

Permit with introductory note

The Environmental Permitting (England & Wales) Regulations 2010

GW Pharma Limited.

Swale Pharmaceuticals
Unit 750 Kent Science Park
Sittingbourne
Kent
ME9 8AG

Permit number

EPR/LP3637VA

Swale Pharmaceuticals

Permit number EPR/LP3637VA

Introductory note

This introductory note does not form a part of the permit

The main features of the permit are as follows.

The installation is located at the southern edge of Kent Science Park, which lies to the south of Broadoak Road 1.5 km to the south east of the village of Tunstall and approximately 3.3 km to the south of Sittingbourne.

The installation consists of a pharmaceutical production process. The relevant scheduled activity under the Environmental Permitting Regulations is as follows:

“ Section 4.5 A(1) (a) Producing pharmaceutical products using a chemical or biological process.”

The main scheduled activity includes pharmaceutical manufacturing process with ethanol raw material storage, usage of Cleaning in Place facilities and Ultra Violet ionisation atmospheric odour abatement.

The directly associated activities are as follows:

- Waste handling and storage
- Use of bulk CO2 and N2
- Compressed air.

The key raw materials to be utilised within the installation are Botanical Raw Material (BRM), ethanol ,liquid carbon dioxide and nitrogen.

There will be six emission points to air, one discharge to sewer and two soakaways linked to the installation.

The operator has submitted plans to minimise environmental impacts from the installation including an Odour Management Plan and Accident Management Plan. The installation emission point A1, the main process emission point, is complete with ionisation technology odour abatement. Two pre-operational conditions and an improvement plan are included to ensure effective commissioning of the odour abatement system and updating of the Odour Management Plan to reflect this commissioning.

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/LP3637VA/A001	Duly made 21/11/14	
Request for information linked to Accident Management Plan	27/02/15	
Request for information linked to Site Condition report additional details	27/02/15	
Schedule 5 dated 17/12/14 received	07/04/15	
Request for information response	22/04/15	Confirmation of installation boundary plan and installation name.
Permit determined EPR/LP3637VA	24/04/15	Permit issued to GW Pharma Limited.

End of introductory note

Permit

The Environmental Permitting (England and Wales) Regulations 2010

Permit number

EPR/LP3637VA

The Environment Agency hereby authorises, under regulation 13 of the Environmental Permitting (England and Wales) Regulations 2010

GW Pharma Limited (“the operator”),

whose registered office is

**GW Pharma Limited
Sovereign House
Vision Park
Histon
Cambridge
CB24 9BZ**

company registration number **3704998**

to operate an installation at

**Swale Pharmaceuticals
Unit 750 Kent Science Park
Sittingbourne
Kent
ME9 8AG**

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

Name	Date
Anne Nightingale	24/04/2015

Authorised on behalf of the Environment Agency

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 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;
- (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.

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.

3.4 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;

- 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 3.3.1 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 and S3.3 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 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.
 - (c) giving the information from such results and assessments as may be required by the forms specified in those tables.
- 4.2.3 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:

- (c) any change in the operator's name or address; and
- (d) any steps taken with a view to the dissolution of the operator.

In any other case:

- (e) the death of any of the named operators (where the operator consists of more than one named individual);
- (f) any change in the operator's name(s) or address(es); and
- (g) any steps taken with a view to the operator, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case of them being in a partnership, dissolving the partnership.

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 “without delay”, in which case it may be provided by telephone.

Schedule 1 – Operations

Table S1.1 activities

Activity listed in Schedule 1 of the EP Regulations	Description of specified activity	Limits of specified activity
Section 4.5 A(1) (a) Pharmaceutical production.	Producing pharmaceutical products using a chemical process	From receipt of raw materials to storage of final product
Directly Associated Activity	Raw Material Bulk Storage	Storage of Bulk liquefied Carbon Dioxide and Nitrogen
Directly Associated Activity	Waste handling and storage	Waste solvent, spent Botanical Material and other waste stream handling and storage prior to site removal
Directly Associated Activity	Provision of compressed air	Generation and supply of compressed air to installation processes and instruments

Table S1.2 Operating techniques

Description	Parts	Date Received
Application EPR/LP3637CVA/A001	Non-Technical Summary, Application Supplementary Report sections 2 to 5 plus duly making responses.	Duly made 21/11/14
Request for information linked to Accident Management Plan	All	27/02/15
Request for information linked to Site Condition report additional details	All	27/02/15
Schedule 5 dated 17/12/14 received	All including Odour Management Plan	07/04/15
Request for information response	All including confirmation of installation boundary plan and installation name.	22/04/15

Table S1.3 Improvement programme requirements

Reference	Requirement	Date
IP1	The Operator shall submit a written report to the Environment Agency on the commissioning of the installation in line with pre-operational condition PO1 commissioning protocol.	1 month after completion of commissioning with raw materials of installation facility.
IP2	<p>The application EPR/LP3637VA/A001 odour management plan specific shall be updated in light of pre-operational condition 1 commissioning report response and in accordance with H4 Odour Management and submitted to the Environment Agency for approval.</p> <p>The plan shall cover a review of relevant odour risk assessment, effectiveness of odour controls, monitoring and contingency action plan in event of abnormal operations</p> <p>The improvement condition will be deemed to have been complied with, on approval in writing by the Environment Agency</p>	3 months after completion of commissioning with raw materials of installation facility

