: To provide for the protection of the environment by way of control and limitation of emissions.

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 of this licence:
 - 6.1.1 Analysis shall be undertaken by competent staff in accordance with documented operating procedures;
 - 6.1.2 Such procedures shall be assessed for their suitability for the test matrix and performance characteristics determined;
 - 6.1.3 Such procedures shall be subject to a programme of Analytical Quality Control using control standards with evaluation of test responses;
 - 6.1.4 Where analysis is sub-contracted it shall be 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 measurement methods to calibrate automated measurement systems,

shall be carried out in accordance with CEN-standards. If CEN standards are not available, ISO, national or international standards which will ensure the provision of data of an equivalent scientific quality shall apply.
- 6.4 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 agreed 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. Agreement for the use of alternative equipment, other than in emergency situations, shall be obtained from the Agency.
- 6.5 Monitoring and analysis equipment shall be operated and maintained as necessary so that monitoring accurately reflects the emission/discharge or ambient conditions.

- 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 with the agreement of 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 underground pipes, tanks, bunding structures and containers and their resistance to penetration by water or other materials carried or stored therein shall be tested and demonstrated by the licensee. This testing shall be carried out by the licensee at least once every three years 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 drainage system, bunds, shall be inspected weekly, desludged as necessary and properly maintained at all times. All sludge and drainage from these operations shall be collected for safe disposal.
- 6.11 An inspection for leaks on all flanges and valves on over-ground pipes used to transport materials other than water shall be carried out weekly
- 6.12 Noise
- The licensee shall carry out a noise survey of the site operations **as required by the Agency**. The survey programme shall be undertaken in accordance with the methodology specified in the 'Environmental Noise Survey Guidance Document' as published by the Agency.
- 6.13 Solvent Emissions
- 6.13.1 The licensee shall report on the use of solvents for each calendar year as part of the AER.
- 6.13.2 The licensee shall prepare a Solvent Management Plan (SMP) for the installation annually. The substances to be included in the SMP shall be determined with reference to the definition of a solvent in Council Directive 1999/13/EC and shall be agreed by the Agency each year. The SMP shall be prepared in accordance with any relevant guidelines in Schedule 6 of the Solvent Regulations or as issued by the Agency and shall be submitted as part of the AER.
- 6.14 Pollutant Release and Transfer Register (PRTR)
- The licensee shall prepare and report a PRTR for the site. The substances and/or waste to be included in the PRTR shall be agreed by the Agency each year by reference to EC Regulation No. 166/2006 concerning the establishment of the European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC. The PRTR shall be prepared in accordance with any relevant guidelines issued by the Agency and shall be submitted electronically in specified format and as part of the AER.
- 6.15 The licensee shall, within six months of the date of grant of this licence, develop and establish a Data Management System for collation, archiving, assessing and graphically presenting the environmental monitoring data generated as a result of this licence.

Reason: To provide for the protection of the environment by way of treatment and monitoring of emissions.

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 grant of this licence. 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 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 the 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 Disposal or recovery of waste on-site shall only take place in accordance with the conditions of this licence and in accordance with the appropriate National and European legislation and protocols.
- 8.2 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.
- 8.3 The licensee shall ensure that waste in advance of transfer to another person 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 shall be stored in designated areas, protected as may be appropriate against spillage and leachate run-off. The waste is to be clearly labelled and appropriately segregated.
- 8.6 No waste classified as green list waste in accordance with the EU Transfrontier Shipment of Waste Regulations (Council Regulation EEC No. 1013/2006, as may be amended) shall be consigned for recovery without the agreement of the Agency.
- 8.7 Waste for disposal/recovery off-site shall be analysed in accordance with *Schedule C: Control & Monitoring* of this licence.
- 8.8 Unless approved in writing 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.

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

Condition 9. Accident Prevention and Emergency Response

- 9.1 The licensee shall, within six months of date of grant of this licence, ensure that a documented Accident Prevention Procedure is in place which will address 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, within six months of date of grant of this licence, ensure that a documented Emergency Response Procedure is in place, which shall address 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 and other relevant authorities.
- 9.3.2 The licensee shall provide a proposal to the Agency for its agreement within one month of the incident occurring or as otherwise agreed by the Agency to:
- (i) identify and put in place measures to avoid reoccurrence of the incident; and
 - (ii) identify and put in place any other appropriate remedial action.

