

Compliance Assessment Report CAR_NRW0048805

Permit being assessed: SP3338LF.

For: Blaenwaun Pharmaceutical Plant, **held by:** Protherics UK Limited

At: Blaenwaun , Ffostrasol, LLANDYSUL, Dyfed, SA44 5JT.

Type of assessment: Site Inspection,

Reason: Routine.

On: 09/07/2025 between 10:00 and 14:00.

Parts of permit assessed: S1 Directly Associated Activity.

NRW Lead Officer: Daren Pike.

Report sent to: Elaine Davies, Senior EHS Manager, on 27/02/2026.

1. Summary of our findings (full details in section 4)

Part of permitted activity assessed (compliance criteria)	Assessment result	Permit condition
IR2A - Installations - Operations - Permitted activities	Assessed (A)	
IR1A - Installations - Management - General Management	Assessed (A)	
IR2B - Installations - Operations - The site	Assessed (A)	

Result types are explained in more detail in the 'Important Information' section below.

Total non-compliances recorded	Total non-compliance score
0	0

How we use the non-compliance score to calculate your annual fee is explained in the 'Important Information' section below.

2. What action is required?

No action required.

3. What will happen next?

Any non-compliance we have identified and recorded on this form is an offence. It can result in criminal prosecution and/or suspension or revocation of your permit.

At this time, we do not intend to take any further action.

This statement does not stop us from taking additional enforcement action if further relevant information comes to light or offences continue.

4. Details of our assessment

Introduction

This Compliance Assessment Report (CAR) details the comments of Natural Resources Wales (NRW) Officer for the site inspection conducted on 9 July 2025 at Protherics UK Limited, Blaenwaun Pharmaceutical Plant, Blaenwaun , Ffostrasol, LLANDYSUL, Dyfed, SA44 5JT for activities undertaken by the named operator under environmental permit EPR-SP3338LF.

The purpose of the visit was to conduct a general inspection of permitted activities in the compliance year 2025/26. There were no permit condition non-compliance scores recorded.

Attendees

- Daren Pike - Senior Regulation Officer, NRW
- Senior EHS Manager, SERB Pharmaceuticals
- Associate EHS Manager, SERB Pharmaceuticals

Inspection Overview

At 10:00 hrs NRW officer arrived at the site reception and signed in where they were met by SERB Pharmaceuticals staff and taken to a meeting room. A introduction was provided with discussions around the general updates including current Permitting Team queues if any variation was being considered, future green initiatives and general updates. No areas of concern were raised or noted by either party.

NRW officer confirmed that the visit would involve a general site walkaround and focus on the following elements of the permit as highlighted below. The focus of the visit was communicated to SERB Pharmaceuticals prior to the visit.

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

Site walkaround

the NRW officer has previously visited site and was aware of the layout and location of the processes involved. The general impression of the site was that it is well-maintained. It was clean with no rubbish / waste visible. Clearly marked bins were apparent with signage indicating the nature of the contents (e.g. general waste, paper recycling etc). Walkways were clearly marked with safety barriers where necessary. Vehicular movement on the site in minimal, and restricted to the effluent processing area and the reception building. First Aid, Fire and Health and Safety signage and equipment were apparent on the walkaround.

Whilst in the vicinity of water purification plant my attention was drawn to a large generator / refrigerator unit on a flatbed lorry trailer. This was a piece of equipment hired by SERB to assist with their operation and was a temporary measure. SERB staff advised that there had been a failure of this equipment resulting in a leak of Hydrotreated Vegetable Oil (HVO) Oil. This was captured in the W2 Surface Water drain. The spill area was contained using the tertiary system and spill booms.

Due to a small fracture in the buried clay pipework, a small quantity of HVO oil entered soil around the area and escaped by the stream area outside of the site boundary. No third party reports of the spill were received by NRW. The Operator confirmed that this was

reported via NRW's Incident Communication Centre. NRW advised that as an initial response this was correct, but that the Permit required a notification via a Schedule 5 notification. NRW assessed that this was a genuine misunderstanding, and the operator immediately rectified this. No further action was considered with regard to this incident which was attributed to the failure of hired equipment on site.

Whilst on site it was observed by the NRW Officer that works were ongoing to rectify the fractured clay pipe. There was no visible evidence of any oil sheen on the nearby water.

No other concerns were noted on the inspection.

NRW and SERB Pharmaceuticals staff returned to the meeting room where a debrief took place, before NRW left at 14:00 hrs.

Daren Pike
Senior Officer - Southwest Wales Industry Regulation Team
daren.pike@cyfoethnaturiolcymru.gov.uk

END OF REPORT

If you have any queries about this report, or to discuss completion of any actions, please contact the NRW Officer named above.

Important information

Legal status of this report

Your permit is issued to you under the Environmental Permitting Regulations. You have a responsibility to comply with the conditions of your permit and prevent pollution/harm of the environment. You must also ensure that you comply with any other relevant legislation that may apply to your site's operations.

This report explains the findings of our assessment and any action you are required to take. We categorise non-compliance using our guidance for assessing non-compliance at regulated sites.

When we find potential non-compliance/s we will normally give you advice on how to maintain compliance.

To correct non-compliance, we may:

- require you to take specific actions
- issue a notice
- review the conditions of your permit.

Any advice and guidance we give will be without prejudice to any other enforcement response that we consider may be required.

