

Compliance Assessment Report CAR_NRW0050936

Permit being assessed: SP3338LF.

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

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

Type of assessment: Report/Data Review,

Reason: Routine.

On: 31/12/2025.

Parts of permit assessed: 2025 Annual Monitoring Returns.

NRW Lead Officer: Daren Pike.

Report sent to: Elaine Davies, Senior EHS Manager, on 04/03/2026.

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

Part of permitted activity assessed (compliance criteria)	Assessment result	Permit condition
IR4B - Installations - Information - Reporting	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) has been issued in response to the submission of the 2024 annual monitoring returns by Protherics UK Ltd (the operator) for activities at Blaenwaun, Ffostrasol, SA44 5JT under permit EPR-SP3338LF.

The Operator is not subject to parameters for the monitoring of site emissions as per the below entry.

4. S4.2 Reporting of Monitoring Data

4.1. Air Emissions In accordance with S3.1 there are no parameters set for the monitoring of air emissions and the site does not produce licensed air emissions.

4.2. Waste / Waste water In accordance with S3.1, there are no parameters for testing set and permanent sampling access is not required.

4.3. Groundwater / Contaminated Land In accordance with S3.1 & 3.2 of the permit, there are no parameters set and permanent sampling access is not required.

4.4. Noise / Odour / Vibration In accordance with S3.3 & 3.4 of the permit, the site is not required to monitor these emissions.

The annual report was received on 23 January 2026 which was within the permitted timescale, and can be found below. This CAR was undertaken on 4 March 2026. However, to ensure that the CCS score is attributed to the correct financial year (for billing) the date on CARS is recorded as 31 December 2025.

Annual Report

WAL-SP-19.022-F01


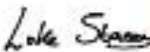
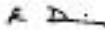
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Protherics UK Ltd
2025 Annual Report
EPR/SP3338LF

Completed by	Senior EHS Technician	 Electronically signed by: Sarah Phillips Reason: I authored this document. Date: 23-Jan-2025 15:47:00 GMT
Initial Review by	EHS Associate Manager	 Electronically signed by: Luke Stearns Reason: I approve this document. Date: 23-Jan-2025 15:46:11 GMT
Final Reviewed by	EHS & Site Services Manager	 Electronically signed by: Elaine Davies Reason: I approve this document. Date: 23-Jan-2025 15:47:52 GMT

Owner(s): Elaine Davies , Robert Evans

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2. Introduction

The purpose of this report is to provide submission of the performance of Protherics UK Ltd environmental activities for the year 2025 (Calendar), in line with the obligations outlined in Permit Number EPR/SP3338LF.

3. Facility Information Summary

Permit Number: EPR/SP3338LF
 Name of Site: Protherics UK Ltd
 Site Location: Blaenwaun, Ffostrasol, Llandysul, Ceredigion, SA44 5JT
 Class of Activity: S4.5 A1(a)
 National Grid Reference: SN36673 46375

The Protherics site is responsible for the production of polyclonal antibody products and the manufacture of materials for clinical development. There have been no changes to the physical infrastructure of the site since the last reporting period.

4. S4.2 Reporting of Monitoring Data

4.1. Air Emissions

In accordance with S3.1 there are no parameters set for the monitoring of air emissions and the site does not produce licensed air emissions.

4.2. Waste / Wastewater

In accordance with S3.1, there are no parameters for testing set and permanent sampling access is not required.

4.3. Groundwater / Contaminated Land

In accordance with S3.1 & 3.2 of the permit, there are no parameters set and permanent sampling access is not required.

4.4. Noise / Odour / Vibration

In accordance with S3.3 & 3.4 of the permit, the site is not required to monitor these emissions, and there were no related complaints from offsite received in 2025.

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5. Waste

Total waste decreased by 20.31% mainly due to decreased hazardous waste output. Hazardous waste decreased by 21.11% due to decreased volume of hazardous waste disposal as overordered expired stock had been disposed of within 2024.

In addition, the comparisons between 2024 and 2025 shows decreased volumes by 23.22% of Trade Effluent production. Continued work has been completed with regards to focus on excess use of water for injection (WFI) and purified water (PFW) in order to reduce the amount that the site uses during the manufacturing process.