Reason: To provide for the protection of the environment.

Condition 10. Decommissioning and Closure

- 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, subsoils, buildings, plant or equipment, or any waste, materials or substances or other matter contained therein or thereon, that may result in environmental pollution.
- 10.2 Residuals Management Plan

- 10.2.1 The licensee shall prepare, to the satisfaction of the Agency, a fully detailed and costed plan for the decommissioning or closure of the site or part thereof. This plan shall be submitted to the Agency for agreement within six months of the date of grant of this licence.
- 10.2.2 The plan shall be reviewed annually and proposed amendments thereto notified to the Agency for agreement as part of the AER. No amendments may be implemented without the agreement of the Agency.
- 10.2.3 The licensee shall have regard to the Environmental Protection Agency Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provision when implementing Conditions 10.2 and 10.3 above.
- 10.3 The Residuals Management Plan shall include, as a minimum, the following:
 - 10.3.1 A scope statement for the plan.
 - 10.3.2 The criteria that define the successful decommissioning of the activity or part thereof, which ensures minimum impact on the environment.
 - 10.3.3 A programme to achieve the stated criteria.
 - 10.3.4 Where relevant, a test programme to demonstrate the successful implementation of the decommissioning plan.
 - 10.3.5 Details of the costings for the plan and the financial provisions to underwrite those costs.
- 10.4 A final validation report to include a certificate of completion for the residuals management plan, for all or part of the site as necessary, shall be submitted to the Agency within three months of execution of the plan. The licensee shall carry out such tests, investigations or submit certification, as requested by the Agency, to confirm that there is no continuing risk to the environment.

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

Condition 11. Notifications, Records and Reports

- 11.1 The licensee shall notify the Agency by both telephone and facsimile, if available, 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) Any release of environmental significance to atmosphere from any potential emission point including bypasses.
 - (ii) Any emission which does not comply with the requirements of this licence.
 - (iii) Any malfunction or breakdown of key control equipment or monitoring equipment set out in *Schedule C: Control & Monitoring* which is likely to lead to loss of control of the abatement system.
 - (iv) Any incident with the potential for environmental contamination of surface water or groundwater, or posing an environmental threat to air or land, or 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.

- 11.2 In the event of any incident which relates to discharges to sewer having taken place, the licensee shall notify the Local and Water Services Authority as soon as practicable, after such an incident.
- 11.3 In the case of any incident which relates to discharges to water, the licensee shall notify the Local Authority and the North Western Regional Fisheries Board as soon as practicable after such an incident.
- 11.4 The licensee shall make a record of any incident. This record shall include details of the nature, extent, and impact of, and circumstances giving rise to, the incident. The record shall include all corrective actions taken to manage the incident, minimise wastes generated and the effect on the environment, and avoid recurrence. The licensee shall, as soon as practicable following incident notification, submit to the Agency the incident record.
- 11.5 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.
- 11.6 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.
- 11.7 The licensee shall as a minimum keep the following documents at the site:
- (i) the licences relating to the installation;
 - (ii) the current EMS for the installation;
 - (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 licence application or EIS documentation referenced in this licence.
- and this documentation shall be available to the Agency for inspection at all reasonable times.
- 11.8 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.
- 11.9 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 as a minimum contain details of the following:
- (i) The tonnages and EWC 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 wastes consigned abroad for Recovery and classified as 'Green' in accordance with the EU Transfrontier Shipment of Waste Regulations (Council Regulation EEC No. 259/1993, as 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.
- 11.10 **The licensee shall notify the Agency, in accordance with condition 1.4, of any changes in the active pharmaceutical ingredients which they propose to produce. The notification shall identify all emissions associated with the proposed production process, scale of such emissions and impact assessment. Production of new active pharmaceutical ingredients shall not commence until the notification and assessment has been agreed with the Agency.**
- 11.11 The licensee shall submit report(s) as required by the conditions of this licence to the Agency's Headquarters in Wexford, or to such other Agency office as may be specified by the Agency.
- 11.12 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 €4,680, 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 Acts 1992 and 2003. The first payment shall be a pro-rata amount for the period from the date of this licence to the 31st day of December, and shall be paid to the Agency within one month from the date 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 Acts 1992 and 2003, 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 defraying its costs in regard to items not covered by the said annual contribution.

