



Permit with introductory note

The Environmental Permitting (England & Wales) Regulations 2016

Pharmaron UK Limited

Pharmaron UK Hoddesdon Site

Hertford Road

Hoddesdon

Hertfordshire

EN11 9BU

Permit number

EPR/AP3933QP

Pharmaron UK Hoddesdon Site

Permit number EPR/AP3933QP

Introductory note

This introductory note does not form a part of the permit

The main features of the permit are as follows:

This permit application is for a new bespoke pharmaceutical production facility. The Hoddesdon plant is an existing site which has been used for many years for pharmaceutical research, development and related non-commercial production outside of the EPR regulations, but has recently been taken over by Pharmaron, the permit holder, who has recommissioned the site including the Fleming building for the performance of laboratory scale commercial research and development, and the Pharmaron Research Preparative Laboratory (PRPL) for the pilot scale commercial research, development and active pharmaceutical ingredients production. The business provides process chemistry and related services to the global pharmaceutical industry which includes process development and production of active pharmaceutical ingredients (API) under commercial contracts with API products supplied to customers for their own use.

The site is located approximately 1 km north west of Hoddesdon town centre, and occupies an area of approximately 7 ha west of Hertford Road at National Grid Reference TL 36626 09501. The site is surrounded to the east and south by housing, including multi-storey dwellings, with a primary school located directly adjacent to the southern boundary of the installation. There is agricultural land, woodland and a number of residential dwellings to the north of the site. The fields currently to the west of the site are to be developed with new housing and a new school. Woollens Brook flows in a southerly direction adjacent to the western boundary of the site and flows into the New River approximately 1 km southeast of the site. There are two designated sites within 10 km of the installation (Wormley-Hoddesdonpark Woods Special Area of Conservation (SAC) and Lee Valley Special Protection Area (SPA) and Ramsar). Hertford Heath Site of Special Scientific Interest (SSSI), Rye Meads SSSI and Wormley-Hoddesdonpark Woods North SSSI are located within 2 km of the installation. There are also a number of other non-statutory sites (National Nature Reserve, Local Wildlife Site and Ancient Woodland) located within 2 km of the installation.

This permit will allow the operator to perform the following scheduled activities and directly associated activities in order to produce API to a maximum of 1,000 kg/annum under commercial research and development contracts:

- EPR activities:
 - Schedule 1 S4.5 Part A(1) (a) – Producing pharmaceutical products i.e. production of API under a multi-product protocol (MPP) in multi-purpose plants located in the Pharmaron Research Preparative Laboratory (PRPL) facility.
 - Schedule 1 S5.4 Part A(1)(a)(ii) – Disposal of non-hazardous waste with a capacity exceeding 50 tonnes per day involving physico-chemical treatment i.e. balancing and pH adjustment of non-hazardous aqueous waste streams arising within the permitted installation in an on-site effluent treatment plant (ETP) which discharges to sewer under the terms of a Trade Effluent Discharge Consent.
- Directly associated activities (DAA):
 - Commercial research and development activities performed in the Fleming building, including small scale non-industrial production of API.
 - Operation of the following supporting utilities:
 - Pre-treatment of raw materials: water.
 - Storage and use of liquefied gases: liquid nitrogen.
 - PRPL facility heat transfer system.
 - Compressed air system.
 - PRPL vacuum system.
 - Storage of wastes generated within the installation.

- Surface and storm water management.
- Firewater management.
- Emergency power generation.

The PRPL facility multi-product plants includes three large scale synthesis modules, a hydrogenation module, a small scale process chemistry support area and two preparative laboratories. API production involves a wide range of chemical (including biochemical) processing techniques performed in staged batch production with the potential for all plant to be operated at any one time over a maximum of 6,272 hours per year. API production within the PRPL facility is under an MPP which is in keeping with the Environment Agency MPP guidance report reference GEHO0511BTUN-E-E. The MPP defines the range of chemical processing techniques, the range of raw materials, the envelope of assessed emissions and the associated controls and abatement techniques. The envelope of assessed emissions includes emissions from the main scheduled activities and the DAAs. The operational controls include limitations on long and short term usage rates for certain raw materials within the PRPL facility and the Fleming building. Abatement techniques used within the PRPL facility include the general area scrubber, reactor condensers (including cryogenic condensation), aqueous scrubbers and high-efficiency particulate air (HEPA) filtration units.

There are two combustion plants directly associated with the main activity: the two diesel fuelled emergency generators associated with the Fleming and Utilities buildings with net rated thermal inputs of 0.58 MWth and 1.96 MWth respectively. These combustion plants are used for production of electrical power during site emergencies only.

Emissions from the permitted activities include noise, waste, waste water to sewer, uncontaminated site surface water to Woollen's Brook and emissions to air.

Noise emissions principally arise from operation of: compressors associated with the compressed air and refrigeration plants; the PRPL module air extraction fans; the Fleming building fume hood fans; the domestic boiler air/combustion air fans and general site transport. Noise emissions have been assessed and do not present a risk of significant impacts at sensitive receptors.

Wastes arise from the PRPL facility API production activities as well as the other DAA and general site activities. Wastes are segregated and stored on-site, pending collection for off-site recovery/disposal, in defined areas with containment designed to minimise the risk of spills and ingress and impacts on soil, groundwater and surface waters. Non-hazardous aqueous waste streams arising from the PRPL facility and the Fleming buildings are directed by the segregated Trade Effluent system to the on-site ETP for pH adjustment prior to discharge to sewer under a Trade Discharge Consent issued by Thames Water. The permit limits emissions of trade effluent to sewer to an average of 90 m³/day and limits the nature and levels of substances to ensure the discharge does not present a risk of significant impact in surface waters.

Uncontaminated site surface water from rainwater run-off is discharged to Woollen's Brook by way of seven discharge points serving different areas of the site (reference points W1 to W7). There are isolation valves associated with all release points except for the Sigal building (W4), Recycling Centre (W6) and Archive building area (W7). The isolation valves may be manually activated to prevent discharges in the event of an incident. The car park drains are passed through oil interceptors before mixing with other clean surface water and /or discharge. Emissions of uncontaminated site surface waters to Woollens Brook do not present a risk of significant impacts. The permit requires the operator to monitor all emission points to surface water for visible hydrocarbon oil and grease on a daily basis and to improve arrangements for the management of surface waters arising from the Archive building area and the PRPL solvent storage compound to minimise the risk of contaminated surface waters entering Woollens Brook during abnormal operating conditions.

Emissions to air arise from point sources associated with the operations within the PRPL facility; the Fleming building; and, from testing and emergency use of the two diesel fuelled emergency generators. There are no significant fugitive emissions sources. Potential emissions to air consist of a wide range of volatile organic compounds (VOCs), inorganic reagents and particulate matter used in the API research, development and production activities and combustion gas emissions from the emergency generators. Emissions to air from the main PRPL process stack (A1) are subject to continuous emissions monitoring (CEMS) for total carbon. The permit includes a pre-operational condition requiring the operator to demonstrate that the CEMS meets MCERTS standard. The potential for emissions to air from the PRPL facility and Fleming building activities are prevented, controlled or minimised to levels which have been assessed as insignificant for ecological

receptors and as presenting no significant risk to human health receptors in accordance with the MPP for the installation.