5.1. Waste Data Table - Previous Year

	2024
Total Waste Produced (kg)	134,345
Total Waste recovered (kg)	55,830
Recovery percentage (kg)	41.56%
Total Hazardous Waste	62,864
Total Liquid Trade Effluent Produced	8,573,818

5.2. Waste Data Table – Current Year

Current Year	2025	Percentage change from previous year
Total Waste Produced (kg)	107,054	20.31% decrease from previous year
Total Waste recovered (kg)	79,908	43.13% Increase from previous year
Recovery percentage (kg)	75%	33.44% Increase from previous year
Total Hazardous Waste (kg)	49,609	21.11% decrease from previous year
Total Liquid Trade Effluent Produced (L)	6,582,134	23.22% decrease from previous year

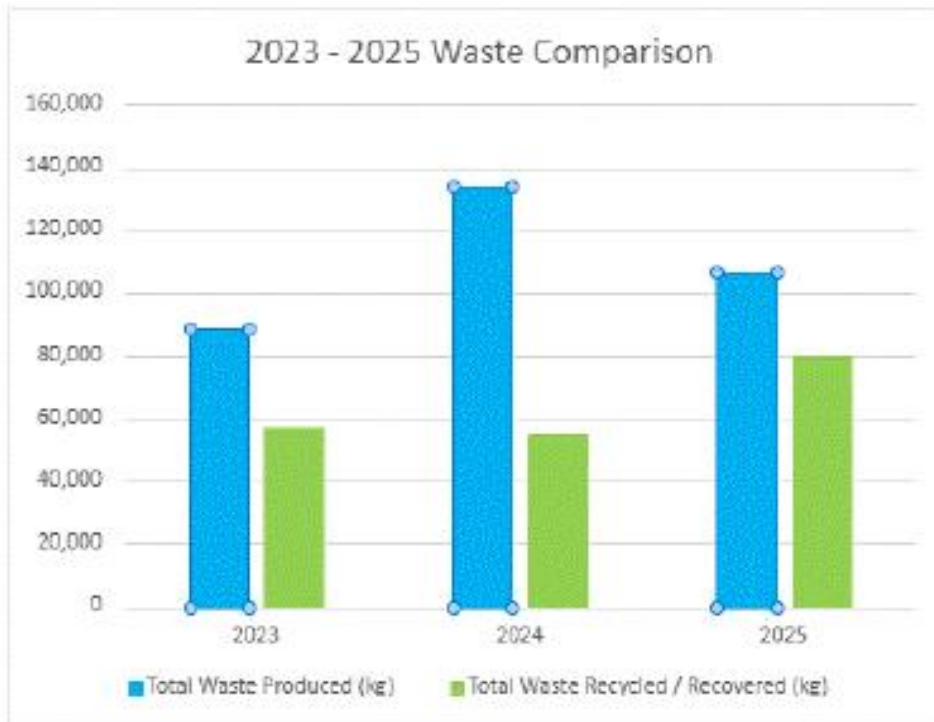
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5.3. Graph of Waste Comparison



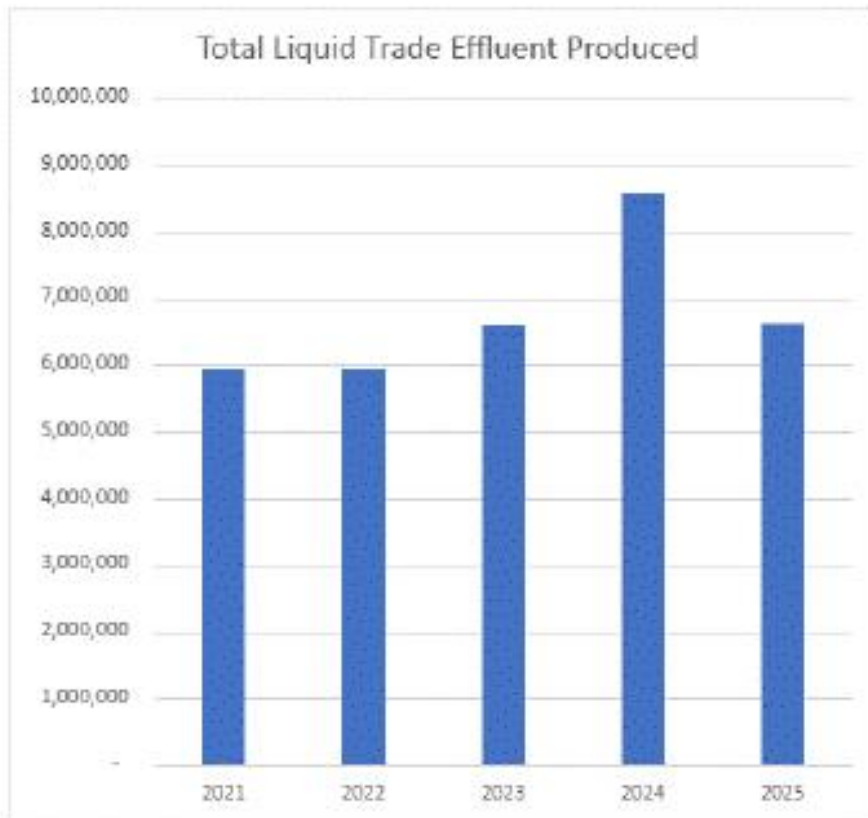
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5.4. Graph of Effluent Chart