12.2 Environmental Liabilities

- 12.2.1 The licensee shall as part of the AER provide an annual statement as to the measures taken or adopted at the site in relation to the prevention of environmental damage, and the financial provisions in place in relation to the underwriting of costs for remedial actions following anticipated events (including closure) or accidents/incidents, as may be associated with the carrying on of the activity.
- 12.2.2 The licensee shall arrange for the completion, by an independent and appropriately qualified consultant, of a comprehensive and fully costed Environmental Liabilities Risk Assessment (ELRA), which addresses the liabilities from past and present activities. The assessment shall include those liabilities and costs identified in Condition 10 for execution of the RMP. A report on this assessment shall be submitted to the Agency for agreement within twelve months of date of grant of this licence. The ELRA shall be reviewed as necessary to reflect any significant change on site, and in any case every three years following initial agreement: review results are to be notified as part of the AER.
- 12.2.3 As part of the measures identified in Condition 12.2.1, the licensee shall, to the satisfaction of the Agency, make financial provision to cover any liabilities identified in Condition 12.2.2. The amount of indemnity held shall be reviewed and revised as necessary, but at least annually. Proof of renewal or revision of such financial indemnity shall be included in the annual 'statement of measures' report identified in Condition 12.2.1.
- 12.2.4 The licensee shall have regard to the Environmental Protection Agency Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provision when implementing Conditions 12.2.1 and 12.2.2 above.

Reason: To provide for adequate financing for monitoring and financial provisions for measures to protect the environment.

SCHEDULE A: Limitations

There are no limitations on the installation specified in the Schedule.

SCHEDULE B: Emission Limits

There shall be no Emissions to Air of environmental significance.

B.2 Emissions to Water

There shall be no Emissions to Water of environmental significance.

B.3 Emission to Sewer

There shall be no Process Effluent Emissions to Sewer.

B.4 Noise Emissions

Daytime dB(A) L_{Aeq} (30 minutes)	Night-time dB(A) L_{Aeq} (30 minutes)
55 ^{Note 1}	45 ^{Note 1}

Note 1: There shall be no clearly audible tonal component or impulsive component in the noise emission from the activity at the **boundary**.

SCHEDULE C: Control & Monitoring

C.1.1 Control of Emissions to Air

There shall be no emissions to air of environmental significance.



C.1.2 Monitoring of Emissions to Air

There shall be no emissions to air of environmental significance.



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.3.1 Control of Emissions to Sewer

There shall be no process effluent emissions to sewer.



C.3.2 Monitoring of Emissions to Sewer

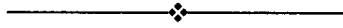
There shall be no process effluent emissions to Sewer.



C.4 Waste Monitoring

Waste Class	Frequency	Parameter	Method
Mixed solvents	Per consignment	To be agreed	Standard Method
Other <small>Note 1</small>			

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

No ambient monitoring is required in this licence.



SCHEDULE D: Annual Environmental Report

Annual Environmental Report Content^{Note 1}

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.
Pollutant Release and Transfer Register – report for previous year.
Pollutant Release and Transfer Register - proposal for current year.
Noise monitoring report summary (as required).
Tank and pipeline testing and inspection 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.
Review of residuals management plan.
Statement of measures in relation to prevention of environmental damage and remedial actions (Environmental Liabilities).
Environmental Liabilities Risk Assessment Review (every three years or more frequently as dictated by relevant on-site change including financial provisions).
Any other items specified by the Agency.

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

Signed on behalf of the said Agency
on the xx day of xxxxxx, 200X

xxxxxxx,

Authorised Person