Table S1.4 Pre-operational measures

Reference	Operation	Pre-operational measures
PO1	Commissioning with raw materials of new installation	<p>At least 4 weeks before the start of facility commissioning with raw materials the Operator shall provide a written commissioning plan, including timelines for completion, for approval by the Environment Agency. The commissioning plan shall include the expected emissions to the environment during the different stages of commissioning linked to potential for odour emissions from the installation.</p> <p>The plan is to specify expected duration of commissioning activities and the actions to be taken to protect the environment and report to the Environment Agency in the event that actual emissions exceed expected emissions.</p> <p>The plan shall give particular attention to the schedule of stack monitoring data to provide evidence of effectiveness of odour controls performance to minimise risk of odour pollution beyond installation boundary and include as a minimum data from three separate batch cycles.</p> <p>Commissioning shall be carried out in accordance with the commissioning plan as approved in writing 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

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Parameter	Source	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
A1 as location on plan in schedule 7	Total Volatile Organic Compounds (expressed as carbon)	Process Vents and Dust extraction vents - HVAC1	75 mg/m3	1 hour	6 monthly	BS EN 12619
A1 as location on plan in schedule 7	Ethanol	Process Vents and Dust extraction vents - HVAC1	30 mg/m3	1 hour	6 monthly	BS EN 13649
A2 as location on plan in schedule 7	-	Room Ventilation - HVAC 2	-	-	-	-
A3 as location on plan in schedule 7	-	Room Ventilation - HVAC 3	-	-	-	-
A4 as location on plan in schedule 7	-	Ethanol storage tank vent	-	-	-	-
A5 as location on plan in schedule 7	-	Waste storage	-	-	-	-
A6 as location on plan in schedule 7	Total Volatile Organic Compounds (expressed as carbon)	Process Vents and Dust Extraction from back up pilot plant facility building	75 mg/m3	1 hour	6 monthly	BS EN 12619
A6 as location on plan in schedule 7	Ethanol	Process Vents and Dust Extraction from back up pilot plant facility building	30 mg/m3	1 hour	As agreed in writing by the Environment Agency	BS EN 13649

Table S3.2 Point source emissions to sewer, effluent treatment plant or other transfers off-site – emission limits and monitoring requirements.						
Emission point ref. & location	Parameter	Source	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
S1 as location on application EPR/LP3637VA/A001 plan Figure 4 dated 30/09/14 Discharge to Land and Sewer.	No parameters set	Domestic effluent and process fugitive emissions	-	-	-	-

Table S3.3 Point source emissions to land– emission limits and monitoring requirements						
Emission point ref. & location	Parameter	Source	Limit (incl. Unit)	Reference period	Monitoring frequency	Monitoring standard or method
L1 as location on application EPR/LP3637VA/A001 plan Figure 4 – Discharge to Land and Sewer.	-	Uncontaminated roof water from service yard and access road, chiller compound and tank compound and half of main production building roof.	-	-	-	-
L2 as location on application EPR/LP3637VA/A001 Figure 4 – Discharge to Land and Sewer.	-	Uncontaminated roof from other half of main production building roof.	-	-	-	-

Schedule 4 – Reporting

Table S4.1 Reporting of monitoring data			
Parameter	Emission or monitoring point/reference	Reporting period	Period begins
Atmospheric emissions	A1 and A6	6 monthly	24/04/15

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 – To be notified immediately

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

(a) Notification requirements for any activity that gives rise to an incident or accident which significantly affects or may significantly affect the environment	
To be notified Immediately	
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 permit condition	
To be notified immediately	
Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	
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
In the event 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:	
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.

“*emissions to land*” includes emissions to groundwater.

“*EP Regulations*” means The Environmental Permitting (England and Wales) Regulations SI 2010 No. 675 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.

“*quarter*” means a calendar year quarter commencing on 1 January, 1 April, 1 July or 1 October.

“*recovery*” means any of the operations provided for in Annex II to Directive 2008/98/EC of the European Parliament and of the Council on waste.

“*Waste code*” means the six digit code referable to a type of waste in accordance with the List of Wastes (England) Regulations 2005, or List of Wastes (Wales) Regulations 2005, as appropriate, and in relation to hazardous waste, includes the asterisk.

“*Waste Framework Directive*” or “*WFD*” means Waste Framework Directive 2008/98/EC of the European Parliament and of the Council on waste.

“*year*” means calendar year ending 31 December.

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.

Schedule 7 – Site plan

Site location plan is as follows:



Installation boundary plan is as follows:



Plan with air emission point locations as follows:

FIGURE A - Air Emission Points

Installation Boundary showing air emission points

Figure 2 & 3



PROJECT: Environmental Permit Application
PROJECT No: 62002970
Client: G-Pharm Limited

Drawn: SC
Checked: SC
Approved: SC
Revision: A
Date: July 2014



END OF NOTICE