The installation is not a solvent emission activity under Schedule 14 of EPR 2016 as the maximum projected total use of solvents does not exceed the solvent consumption threshold of 50 tonnes/year for manufacturing of pharmaceutical products. The operator has committed to managing solvents to minimise emissions of VOCs in accordance with BAT for the manufacturing of pharmaceutical products and has specifically committed to compliance with the waste gas emission limit value of 20 mgC/m³ as set out in Annex VII of the IED.

The operator has an Environmental Management System which is designed to meet the requirements of ISO 14001:2015.

The status log of the permit sets out the permitting history, including any changes to the permit reference number.

Status log of the permit		
Description	Date	Comments
Application EPR/AP3933QP/A001	Duly made 04/06/18	Application to produce active pharmaceutical ingredients (API) under commercial research and development contracts with production in multi-purpose plants under the terms of a multi-product protocol (MPP).
Additional information received	18/10/18	Email summary of response to the Schedule 5 Notice issued 24/09/18 including associated documents.
Additional information received	01/11/18	Email summary of response to the Schedule 5 Notice issued 02/10/18 including associated documents.
Additional information received	05/03/19	Operator's email responses to the Schedule 5 notice issued 03/12/18 confirming intention to undertake baseline and subsequent ongoing monitoring of the condition of soil and groundwater beneath the installation and surface waters (Woollens Brook) including associated documents.
Additional information received	22/03/19	Email summary of responses to the Schedule 5 Notice issued 03/12/18 including associated documents.
Additional information received	17/04/19	Email summary of response to the Schedule 5 Notice issued 02/10/18 including associated documents.
Additional information received	17/04/19	Email summary of response to the Schedule 5 Notice issued 03/12/18 including associated documents.
Additional information received	17/04/19	Email summary of responses to the Schedule 5 Notice issued 19/12/18 including associated document.
Additional information received	30/04/19	Email summary of the air dispersion modelling files required in response to the Schedule 5 Notice issued 19/12/18 and the air dispersion modelling data files.
Additional information received	26/06/19	Email summary of responses to the Schedule 5 Notice issued 13/06/19 including associated documents.
Additional information received	08/07/19	Response to the Schedule 5 Notice issued 13/06/19 including associated documents – Application Site Condition Report (SCR) and Environmental Risk Assessment (ERA) V2.
Additional information received	26/07/19	Multi-product protocol (MPP)

Status log of the permit		
Description	Date	Comments
Permit determined EPR/AP3933QP (Billing ref. AP3933QP)	20/08/19	Permit issued to Pharmaron UK Limited.

End of introductory note

Permit

The Environmental Permitting (England and Wales) Regulations 2016

Permit number

EPR/AP3933QP

The Environment Agency hereby authorises, under regulation 13 of the Environmental Permitting (England and Wales) Regulations 2016

Pharmaron UK Limited (“the operator”),

whose registered office is

The Old Glassworks

Nettlefold Road

Cardiff

CF24 5JQ

company registration number 08755111

to operate an installation at

Pharmaron UK Hoddesdon Site

Hertford Road

Hoddesdon

Hertfordshire

EN11 9BU

to the extent authorised by and subject to the conditions of this permit.

Name	Date
Eleanor Blackeby	20/08/2019

Authorised on behalf of the Environment Agency

Conditions

1 Management

1.1 General management

- 1.1.1 The operator shall manage and operate the activities:
- (a) in accordance with a written management system that identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents, non-conformances, closure and those drawn to the attention of the operator as a result of complaints; and
 - (b) using sufficient competent persons and resources.
- 1.1.2 Records demonstrating compliance with condition 1.1.1 shall be maintained.
- 1.1.3 Any person having duties that are or may be affected by the matters set out in this permit shall have convenient access to a copy of it kept at or near the place where those duties are carried out.

1.2 Energy efficiency

- 1.2.1 The operator shall:
- (a) take appropriate measures to ensure that energy is used efficiently in the activities;
 - (b) review and record at least every four years whether there are suitable opportunities to improve the energy efficiency of the activities; and
 - (c) take any further appropriate measures identified by a review.

1.3 Efficient use of raw materials

- 1.3.1 The operator shall:
- (a) take appropriate measures to ensure that raw materials and water are used efficiently in the activities;
 - (b) maintain records of raw materials and water used in the activities;
 - (c) review and record at least every four years whether there are suitable alternative materials that could reduce environmental impact or opportunities to improve the efficiency of raw material and water use; and
 - (d) take any further appropriate measures identified by a review.

1.4 Avoidance, recovery and disposal of wastes produced by the activities

- 1.4.1 The operator shall take appropriate measures to ensure that:
- (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and
 - (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
 - (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.
- 1.4.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

1.5 Multi product protocol

1.5.1 Where the operator proposes to make a change under a multi-product protocol that is not otherwise the subject of an application for approval under the Regulations or this permit:

- (a) the Environment Agency shall be notified of the proposed change;
- (b) the notification shall contain a description of the change including: an assessment of its environmental impact; any relevant supporting assessments and drawings; and the proposed implementation date;
- (c) the change shall not be implemented unless approved in writing by the Environment Agency;
- (d) as from any approved implementation date, the operator shall operate in accordance with the changed multi product protocol in place of the previously approved version.

2 Operations

2.1 Permitted activities

2.1.1 The operator is only authorised to carry out the activities specified in schedule 1 table S1.1 (the “activities”).

2.2 The site

2.2.1 The activities shall not extend beyond the site, being the land shown edged in green on the site plan at schedule 7 to this permit.

2.3 Operating techniques

2.3.1 The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1, table S1.2, unless otherwise agreed in writing by the Environment Agency.

2.3.2 If notified by the Environment Agency that the activities are giving rise to pollution, the operator shall submit to the Environment Agency for approval within the period specified, a revision of any plan or other documentation (“plan”) specified in schedule 1, table S1.2 or otherwise required under this permit which identifies and minimises the risks of pollution relevant to that plan, and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by the Environment Agency.

2.3.3 Any raw materials or fuels listed in schedule 2 table S2.1 shall conform to the specifications set out in that table.

2.3.4 The operator shall ensure that where waste produced by the activities is sent to a relevant waste operation, that operation is provided with the following information, prior to the receipt of the waste:

- (a) the nature of the process producing the waste;
- (b) the composition of the waste;
- (c) the handling requirements of the waste;
- (d) the hazardous property associated with the waste, if applicable; and
- (e) the waste code of the waste.

2.3.5 The operator shall ensure that where waste produced by the activities is sent to a landfill site, it meets the waste acceptance criteria for that landfill.

2.4 Improvement programme

- 2.4.1 The operator shall complete the improvements specified in schedule 1 table S1.3 by the date specified in that table unless otherwise agreed in writing by the Environment Agency.
- 2.4.2 Except in the case of an improvement which consists only of a submission to the Environment Agency, the operator shall notify the Environment Agency within 14 days of completion of each improvement.

2.5 Pre-operational conditions

- 2.5.1 The activities shall not be brought into operation until the measures specified in schedule 1 table S1.4 have been completed.

3 Emissions and monitoring

3.1 Emissions to water, air or land

- 3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 3 tables S3.1, S3.2 and S3.3.
- 3.1.2 The limits given in schedule 3 shall not be exceeded.
- 3.1.3 Periodic monitoring shall be carried out at least once every 5 years for groundwater and 10 years for soil, unless such monitoring is based on a systematic appraisal of the risk of contamination.