Assessment results and non-compliance categories (used in section 1):

Assessment result	Description
Assessed (A)	Assessed or assessed in part, no evidence of non-compliance found
Action only (X)	Action required for the permit condition assessed to avoid non-compliance. No non-compliance scored at this time
Ongoing (O)	Ongoing non-compliance, not scored

Non-compliance category	Description	Score
C1 Major	Potential to have a major, serious, persistent and/or extensive impact or effect on the environment, people and/or property	60
C2 Significant	Potential to have a significant impact or effect on the environment, people and/or property	31
C3 Minor	Potential to have a minor or minimal impact or effect on the environment, people and/or property	4
C4 No environmental impact	Non-compliance at a regulated site that cannot foreseeably have any impact on the environment, people and/or property	0.1

How we use assessment scores

The number and severity of non-compliances recorded in a year will affect your annual subsistence fee the following year. A non-compliance factor is added to your site's Operator Performance Risk Appraisal (OPRA) score when we calculate your fee to reflect the additional resource we use to assess permit compliance.

If your assessment result in Section 1 is suspended, what does this mean?

In line with our guidance, we may suspend scores for up to six months to allow time for remedial action to be taken. Suspended scores will be re-instated if the action is not completed.

Full list of Industry compliance criteria (used in section 1 and 2):**1. Management**

- IR1A – General management
- IR1B – Finance (only applicable to Landfill)
- IR1C – Energy efficiency
- IR1D - Efficient use of raw materials
- IR1E - Avoidance, recovery and disposal of wastes produced by the activities
- IR1F - Multiple operator installations

2. Operations

- IR2A – Permitted activities
- IR2B – The site
- IR2C – Operating techniques
- IR2D – Technical requirements
- IR2E – Improvement programme
- IR2F – Pre-operational conditions
- IR2G – Landfill engineering (only applicable to Landfill)
- IR2H – Waste acceptance (only applicable to Landfill)
- IR2I – Leachate levels (only applicable to Landfill)
- IR2J – Closure and aftercare (only applicable to Landfill)
- IR2K – Landfill gas management (only applicable to Landfill)

3. Emission and Monitoring

- IR3A(1) – Emissions to water
- IR3A(2) – Emissions to air
- IR3A(3) – Emissions to land
- IR3B – Emissions of substances not controlled by emission limits
- IR3C – Odour
- IR3D – Noise and vibration
- IR3E – Monitoring
- IR3F – Pests
- IR3G – Air quality management plans
- IR3H – Monitoring for the purposes of the Industrial Emissions Directive (this heading includes Large Combustion Plants)
- IR3I – Fire

4. Information

- IR4A – Records
- IR4B – Reporting
- IR4C – Notification

Enforcement response

Any non-compliance with a permit condition is an offence and we may take legal action against you. Action we take can include prosecution, serving a notice on you and/or suspension or revocation of your permit. See our Enforcement and Sanctions Guidance for further information.

Data protection notice

You should make sure that anyone named in this report knows that the information it contains will be processed by Natural Resources Wales to fulfil its regulatory and monitoring functions and to maintain the relevant public register(s).

We may also use and/or disclose the report in connection with:

- offering or providing you with our literature or services relating to environmental matters
- consulting with the public, public bodies and other organisations (e.g. Health and Safety Executive, local authorities) on environmental issues
- carrying out statistical analysis, research and development on environmental issues
- providing public register information to enquirers
- investigating possible breaches of environmental law
- assessing customer service satisfaction and improving our service
- Freedom of Information Act or Environmental Information Regulations requests.

We may also pass it on to our agents or representatives to do these things on our behalf.

Disclosure of information – this report will be available to view on-line

If you think this report contains commercially confidential information that should not be placed on our public register, you must contact your local Natural Resources Wales office within **fifteen working days** of receiving this report, using the contact details in the accompanying email or letter. You must give a full explanation of why it should not be added to our public register, including specifying which information is commercially confidential. We will assess your request and respond to you within twenty working days to let you know if we agree to your request.

Disputing the Content of this Compliance Assessment Report Form

If you disagree with the content of this Compliance Assessment Report form, you should submit your concerns, in writing, to the regulating officer who issued it within **15 working days** of its issue. This will be treated as a **Stage 1 review**.

If you are not satisfied with the outcome of the stage 1 review, you may request a **Stage 2 appeal**. This request must be submitted **within 21 working days** of receiving the response from the stage 1 review.

Further details on our review and appeal process are available at: [Natural Resources Wales / Appeal a regulatory decision from Natural Resources Wales](#)

Concerns Not Related to the Content of this Compliance Assessment Report Form

If your concerns do not relate to the content of the Compliance Assessment Report form, you should first attempt to resolve the issue with the regulating officer or their line manager.

If the issue remains unresolved, please contact our **Customer Contact Team**:

- **Telephone:** 0300 065 3000 (Monday to Friday, 09:00–17:00)
- **Email:** enquiries@naturalresourceswales.gov.uk

They will provide details on how to escalate your concerns through our **Complaints and Commendations procedure**.

If you are dissatisfied with our response, you may contact the **Public Services Ombudsman for Wales**:

- **Telephone:** 0300 790 0203
- **Email:** ask@ombudsman.wales

Welsh Language Standards

We are committed to establishing Natural Resources Wales as a naturally bilingual organisation. We will provide compliance reports in your preferred language.