



**Cyfoeth
Naturiol
Cymru
Natural
Resources
Wales**

Permit with introductory note

The Environmental Permitting (England & Wales) Regulations 2016

Protherics UK Limited

**Pharmaceutical Plant Blaenwaun
Blaenwaun
Ffostrasol
Llandysul
Ceredigion
SA44 5JT**

Permit number

EPR/SP3338LF

Pharmaceutical Plant Blaenwaun

Permit number EPR/SP3338LF

Introductory note

This introductory note does not form a part of the permit

The main features of the permit are as follows.

The operator is an integrated biopharmaceutical company focusing on the manufacture of critical care products, and is licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) to carry out the production of polyclonal antibody products.

The site has a main manufacturing facility and also a suite that is completely segregated from the facility which is currently not in use. The main process stages involved in producing the pharmaceutical products are:

- Step 1 - Pooling of Serum and Isolation of IgG
- Step 2 - Enzymatic Digestion to yield Total Fab
- Step 3 - Ion Exchange Chromatography
- Step 4 - Affinity Purification and low pH hold viral inactivation
- Step 5 – Combination Mono specific Fabs and Viral Filtration
- Step 6 - Diafiltration and final concentration
- Step 7 - Sterile Filtration

Emissions to air arise from two 698 kW Steam Generators used to provide steam for space heating. There are no emissions of process effluent to controlled water or sewer with the exception of unused purified water which is discharged to the River Chwechyr along with surface water run-off.

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 SP3338LF	Duly made 13/04/06	
Additional Information Received	10/11/06	
Permit determined	22/12/06	
Application PAN-001414 (EPR/SP3338LF/V002)	Duly made 28/04/17	Variation application to add water purification plant and add emission to surface water.
Additional information requested	05/07/17	Schedule 5 Notice sent requesting clarification of effluent volume calculations and requesting clarification on risk assssment

Status log of the permit		
Description	Date	Comments
Additional information received	31/07/17	Confirmation of effluent calculations and revised risk assessment.
Additional information received	07/09/17	Revised site plan and confirmation of correct discharge point.
Permit determined	11/09/17	Consolidated Permit issued

End of introductory note

Permit

The Environmental Permitting (England and Wales) Regulations 2016

Permit number
EPR/SP3338LF

This is the consolidated permit referred to in the variation and consolidation notice for EPR/SP3338LF/V002 authorising

Protherics UK Limited ("the operator"),
whose registered office is

**Blaenwaun
Ffostrasol
Llandysul
Ceredigion
SA44 5JT**

company registration number **03464264**

to operate an installation at

**Pharmaceutical Plant Blaenwaun
Blaenwaun
Ffostrasol
Llandysul
Ceredigion
SA44 5JT**

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

Signed

Date

	11/09/2017
---	-------------------

Iwan Hughes

Principal Permitting Officer (Regulated Industry)

Authorised on behalf of Natural Resources Wales

Conditions

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.

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 (a) 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 Natural Resources Wales.
- (b) If notified by Natural Resources Wales that the activities are giving rise to pollution, the operator shall submit to Natural Resources Wales 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 Natural Resources Wales.
- 2.3.2 Any raw materials or fuels listed in schedule 2 table S2.1 shall conform to the specifications set out in that table.
- 2.3.3 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.
- 2.3.4 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.

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 and S3.2.

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 The operator shall:
- (a) if notified by Natural Resources Wales that the activities are giving rise to pollution, submit to Natural Resources Wales for approval within the period specified, an emissions management plan which identifies and minimises the risks of pollution from emissions of substances not controlled by emission limits;
 - (b) implement the approved emissions management plan, from the date of approval, unless otherwise agreed in writing by Natural Resources Wales.
- 3.2.3 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 Natural Resources Wales, 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 Natural Resources Wales that the activities are giving rise to pollution outside the site due to odour, submit to Natural Resources Wales 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 Natural Resources Wales.

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 Natural Resources Wales, 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 Natural Resources Wales that the activities are giving rise to pollution outside the site due to noise and vibration, submit to Natural Resources Wales 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 Natural Resources Wales.

3.5 Monitoring

- 3.5.1 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.
- 3.5.2 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 and S3.2 etc unless otherwise agreed in writing by Natural Resources Wales.

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 Natural Resources Wales, 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 Natural Resources Wales.