3.2 Emissions of substances not controlled by emission limits

- 3.2.1 Emissions of substances not controlled by emission limits (excluding odour) shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures, including, but not limited to, those specified in any approved emissions management plan, have been taken to prevent or where that is not practicable, to minimise, those emissions.
- 3.2.2 All liquids in containers, whose emission to water or land could cause pollution, shall be provided with secondary containment, unless the operator has used other appropriate measures to prevent or where that is not practicable, to minimise, leakage and spillage from the primary container.

3.3 Odour

- 3.3.1 Emissions from the activities shall be free from odour at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved odour management plan, to prevent or where that is not practicable to minimise the odour.
- 3.3.2 The operator shall:
 - (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to odour, submit to the Environment Agency for approval within the period specified, an odour management plan which identifies and minimises the risks of pollution from odour;
 - (b) implement the approved odour management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.4 Noise and vibration

- 3.4.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved noise and vibration management plan to prevent or where that is not practicable to minimise the noise and vibration.
- 3.4.2 The operator shall:
- (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to noise and vibration, submit to the Environment Agency for approval within the period specified, a noise and vibration management plan which identifies and minimises the risks of pollution from noise and vibration;
 - (b) implement the approved noise and vibration management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.5 Monitoring

- 3.5.1 The operator shall, unless otherwise agreed in writing by the Environment Agency, undertake the monitoring specified in the following tables in schedule 3 to this permit:
- (a) point source emissions specified in tables S3.1, S3.2 and S3.3.
 - (b) process monitoring specified in table S3.4.
- 3.5.2 The operator shall maintain records of all monitoring required by this permit including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.
- 3.5.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme and the environmental or other monitoring specified in condition 3.5.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate), where available, unless otherwise agreed in writing by the Environment Agency.
- 3.5.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 3 tables S3.1, S3.2, S3.3 and S3.4 unless otherwise agreed in writing by the Environment Agency.

4 Information

4.1 Records

- 4.1.1 All records required to be made by this permit shall:
- (a) be legible;
 - (b) be made as soon as reasonably practicable;
 - (c) if amended, be amended in such a way that the original and any subsequent amendments remain legible, or are capable of retrieval; and
 - (d) be retained, unless otherwise agreed in writing by the Environment Agency, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:
 - (i) off-site environmental effects; and
 - (ii) matters which affect the condition of the land and groundwater.

4.1.2 The operator shall keep on site all records, plans and the management system required to be maintained by this permit, unless otherwise agreed in writing by the Environment Agency.

4.2 Reporting

4.2.1 The operator shall send all reports and notifications required by the permit to the Environment Agency using the contact details supplied in writing by the Environment Agency.

4.2.2 A report or reports on the performance of the activities over the previous year shall be submitted to the Environment Agency by 31 January (or other date agreed in writing by the Environment Agency) each year. The report(s) shall include as a minimum:

- (a) a review of the results of the monitoring and assessment carried out in accordance with the permit including an interpretive review of that data;
- (b) the annual production /treatment data set out in schedule 4 table S4.2; and
- (c) the performance parameters set out in schedule 4 table S4.3 using the forms specified in table S4.4 of that schedule.

4.2.3 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Environment Agency, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:

- (a) in respect of the parameters and emission points specified in schedule 4 table S4.1;
- (b) for the reporting periods specified in schedule 4 table S4.1 and using the forms specified in schedule 4 table S4.4; and
- (c) giving the information from such results and assessments as may be required by the forms specified in those tables.

4.2.4 The operator shall, unless notice under this condition has been served within the preceding four years, submit to the Environment Agency, within six months of receipt of a written notice, a report assessing whether there are other appropriate measures that could be taken to prevent, or where that is not practicable, to minimise pollution.

4.3 Notifications

4.3.1 In the event:

- (a) that the operation of the activities gives rise to an incident or accident which significantly affects or may significantly affect the environment, the operator must immediately—
 - (i) inform the Environment Agency,
 - (ii) take the measures necessary to limit the environmental consequences of such an incident or accident, and
 - (iii) take the measures necessary to prevent further possible incidents or accidents;
- (b) of a breach of any permit condition the operator must immediately—
 - (i) inform the Environment Agency, and
 - (ii) take the measures necessary to ensure that compliance is restored within the shortest possible time;
- (c) of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment, the operator must immediately suspend the operation of the activities or the relevant part of it until compliance with the permit conditions has been restored.

- 4.3.2 Any information provided under condition 4.3.1 shall be confirmed by sending the information listed in schedule 5 to this permit within the time period specified in that schedule.
- 4.3.3 Where the Environment Agency has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform the Environment Agency when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to the Environment Agency at least 14 days before the date the monitoring is to be undertaken.
- 4.3.4 The Environment Agency shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:
- Where the operator is a registered company:
- (a) any change in the operator's trading name, registered name or registered office address; and
 - (b) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.
- Where the operator is a corporate body other than a registered company:
- (a) any change in the operator's name or address; and
 - (b) any steps taken with a view to the dissolution of the operator.
- 4.3.5 Where the operator proposes to make a change in the nature or functioning, or an extension of the activities, which may have consequences for the environment and the change is not otherwise the subject of an application for approval under the Regulations or this permit:
- (a) the Environment Agency shall be notified at least 14 days before making the change; and
 - (b) the notification shall contain a description of the proposed change in operation.
- 4.3.6 The Environment Agency shall be given at least 14 days notice before implementation of any part of the site closure plan.

4.4 Interpretation

- 4.4.1 In this permit the expressions listed in schedule 6 shall have the meaning given in that schedule.
- 4.4.2 In this permit references to reports and notifications mean written reports and notifications, except where reference is made to notification being made "immediately", in which case it may be provided by telephone.

Schedule 1 – Operations

Table S1.1 activities			
Activity reference	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity	Limits of specified activity
AR1	S4.5 A1 (a)	Producing pharmaceutical products	<p>Producing pharmaceutical products by chemical processing in multi-purpose plants located in the PRPL facility to the terms of a MPP to produce API under commercial research and development contracts.</p> <p>From receipt and preparation (including milling) of raw materials to production of API using chemical (including biochemical) processing, to packaging, chemical testing and quality control of produced API and storage and despatch of API from the PRPL facility.</p> <p>API production maximum capacity 1,000 kg/annum. Maximum operating duration for the facility: 6,272 hour per annum.</p> <p>Storage, pending off-site recovery and/or disposal of untreated waste materials generated during API production within the PRPL facility. Storage of waste waters, pending off-site recovery and/or disposal or release to sewer by way of the on-site ETP.</p>
AR2	S5.4 A1 (a) (ii)	Disposal of non-hazardous waste with a capacity exceeding 50 tonnes per day involving physico-chemical treatment	<p>Neutralisation in an on-site ETP of non-hazardous aqueous waste streams arising within the permitted installation.</p> <p>From receipt of raw materials and storage pending use in the ETP to discharge of treated waste water to foul sewer under the terms of a Consent to the Discharge of Trade Effluent issued by Thames Water.</p>
Directly Associated Activity			
AR3	Commercial research and development activities.	Commercial research and development activities supporting production of API in the PRPL facility or associated with small scale non-industrial production of API within the Fleming building.	From receipt and preparation of raw materials to storage, pending off-site recovery and/or disposal of untreated waste materials.
AR4	Pre-treatment of raw materials: water.	Treatment of mains water and stored mains water (plant water) within the Utilities and	From receipt and storage of mains water to storage, pending off-site recovery and/or disposal, of untreated waste water generated in the treatment processes. Includes receipt, storage and use of raw materials associated with water treatment.

