

Compliance Assessment Report CAR_NRW0051585

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: 22/04/2026.

Parts of permit assessed: CCRA Submission.

NRW Lead Officer: Daren Pike.

Report sent to: Elaine Davies, Senior EHS Manager, Internal Manufacturing , on 22/04/2026.

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

Part of permitted activity assessed (compliance criteria)	Assessment result	Permit condition
IR1A - Installations - Management - General Management	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

Climate Change Risk Assessment (Light-Touch Review)

Type of assessment: Report / Data review

Event type / reason: Routine

Parts of permit assessed: General Management – Climate Change Risk Assessment

Compliance criteria: IR1A Installations – Management – General Management

Permit condition: 1.1.1(a)

Assessment result: A – Assessed, no evidence of non-compliance

Recommended enforcement action: No further action

Enforcement response: No further action

Assessment against NRW CCRA checklist (Appendix 1)

1. Is it site-specific?

Assessment: Yes

Comments:

The climate change risk assessment is clearly specific to the permitted installation and its location. It considers site setting, operational activities and the local receiving environment, rather than relying on generic sector-level assumptions. This provides sufficient confidence that climate change risks have been considered in the context of the permitted activities.

2. Have climate hazards and risks relevant to the sector been considered?

Assessment: Yes

Comments:

The assessment identifies climate hazards that are relevant to the nature of the installation and its operations, including those that could reasonably affect regulated activities and environmental controls. Consideration of sector-relevant risks demonstrates an appropriate understanding of how climate change pressures could impact compliance with permit requirements.

3. Have short, medium and long-term climate risks been included?

Assessment: Yes

Comments:

The assessment considers climate change risks over appropriate time horizons, including current conditions as well as projected short, medium and longer-term impacts. This approach aligns with expectations for identifying both existing and emerging risks that could affect environmental performance over the life of the permit.

4. Are current and future climate projections or scenarios referenced?**Assessment:** Yes**Comments:**

The assessment makes reference to recognised climate change projections to inform future risk evaluation. This provides an appropriate evidence base for identifying how climate-related impacts may change over time and supports a forward-looking risk assessment.

5. Does it describe what elements are exposed (at risk) and have these been prioritised?**Assessment:** Yes**Comments:**

The assessment identifies key elements that could be exposed to climate change impacts, including infrastructure, operations and environmental receptors. Risks have been prioritised in a proportionate manner to focus attention on those elements that could present the greatest potential environmental risk if climate-related impacts were not adequately managed.

6. Does it propose actions to manage the high risks, and are these realistic and relevant?**Assessment:** Yes**Comments:**

Appropriate mitigation and adaptation measures are identified to manage higher-level climate change risks. The actions described are realistic, relevant to the site and consistent with good environmental management practice. Measures are aligned with existing site controls and management arrangements where appropriate.

7. Does it include key performance indicators (KPIs)?**Assessment:** Yes**Comments:**

The assessment references the use of monitoring and performance measures to support management of climate-related risks. This provides a mechanism to track effectiveness and supports ongoing review of environmental performance under changing climate conditions.

8. Is there a plan to regularly update the assessment and enable continuous improvement?**Assessment:** Yes**Comments:**

The assessment recognises that climate change risk assessment is a live process and includes provisions for periodic review and update. This aligns with expectations that the CCRA will be reviewed as part of the environmental management system and following significant climate-related events, operational changes or relevant near misses.

Overall CAR Conclusion

Thank you for submitting your climate change risk assessment.

We have carried out a basic light-touch review of the assessment against our current climate change risk assessment requirements and are satisfied that it meets these requirements. The assessment adequately addresses site-specific climate risks, includes consideration of current and future impacts, and links appropriately to the site's management arrangements.

There is no further action required at this stage. However, the climate change risk assessment is a live document and should be reviewed periodically as part of the environmental management system and following any significant climate-related events or near misses.

This review has been undertaken at a high level in line with the current regulatory approach and does not constitute a detailed technical audit.

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.