4.2 Reporting

- 4.2.1 The operator shall send all reports and notifications required by the permit to Natural Resources Wales using the contact details supplied in writing by Natural Resources Wales.
- 4.2.2 A report or reports on the performance of the activities over the previous year shall be submitted to Natural Resources Wales by 31 January (or other date agreed in writing by Natural Resources Wales) 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 The operator shall, unless notice under this condition has been served within the preceding four years, submit to Natural Resources Wales, 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 (a) In the event 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 Natural Resources Wales,
 - (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) in the event of a breach of any permit condition the operator must immediately—
- (i) inform Natural Resources Wales, and
 - (ii) take the measures necessary to ensure that compliance is restored within the shortest possible time;
- (c) 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, 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 [(a)(i), or 4.3.1 (b)(i) where the information relates to the breach of a limit specified in the permit,] 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 Natural Resources Wales has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform Natural Resources Wales when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to Natural Resources Wales at least 14 days before the date the monitoring is to be undertaken.
- 4.3.4 Natural Resources Wales 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.
- In any other case:
- (a) the death of any of the named operators (where the operator consists of more than one named individual);
 - (b) any change in the operator's name(s) or address(es); and
 - (c) 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) Natural Resources Wales 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 Natural Resources Wales shall be given at least 14 days notice before implementation of any part of the site closure plan.
- 4.3.7 Where the operator has entered into a climate change agreement with the Government, Natural Resources Wales shall be notified within one month of:
- (a) a decision by the Secretary of State not to re-certify the agreement;
 - (b) a decision by either the operator or the Secretary of State to terminate the agreement; and
 - (c) any subsequent decision by the Secretary of State to re-certify such an agreement.

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
S4.5 A1 (a)	Production of polyclonal antibody products.	From receipt of raw materials to storage of products and wastes
Directly Associated Activity		
Steam supply	Steam supply Two 698 kW boilers fired on gas oil.	Includes oil receipt and storage.
Water Purification	Purification of potable water for use in manufacturing process.	From receipt to discharge of excess water.
Effluent Removal	Transfer of effluent by tanker	Removal of effluent via vacuum tanker to be carried out on impermeable surface.

Table S1.2 Operating techniques

Description	Parts	Date Received
Application	The response to section 2.1, 2.2, 2.10.1 and 2.10.3 in the Application.	13/04/06
Further information	The responses provided under headings B2.1 and B2.2	10/11/06
Application	The response to section 3 and 4 in the application	28/04/17
Response to Schedule 5 Notice dated 05/07/17	Purified Water Discharge Further Information Request and Purified Water Discharge Risk Assessment	31/07/17

Schedule 2 - Waste types, raw materials and fuels

Table S2.1 Raw materials and fuels

Raw materials and fuel description	Specification
Gas oil	Less than or equal to 0.1% w/w sulphur content

Schedule 3 – Emissions and monitoring

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
A1 and A2 [Point A1 and A2 on site plan in Schedule 7]	Boiler Plant	None	-	-	-	-

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
W2 on site plan in schedule 7 emission to Afon/River Cwarchyr	Water purification plant and uncontaminated surface water.	None	-	-	-	-

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
None	-	-	-

Table S4.2: Annual production/treatment

Parameter	Units
Production of serum	Kg/year

Table S4.3 Performance parameters

Parameter	Frequency of assessment	Units
Water usage	Annually	tonnes
Energy usage	Annually	MWh
Specific water consumption	Annually	m ³ water / kg serumkg serum
Specific energy consumption	Annually	MWh energy / kg serum

Table S4.4 Reporting forms

Media/parameter	Reporting format	Date of form
Water usage	Form water usage 1 or other form as agreed in writing by Natural Resources Wales	01/11/06
Energy usage	Form energy 1 or other form as agreed in writing by Natural Resources Wales	01/11/06
Other performance indicators	Form performance 1 or other form as agreed in writing by Natural Resources Wales	01/11/06

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 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

(c) 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:

To be notified immediately	
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.

"*annually*" means once every year.

"*authorised officer*" means any person authorised by Natural Resources Wales 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.

"*fugitive emission*" means an emission to air, water or land from the activities which is not controlled by an emission 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

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

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:

- (a) 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
- (b) 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



© Crown Copyright and database right 2017. Ordnance Survey licence number 100019741.

END OF PERMIT