Table S1.1 activities			
Activity reference	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity	Limits of specified activity
		PRPL facility for use in the PRPL and Fleming buildings.	
AR5	Storage and use of liquefied gas: nitrogen.	Storage and use of liquefied nitrogen, for use as liquid and gaseous nitrogen in the PRPL facility.	From receipt and storage of liquid nitrogen in the liquid nitrogen tank located in the PRPL utilities area to use in the PRPL facility and ultimate emission to atmosphere via the PRPL process stack.
AR6	PRPL facility heat transfer system.	Use of Syltherm XLT as a heat transfer fluid in the PRPL facility.	From receipt and storage pending use, to use of Syltherm XLT as a heat transfer fluid in the PRPL facility.
AR7	Compressed air system.	Compression system for production of pressurised air.	From receipt of raw materials to storage, pending off-site recovery and/or disposal, of untreated waste materials generated within the compressed air and breathing air treatment processes located within the Utilities building and PRPL facility.
AR8	Vacuum system.	Vacuum system for generation of process vacuum in reactor vessels within the PRPL facility.	From receipt of raw materials to storage, pending off-site recovery and/or disposal, of untreated waste materials generated during maintenance of the four electrically powered vacuum pumps associated with the vacuum system located within the PRPL facility.
AR9	Storage of wastes generated within the installation.	Waste storage pending off-site recovery/disposal for wastes arising from the installation activities.	Storage pending off-site recovery and/or disposal of wastes arising from the installation activities other than those associated with API production in the PRPL facility or synthesis in the Fleming building.
AR10	Surface and storm water management.	Collection and storage of site surface water and storm water.	From collection to discharge to Woollens Brook by way of one of seven discharge points.
AR11	Firewater management.	Production, collection and storage of firewater.	From delivery of firewater including by way of the diesel fuelled firewater pump to collection of firewater arising from deluge in the PRPL building and associated Solvent Store to storage in three glass reinforced plastic (GRP) underground firewater retention tanks (located adjacent to the surface water compound) pending collection for off-site disposal or discharge of clean firewater to Woollens Brook via discharge point W1.
AR12	Emergency power generation.	Power generation using up to two diesel fired back-up generators during on-site	Operation of up to two diesel fired back-by generators (with net rated thermal inputs of approximately 1.96 MWth and 0.58 MWth respectively) for supply of electricity to meet on-site demands during emergencies only.

Table S1.1 activities			
Activity reference	Activity listed in Schedule 1 of the EP Regulations	Description of specified activity	Limits of specified activity
		emergencies only.	

Table S1.2 Operating techniques		
Description	Parts	Date Received
Application EPR/AP3933QP/A001	The response to section 3a – technical standards, Part B3 of the application form referencing sector guidance EPR 4.02 for the speciality organic chemicals sector.	Duly Made 04/06/18
Response to Schedule 5 Notice dated 24/09/18	Operating techniques described in the responses to the Notice: Response 6 (SPT-HOD-0125 EHS Complaints Procedure). Responses 5 and 15 (SPT-HOD-0103 Emergency response and Business Continuity Plan and Business Continuity Assessment Hoddesdon v2). Responses 5, 7 and 15 techniques to prevent and manage spills - SPT-HOD-0041 PRPL Spill Containment and SPT-HOD-0023 Process Chemistry and Analytical Chemistry Hygiene Plan). Response 14 (Management of risk EHS-HOD-003 PRPL Heat Transfer System Risk Assessment).	18/10/18
Response to Schedule 5 Notice dated 03/12/18	Operating techniques described in the responses to the Notice: Response 1 (confirmation to undertake ongoing site condition monitoring). Response 16 (arrangements for continuous emissions monitoring (CEMs) - EHS-HOD-004 M1 Assessment for the Hoddesdon Site). Response 19 (management of activities to minimise emissions and impacts – sections 4-10 of EHS-HOD-001 Hoddesdon Best Available Techniques and sections 2 and 3 of EHS-HOD-010 Hoddesdon Site and Facility Description).	05/03/19
Response to Schedule 5 Notice dated 03/12/18	Operating techniques described in the responses to the Notice: Responses 5, 9 and 10 (management of bunds, sumps and drainage systems - SPT-HOD-0129 V2.0).	17/04/19
Response to Schedule 5 Notice dated 19/12/18	Operating techniques described in the response to the Notice: Response 2 (management of emissions to air for operation within the scope of assessed emissions for the multi-product protocol - sections 5-15, 17, 23, 26-28 and Tables 87-90 of section 40 of the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5).	17/04/19
Response to Schedule 5 Notice dated 13/06/19	Operating techniques described in the responses to the Notice:	26/06/19

Table S1.2 Operating techniques		
Description	Parts	Date Received
	Response 2 (management of emissions to surface waters - EHS-HOD-007 Surface Water Pollution Risk Assessment V2). Responses 4 and 7 (prevention and management of spills - SPT-HOD-0127 Hoddesdon Site Spill Procedure V2 and SPT-HOD-0130 Refuelling of the Site Generators and Bowser V2).	
Response to Schedule 5 Notice dated 13/06/19	Operating techniques described in the response to the Notice: Response 2 (techniques to prevent pollution of soil, groundwater and surface water - sections 4 and 7 of the Application Site Condition Report).	08/07/19
Additional information	Environmental permit application multi-product protocol (MPP).	26/07/19
Additional information	Multi-product protocol MPP Notification document.	Updated and approved as required by pre-operational condition 1.

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
IP1	The operator shall submit a report to the Environment Agency. The report shall contain the results of the baseline monitoring proposed in application EPR/AP3933QP/A001 and undertaken in July 2019. The operator shall update their Site Condition Report to reference the baseline assessment results in line with the Environment Agency site condition report H5 guidance.	20/11/19
IP2	The operator shall submit a report to the Environment Agency for technical assessment and approval. The report shall contain a review of the continued suitability of existing hardstanding and concreted areas of the site to provide surfaces which are impermeable to potential pollutants and offer protection of soil, groundwater and surface water from ingress of pollutants in the event of foreseeable accidents or incidents. The review shall be based on the findings of a site survey of the condition of the hardstanding and concreted areas (including bunds, sumps and gulleys) and shall include reference to statements made within the Application Site Condition Report, and associated Environmental Risk Assessment, regarding the impermeable nature of these surfaces. The review shall take into account the standards for BAT described in the sector guidance note EPR 4.02 and/or any other relevant guidance notified to the operator and confirmed in writing by the Environment Agency. The report shall include a review of any improvement options against the relevant BAT and an improvement plan, with timescales for delivery of these improvements. Once approved in writing and from the date stipulated by the Environment Agency, the improvement plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.	20/11/19
IP3	The operator shall provide a written plan to the Environment Agency for technical assessment and approval which describes how the operator's	20/11/19