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6. S4.2 Annual Production / Treatment

Annual production output of drug substance (Kg) for 2024	722.11 Kg
Annual production output of drug substance (Kg) for 2025	612.56 Kg
Percentage change from previous year:	15.17 % lower than previous year
Comments	The production output for the 2025 reporting period decreased by 109.55 Kg This was mainly due to normal supply/demand requirements from forecasted units

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7. S4.3 & 4.4 Performance Parameters

Following review of the previous 12 months, a review of the Electric usage was undertaken as this has increased slightly within 2025. Increase in electricity consumption can be attributed to reduced usage of the backup generator, Gas oil consumption shows a decrease in correlation.

7.1. Utilities Data Table – Previous Year

Previous Year	2024	Percentage change from previous year
Water Usage	13,196.4 M ³	21.85% Lower than 2023
Specific Water Consumption	18.27 m ³ /kg DS	33.15% lower than 2023
Electricity Usage	1,873,450 kWh	11.44% lower than 2023
Specific Energy Consumption	2,594.41 kWh / Kg DS	24.26% higher than 2023
Gas Oil Usage	94,771 Ltrs	73.95% Lower than 2023
Specific Gas Oil consumption	131.24 Ltrs/Kg DS	77.72% lower than 2023
HVO Oil Usage	303,097 Ltrs	N/A**
Specific HVO consumption	419.74 Ltrs/Kg DS	N/A**
LPG usage	Nil*	Nil*
Specific LPG consumption	N/A*	N/A*

** HVO system implemented to replace primary gas oil system in 2024.

7.2. Utilities Data Table – Current Year

	2025	Percentage change from previous year
Water Usage	11,718.1 M ³	11.20% Lower than 2024
Specific Water Consumption	19.13 m ³ /kg DS	4.70% Higher than 2024
Electricity Usage	1,940,216 kWh	3.56% Higher than 2024
Specific Energy Consumption	3,167.39 kWh / Kg DS	22.08% Higher than 2024
Gas Oil Usage	66,675 Ltrs	29.65% Lower than 2024
Specific Gas Oil consumption	108.84 Ltrs/Kg DS	17.06% Lower than 2024
HVO Oil Usage	279,982 Ltrs	7.63% Lower than 2024
Specific HVO consumption	457.06 Ltrs/Kg DS	8.89% Higher than 2024
LPG usage	Nil*	Nil*
Specific LPG consumption	N/A*	N/A*

* LPG is no longer used on the Protherics / BTG Wales site. This was removed from use in September 2017.

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9. Energy Usage

Permit Number: EPR/SP3338LF

Operator: Protherics UK Ltd

Installation: Pharmaceutical Plant, Blaenwaun

9.1. Reporting of Energy Usage for the year 2025

Energy Source	Quantity	Specific Usage
LPG	N/A	N/A
Electricity	1,940,216 kWh	3,167.39 kWh / Kg DS
Gas Oil (white diesel)	66,675 Ltrs	108.84 Ltrs/Kg DS
HVO Oil	279,992 Ltrs	447.06 Ltrs/Kg DS

9.2. Energy Usage Conclusion

LPG is no longer utilised on site and the storage tank has been removed.

The electrical energy usage on site shows a decrease in comparison to 2024 and the gas oil usage shows a decrease in comparison to 2024. The decrease in electrical usage may be attributable to the decrease of production output by 15.2 %, and the solar panels which were fitted in August 2022, and further additions of Thorlux lighting across site.

Luke Stevens
Electronically signed by Luke Stevens
 Reason: I Approve this document
 Date: 23-Jan-2026 13:46:13 GMT
 Signed Date 23-Jan-2026

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10. Production – Drug Substance

Permit Number: EPR/SP3338LF

Operator: Protherics UK Ltd

Installation: Pharmaceutical Plant, Blaenwaun, Ffostrasol, Llandysul, Ceredigion, SA44 5JT

10.1. Reporting of other performance indicators for the Period 2025

Parameter	Units
Production of Serum (Drug Substance)	612.56 Kg

10.2. Other Indicator Performance

During the 2025 production period, there was a decrease of 15.2 % in the manufacturing productivity in comparison to 2024. This was mainly due to normal supply/demand requirements from forecasted units

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Daren Pike

Senior Industry Regulator

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.