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
	<p>proposed arrangements for self-monitoring of the discharge to sewer, as required by condition 3.5.1 of the permit, meet the MCERTS standards required by condition 3.5.3 of the permit.</p> <p>Once approved in writing and from the date stipulated by the Environment Agency, the plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.</p>	
IP4	<p>The operator shall submit a report to the Environment Agency for technical assessment and approval.</p> <p>The report shall contain a review of the continued suitability of existing containment arrangements for the Fleming building effluent tank and include assessment of the suitability of:</p> <ul style="list-style-type: none"> • the bund lining material for containment of contaminated waste water; and, • the risks of temporary loss of the bund capacity with respect to the proposed continued use of the catchment tank during periods when the bund is used to store contaminated effluent pending collection for off-site disposal (as described in part 7.3.3 of SPT-HOD-0127 Hoddesdon Site Spill Procedure). <p>The report shall include a review of any improvement options against the relevant BAT and an improvement plan, with timescales for delivery of these improvements.</p> <p>Once approved in writing and from the date stipulated by the Environment Agency, the improvement plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.</p>	20/12/19
IP5	<p>The operator shall submit a written plan to the Environment Agency for technical assessment and approval. The plan shall detail the proposed improvements to the management of surface water and firewater to deliver the recommendations for improvement identified in the Application Site Condition Report and the Sumps, Bunds and Gullies spreadsheet which was submitted with the Application.</p> <p>The improvements identified shall include changes to arrangements for management of:</p> <ul style="list-style-type: none"> • the PRPL external roadway sump; • firewater associated with the Winchester store to improve containment of firewater outside of the building; and, • firewater collected in the firewater retention tanks to facilitate use of the surface water retention pond to provide additional firewater retention capacity. <p>Once approved in writing and from the date stipulated by the Environment Agency, the improvement plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.</p>	20/01/20
IP6	<p>The operator shall submit a report to the Environment Agency for technical assessment and approval.</p> <p>The report shall validate the key assumptions made in developing the envelope of assessed emissions for the MPP. The key assumptions are described in section 4.2.2 of the MPP. The report shall be based on the first three months of monitoring data and other observations collated during production of API in the PRPL facility. If appropriate, the report should include an improvement plan, with timescales for deliveries of these improvements.</p>	20/01/20

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
	Once approved in writing and from the date stipulated by the Environment Agency, the improvement plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.	
IP7	The operator shall review and update the Environmental Management System for the Hoddesdon installation to meet the requirements of the EPR permit conditions with respect to the standards for Best Available Techniques (BAT) described in the sector guidance note EPR 4.02 and/or any other relevant guidance notified to the operator and confirmed in writing by the Environment Agency. As a minimum, the Environmental Management System must be updated to include a system for ongoing monitoring and recording of the condition of surface water, ground water and soil and maintenance of an operational Site Condition Report.	20/02/20
IP8	<p>The operator shall submit a written plan to the Environment Agency for technical assessment and approval. The plan shall detail the proposed changes to manage the impacts on site operations of the incoming ban on the use of HFC gases with global warming potential (GWP) greater than 2,500 to refill existing refrigeration systems. The ban being imposed from 01/01/20 under Article 13 of Regulation EU/517/2014 of the European Parliament and Council (the second F-gas Regulation) as outlined in our online guidance available on https://www.gov.uk/guidance/f-gas-in-refrigeration-air-conditioning-and-fire-protection-systems (web link correct as of 20/08/19).</p> <p>The plan shall take into consideration the feasibility of continued reliance on the HFC refrigerant R125 (pentafluoroethane) used in the existing Syltherm XLT refrigeration system and any implications with respect to the effectiveness of the refrigeration system in maintaining the Syltherm XLT heat transfer fluid within the bulk storage tank TA1631 at -25°C.</p> <p>Once approved in writing and from the date stipulated by the Environment Agency, the plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.</p>	01/10/19
IP9	<p>The operator shall submit a written plan to the Environment Agency for technical assessment and approval. The plan shall detail and justify any changes to the monitoring locations for the discharges to surface water referenced W6 and W7 identified in table S3.2 of the permit.</p> <p>Once approved in writing and from the date stipulated by the Environment Agency, the plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.</p>	20/11/19

Table S1.4 Pre-operational measures	
Reference	Pre-operational measures
1	<p>At least two weeks before commencing production of API for commercial purposes within the multi-purpose plants, the operator shall provide in writing, the format and content of the notification documentation required by condition 1.5.1 and the MPP, and obtain the Environment Agency's written approval to it. The notification documentation must be in accordance with the Environment Agency MPP guidance report reference GEHO0511BTUN-E-E.</p> <p>Once approved in writing and from the date stipulated by the Environment Agency, the agreed notification documentation format and content shall be used in accordance with the MPP, subject to such amendments or additions as notified by the Environment Agency.</p>
2	<p>At least two weeks before commencing production of API for commercial purposes within the multi-purpose plants, the operator shall submit checklists and/or procedures for review and approval by the Environment Agency. The checklists and/or procedures shall formalise and record the inspections of containment arrangements as recommended in the Application Site Condition Report. The checklists and /or procedures must be referenced within a revised version of the document SPT-HOD-0129 Management of bunds, sumps and drainage systems at the Hoddesdon site and must include formalisation of regular inspections of:</p> <ul style="list-style-type: none"> • containment within process and materials /waste storage areas including the PRPL facility solvent store sump; • ground surfaces beneath overground pipework; • the bowser; and • roadways and pavement. <p>Once approved in writing by the Environment Agency, the revised procedure SPT-HOD-0129 and associated checklists /procedures relating to formalisation of the inspection of containment arrangements shall be adopted, subject to such amendments or additions as notified by the Environment Agency.</p>
3	<p>At least two weeks before commencing production of API for commercial purposes within the multi-purpose plants, the operator shall submit a procedure for review and approval by the Environment Agency. The procedure shall formalise the arrangements for chemical analysis, or other suitable assessment, of surface waters collected in the following sumps prior to release to surface waters:</p> <ul style="list-style-type: none"> • PRPL solvent store sump • PRPL external roadway sump • PRPL scrubber compound bund • Recycling Centre sump <p>Once approved in writing by the Environment Agency, the approved procedure shall be adopted, subject to such amendments or additions as notified by the Environment Agency.</p>
4	<p>At least two weeks before commencing production of API for commercial purposes within the multi-purpose plants, the operator shall submit a revised procedure for review and approval by the Environment Agency. The procedure shall be a revised version of the following procedure: SPT-HOD-0127 Hoddesdon Site Spill Procedure which incorporates arrangements for notifying the Environment Agency of accidents or incidents relating to spills as required by conditions 4.3.1 and 4.3.2 of the permit.</p> <p>Once approved in writing by the Environment Agency, the approved procedure shall be adopted, subject to such amendments or additions as notified by the Environment Agency.</p>
5	<p>At least two weeks before commencing production of API for commercial purposes within the multi-purpose plants, the operator shall confirm in writing with the Environment Agency that raw materials and wastes stored in the areas of the Winchester Store and Highly Toxic Hazardous Material Store have additional suitable</p>

Table S1.4 Pre-operational measures	
Reference	Pre-operational measures
	temporary containment provided to prevent spills to the bunds and contained hardstanding within these areas pending completion of IP2.
6	At least two weeks before commencing production of API for commercial purposes within the multi-purpose plants, the operator shall provide a written report to the Environment Agency which summarises the arrangements required by condition 3.5.1 of the permit for self-monitoring of total VOC emissions to air from the PRPL facility process stack (reference A1) and confirming that the arrangements meet the MCERTS standards required by condition 3.5.3 of the permit.
7	<p>At least eight weeks before re-instating the Effluent Treatment Plant (ETP) neutralisation facility, the operator shall submit a report to the Environment Agency for review and approval.</p> <p>The report shall include a review of the continued suitability of the tanks and other infrastructure, including containment arrangements, associated with the neutralisation of trade effluent treatment within the on-site ETP. The review shall take into account the standards for BAT described in the sector guidance note EPR 4.02 and /or any other relevant guidance notified to the operator and confirmed in writing by the Environment Agency. The report shall include a review of any improvement options against the relevant BAT and an improvement plan, with timescales for delivery of these improvements.</p> <p>Once approved in writing and from the date stipulated by the Environment Agency, the improvement plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.</p>

Schedule 2 – Waste types, raw materials and fuels

Table S2.1 Raw materials and fuels	
Raw materials and fuel description	Specification
-	-

Schedule 3 – Emissions and monitoring

Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
A1 [Point A1 on site plan in Schedule 7]	PRPL process stack	VOC expressed as carbon	20 mgC/Nm ³	24 hour average of hourly averages	Continuous	FID (high range)
		Acetone	Note 1	Note 2	Note 3	By calculation [Note 4]
		Acetonitrile	Note 1	Note 2	Note 3	By calculation [Note 4]
		1,2-dimethoxyethane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Dichloromethane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Dimethylformamide	Note 1	Note 2	Note 3	By calculation [Note 4]
		Ethanol	Note 1	Note 2	Note 3	By calculation [Note 4]
		Ethyl Acetate	Note 1	Note 2	Note 3	By calculation [Note 4]
		n-Heptane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Hexane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Isopropyl Acetate	Note 1	Note 2	Note 3	By calculation [Note 4]
		Methanol	Note 1	Note 2	Note 3	By calculation [Note 4]
		Methyl Ethyl Ketone	Note 1	Note 2	Note 3	By calculation [Note 4]
		Methyl tertiary butyl ether	Note 1	Note 2	Note 3	By calculation [Note 4]
2-Methyl Tetrahydrofuran	Note 1	Note 2	Note 3	By calculation [Note 4]		

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
		N-methylpyrrolidine	Note 1	Note 2	Note 3	By calculation [Note 4]
		Propan-2-ol	Note 1	Note 2	Note 3	By calculation [Note 4]
		Tetrahydrofuran	Note 1	Note 2	Note 3	By calculation [Note 4]
		Triethylamine	Note 1	Note 2	Note 3	By calculation [Note 4]
		Toluene	Note 1	Note 2	Note 3	By calculation [Note 4]
		Benzene	Note 1	Note 2	Note 3	By calculation [Note 4]
		Acetic anhydride	Note 1	Note 2	Note 3	By calculation [Note 4]
		Acrylic acid	Note 1	Note 2	Note 3	By calculation [Note 4]
		Acrylonitrile	Note 1	Note 2	Note 3	By calculation [Note 4]
		Aniline	Note 1	Note 2	Note 3	By calculation [Note 4]
		Benzyl chloride	Note 1	Note 2	Note 3	By calculation [Note 4]
		Butane	Note 1	Note 2	Note 3	By calculation [Note 4]
		1,2-Dibromoethane	Note 1	Note 2	Note 3	By calculation [Note 4]
		1,2-Dichloroethane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Dimethyl sulphate	Note 1	Note 2	Note 3	By calculation [Note 4]
		1,4-Dioxane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Formaldehyde	Note 1	Note 2	Note 3	By calculation [Note 4]

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
		Styrene	Note 1	Note 2	Note 3	By calculation [Note 4]
		Vinyl acetate	Note 1	Note 2	Note 3	By calculation [Note 4]
		Allyl Alcohol	Note 1	Note 2	Note 3	By calculation [Note 4]
		Ethyl Acrylate	Note 1	Note 2	Note 3	By calculation [Note 4]
		Propan-1-ol	Note 1	Note 2	Note 3	By calculation [Note 4]
		Phosgene	Note 1	Note 2	Note 3	By calculation [Note 4]
		Hydrazine	Note 1	Note 2	Note 3	By calculation [Note 4]
		Ammonia	Note 1	Note 2	Note 3	By calculation [Note 4]
		Hydrochloric acid	Note 1	Note 2	Note 3	By calculation [Note 4]
		Particulate matter	Note 1	Note 2	Note 3	By calculation [Note 4]
		Orthophosphoric acid	Note 1	Note 2	Note 3	By calculation [Note 4]
		Sodium hydroxide	Note 1	Note 2	Note 3	By calculation [Note 4]
		Nitric Acid	Note 1	Note 2	Note 3	By calculation [Note 4]
		Bromine	Note 1	Note 2	Note 3	By calculation [Note 4]
A2 [Point A2 on site plan in Schedule 7]	PRPL synthesis module 1 atmospheric vent header	Acetone	Note 1	Note 2	Note 3	By calculation [Note 4]
		Dichloromethane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Hydrogen	No limit set	--	--	--

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
A3 [Point A3 on site plan in Schedule 7]	PRPL synthesis module 2 atmospheric vent header	Acetone	Note 1	Note 2	Note 3	By calculation [Note 4]
		Dichloromethane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Hydrogen	No limit set	--	--	--
A4 [Point A4 on site plan in Schedule 7]	PRPL synthesis module 3 atmospheric vent header	Acetone	Note 1	Note 2	Note 3	By calculation [Note 4]
		Dichloromethane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Hydrogen	No limit set	--	--	--
A5 [Point A5 on site plan in Schedule 7]	PRPL hydrogenation module reactor vent	Acetone	Note 1	Note 2	Note 3	By calculation [Note 4]
		Dichloromethane	Note 1	Note 2	Note 3	By calculation [Note 4]
		Carbon monoxide	Note 1	Note 2	Note 3	By calculation [Note 4]
A6 [Point A6 on site plan in Schedule 7]	PRPL general area HVAC vent	No parameters set	No limit set	--	--	--
A7 [Point A7 on site plan in Schedule 7]	PRPL general area HVAC vent	No parameters set	No limit set	--	--	--
A8 [Point A8 on site plan in Schedule 7]	PRPL general area HVAC vent	No parameters set	No limit set	--	--	--
A9 [Point A9 on site plan in Schedule 7]	PRPL general area HVAC vent	No parameters set	No limit set	--	--	--
A10 [Point A10 on site plan in Schedule 7]	Fleming building 1 st floor fume hood emission vent 1	No parameters set	No limit set	--	--	--
A11 [Point A11 on site plan in Schedule 7]	Fleming building 1 st floor fume hood emission vent 2	No parameters set	No limit set	--	--	--
A12 [Point A12 on site plan in Schedule 7]	Fleming building 1 st floor fume hood emission vent 3	No parameters set	No limit set	--	--	--

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
A13 [Point A13 on site plan in Schedule 7]	Fleming building 1 st floor fume hood emission vent 4	No parameters set	No limit set	--	--	--
A14 [Point A14 on site plan in Schedule 7]	Fleming building 2 nd and/or 3 rd floor fume hood emission vent 5	No parameters set	No limit set	--	--	--
A15 [Point A15 on site plan in Schedule 7]	Fleming building 2 nd and/or 3 rd floor fume hood emission vent 6	No parameters set	No limit set	--	--	--
Vents from tank TA1631 [PSV 16311 and PSV 16312 as identified in figure HO-B40-ALL-09_16310001rev3 (Syltherm storage and generation)]	Syltherm XLT storage emergency pressure safety vents (PSV)	No parameters set	No limit set	--	--	--

Note 1: The worst case short and long term emission concentrations defined for the envelope of assessed emissions within the MPP. The emission concentrations are those specified for the Maximum Operational Throughput (MOT) scenario in section 23.3 of the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5. The emission concentrations are associated with the maximum daily and annual average usage rates for each parameter set out in section 40 of the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5.

Note 2: As dictated by the MPP.

Note 3: As dictated by the MPP.

Note 4: By calculation based on the methodology set out in the EHS-HOD-002 H1 Environmental Assessment for Hoddesdon V5.

Table S3.2 Point source emissions to water (other than sewer) and land – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
W1 on site plan in schedule 7 emission to Woollens Brook [Note 1]	Surface water collected in the surface water compound arising from building	Oil and grease	None visible	Instantaneous	Daily	Visual inspection

Table S3.2 Point source emissions to water (other than sewer) and land – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
	rainwater drains, roads and hardstanding to the south of the site via oil interceptor.					
W2 on site plan in schedule 7 emission to Woollens Brook	Surface water collected in three storm water collection ponds arising from the Hilleman and Cafeteria building rainwater drains.	Oil and grease	None visible	Instantaneous	Daily	Visual inspection
W3 on site plan in schedule 7 emission to Woollens Brook	Surface water collected in the visitor car park drainage via oil interceptor, road drainage for the north and west of the Fleming building and the Fleming building rainwater drains.	Oil and grease	None visible	Instantaneous	Daily	Visual inspection
W4 on site plan in schedule 7 emission to Woollens Brook	Surface water collected in the Sigal building rainwater drains.	Oil and grease	None visible	Instantaneous	Daily	Visual inspection
W5 on site plan in schedule 7 emission to Woollens Brook	Surface water collected in the multi-storey carpark drains via oil interceptors.	Oil and grease	None visible	Instantaneous	Daily	Visual inspection

Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
W6 on site plan in schedule 7 emission to Woollens Brook [Note 2]	Surface water collected in the Recycling Centre sump via oil interceptor.	Oil and grease	None visible	Instantaneous	Daily	Visual inspection
W7 on site plan in schedule 7 emission to Woollens Brook [Note 2]	Surface waters collected in the Cafeteria roof drains, road drains from south of the Cafeteria building and the ground around the Archive building.	Oil and grease	None visible	Instantaneous	Daily	Visual inspection

Note 1: Monitoring location at the surface water compound.

Note 2: Pending delivery of IP9 a surrogate monitoring location downstream of the emission point may be used.

Emission point ref. & location	Source	Parameter	Limit (incl. Unit)	Reference period	Monitoring frequency	Monitoring standard or method
S1 on site plan in schedule 7 emission to Thames Water Rye Meads Sewage Treatment Works	Site effluent treatment plant	Copper - dissolved	0.10 mg/l	Spot sample [Note 1]	Monthly	BS EN ISO 17294-1 BS EN ISO 11885
S1 on site plan in schedule 7 emission to Thames Water Rye Meads Sewage Treatment Works	Site effluent treatment plant	Zinc - dissolved	1.60 mg/l	Spot sample [Note 1]	Monthly	BS EN ISO 17294-1 BS EN ISO 11885
S1 on site plan in schedule 7 emission to Thames Water Rye Meads Sewage Treatment Works	Site effluent treatment plant	Volume of discharge	90 m ³ per day	Annual average of daily averages	Continuous	MCERTS self-monitoring of effluent flow scheme

Table S3.3 Point source emissions to sewer, effluent treatment plant or other transfers off-site – emission limits and monitoring requirements

Emission point ref. & location	Source	Parameter	Limit (incl. Unit)	Reference period	Monitoring frequency	Monitoring standard or method
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Note 1: Unless otherwise agreed in writing with the Environment Agency.

Table S3.4 Process monitoring requirements

Emission point reference or source or description of point of measurement	Parameter	Monitoring frequency	Monitoring standard or method	Other specifications
General area scrubber liquor	pH	Daily	Not applicable	--
Syltherm XLT heat transfer fluid tank TA1631 outlet	Temperature	Daily	Not applicable	--
PRPL reactor vessel scrubbers	pH	Note 1	Not applicable	--
PRPL reactor vessel condensers	Heat transfer fluid inlet and outlet temperature	Note 1	Not applicable	--
PRPL hydrogenator vent [Point A5 on site plan in Schedule 7]	Frequency of releases and nature of emissions (H ₂ or CO gas)	Note 1	Not applicable	No more than one release per month for hydrogen gas and one release per annum for carbon monoxide gas.
PRPL synthesis modules 1, 2 and 3 atmospheric vent headers [Points A2, A3 and A4 on site plan in Schedule 7]	Frequency of releases	Note 1	Not applicable	No more than an aggregated total of twelve releases per annum for these emission points.

Note 1: As dictated by the MPP.

Schedule 4 – Reporting

Parameters, for which reports shall be made, in accordance with conditions of this permit, are listed below.

Table S4.1 Reporting of monitoring data			
Parameter	Emission or monitoring point/reference	Reporting period	Period begins
Emissions to air Parameters as required by condition 3.5.1.	A1, A2, A3, A4, A5	Every 6 months [Note 1]	1 January, 1 July
Emissions to water Parameters as required by condition 3.5.1	W1, W2, W3, W4, W5, W6, W7	Every 6 months	1 January, 1 July
Emissions to water Parameters as required by condition 3.5.1	S1	Every 6 months	1 January, 1 July,

Note 1: Unless otherwise agreed in writing with the Environment Agency.

Table S4.2 Annual production	
Parameter	Units
Active pharmaceutical ingredients (API), total	kg

Table S4.3 Performance parameters		
Parameter	Frequency of assessment	Units
Water usage	Annually	Tonnes
Energy usage	Annually	MWh
Average and maximum VOC emission levels (expressed as carbon) from PRPL process stack [Point A1 on site plan in Schedule 7]	Monthly [Note 1]	mg/m ³
Solvent usage in accordance with MPP annual and short term limits with split for PRPL and Fleming building usage	Monthly [Note 1]	Tonnes and % maximum, per solvent per facility
Inorganic reagent usage in accordance with MPP annual and short term limits with split for PRPL and Fleming building usage	Monthly [Note 1]	Tonnes and % maximum, per inorganic reagent per facility
Solvent consumption [Note 2]	Annually	Tonnes
Total mass emissions of VOCs (including fugitive and point source waste gas emissions)	Annually	As % of solvent input [Note 3]

Note 1: With monthly reporting for one year and quarterly reporting thereafter subject to written agreement with the Environment Agency.
 Note 2: As defined in Article 57 of the IED.
 Note 3: As defined in Article 57 of the IED.

Table S4.4 Reporting forms		
Media/parameter	Reporting format	Date of form
Air	Form air 1 or other form as agreed in writing by the Environment Agency	20/08/19
Water	Form water 1 or other form as agreed in writing by the Environment Agency	20/08/19
Sewer	Form sewer 1 or other form as agreed in writing by the Environment Agency	20/08/19
Water usage	Form water usage 1 or other form as agreed in writing by the Environment Agency	20/08/19
Energy usage	Form energy 1 or other form as agreed in writing by the Environment Agency	20/08/19
Other performance indicators	Forms performance 1 and 2 or other form as agreed in writing by the Environment Agency	20/08/19

Schedule 5 – Notification

These pages outline the information that the operator must provide.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the EP Regulations.

Part A

Permit Number	
Name of operator	
Location of Facility	
Time and date of the detection	

(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or emission of a substance not controlled by an emission limit which has caused, is causing or may cause significant pollution	
To be notified within 24 hours of detection	
Date and time of the event	
Reference or description of the location of the event	
Description of where any release into the environment took place	
Substances(s) potentially released	
Best estimate of the quantity or rate of release of substances	
Measures taken, or intended to be taken, to stop any emission	
Description of the failure or accident.	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
Measures taken, or intended to be taken, to stop the emission	

Time periods for notification following detection of a breach of a limit	
Parameter	Notification period

(c) Notification requirements for the detection of any significant adverse environmental effect	
To be notified within 24 hours of detection	
Description of where the effect on the environment was detected	
Substances(s) detected	
Concentrations of substances detected	
Date of monitoring/sampling	

Part B – to be submitted as soon as practicable

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment which has been or may be caused by the emission	
The dates of any unauthorised emissions from the facility in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of the operator

Schedule 6 – Interpretation

“accident” means an accident that may result in pollution.

“application” means the application for this permit, together with any additional information supplied by the operator as part of the application and any response to a notice served under Schedule 5 to the EP Regulations.

“authorised officer” means any person authorised by the Environment Agency under section 108(1) of The Environment Act 1995 to exercise, in accordance with the terms of any such authorisation, any power specified in section 108(4) of that Act.

“EP Regulations” means The Environmental Permitting (England and Wales) Regulations SI 2016 No.1154 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

“emissions of substances not controlled by emission limits” means emissions of substances to air, water or land from the activities, either from the emission points specified in schedule 3 or from other localised or diffuse sources, which are not controlled by an emission or background concentration limit.

“groundwater” means all water, which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

“Industrial Emissions Directive” means DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions

“MCERTS” means the Environment Agency’s Monitoring Certification Scheme.

“Medium Combustion Plant” or “MCP” means a combustion plant with a rated thermal input equal to or greater than 1 MW but less than 50 MW.

“Medium Combustion Plant Directive” or “MCPD” means Directive 2015/2193/EU of the European Parliament and of the Council on the limitation of emissions of certain pollutants into the air from medium combustion plants.

“Multi-Product Protocol” (MPP) - means a procedure written by an operator and approved by the Environment Agency, which is referenced in the operational techniques table of this permit. It describes the operators management process which can be used to request changes, within the limits in that document only, to the original permit without the need for a formal permit variation application.

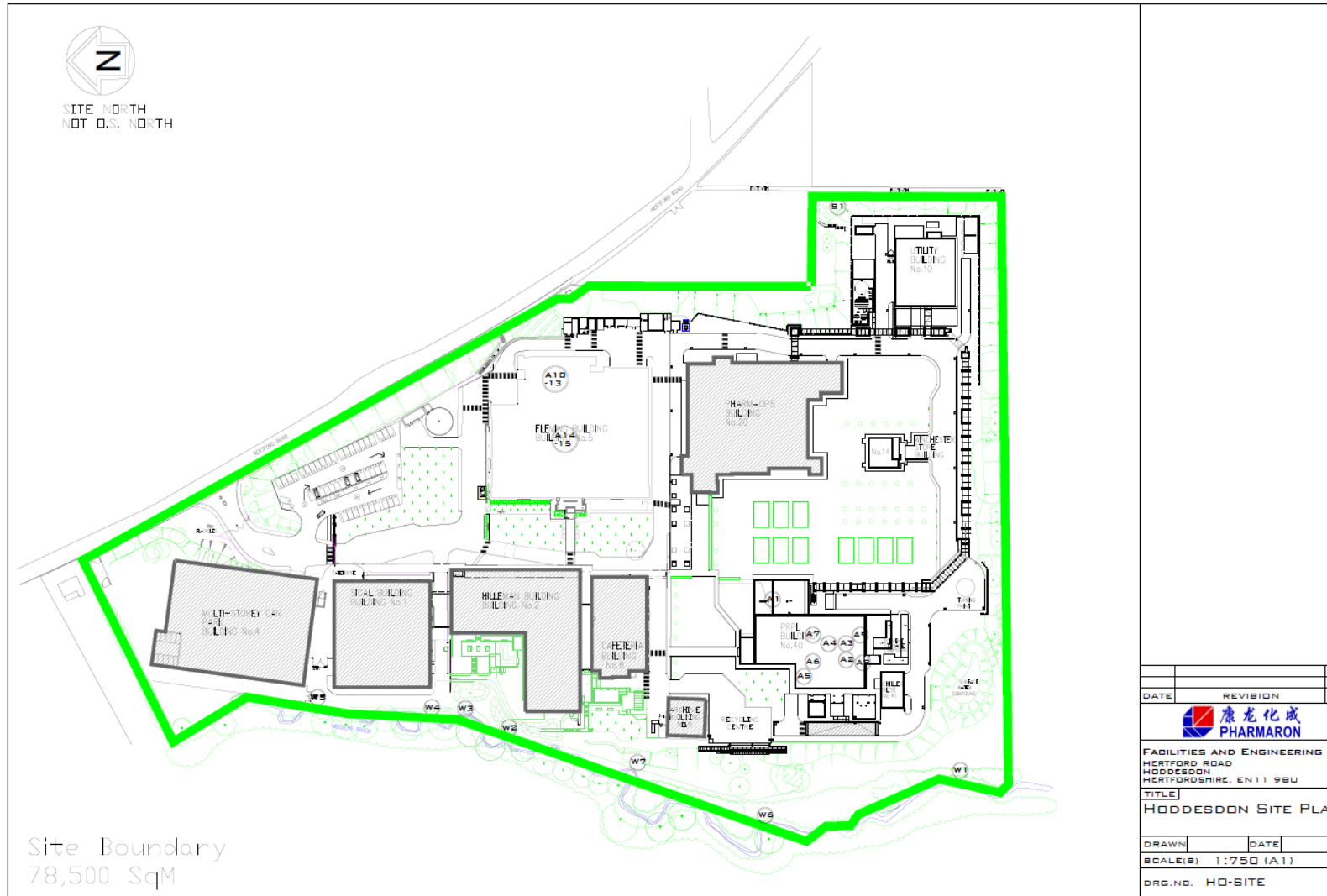
Where a minimum limit is set for any emission parameter, for example pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

Unless otherwise stated, any references in this permit to concentrations of substances in emissions into air means:

- in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or
- in relation to emissions from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content.

“year” means calendar year ending 31 December.

Schedule 7 – Site plan



END OF PERMIT

Permit number
EPR/AP3933QP