

Compliance Assessment Report CAR_NRW0051144

Permit being assessed: SP3030LZ.

For: Wrexham Pharmaceutical Works, **held by:** Ipsen Biopharm Limited

At: Unit 9 Ash Road North , Wrexham Industrial Estate, Wrexham, WREXHAM, Clwyd, LL13 9UF.

Type of assessment: Site Inspection,

Reason: Routine.

On: 23/03/2026 between 10:10 and 12:00.

Parts of permit assessed: See below.

NRW Lead Officer: Libby Hughes, accompanied by Hannah Ibbotson.

Report sent to: Senior EHS Advisor, Senior EHS Advisor, on 10/04/2026.

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

Part of permitted activity assessed (compliance criteria)	Assessment result	Permit condition
IR2B - Installations - Operations - The site	Action only (X)	
IR2A - Installations - Operations - Permitted activities	Action only (X)	

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?

Criteria	Action needed	Complete by
IR2B	Submit permit application	Already completed
IR2A	See Action 1 below	30/04/2026

Compliance criteria codes are listed in the 'Important information' section below.

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

This Compliance Assessment Report (CAR) Form has been completed following a site familiarisation visit to Wrexham Biopharmaceutical Works at 10:10 am on Monday 23rd March 2026.

Site visit

The visit was primarily a site familiarisation visit, and an opportunity to meet key personnel. It included a general walk around the non-operational areas of the existing facility, accompanied by the Senior EHS Advisor and EHS Advisor. It was found to be clean and tidy, with no apparent issues.

The visit also included a tour inside the new facility with the Senior Principal Process Engineer. The building is still under construction, but is being constructed using low carbon technologies, which were discussed during the visit.

IR2A Permitted Activities

There was discussion around the new development. Ipsen Biopharm Ltd was advised previously that a permit variation would need to be submitted and determined prior to production commencing at the new facility - see **CAR_NRW0048557** - June 2025 - excerpt below

"Current timescales are estimated to be as follows:

- Q2 2026 - Validation batch production
- Q1 2027 - The plant will "go live" as a commercial production line.

The operator has been advised that a permit variation will be required prior to the commencement of any production at the new facility. A permit variation application and all relevant supporting information should be submitted at the earliest opportunity to minimise the risk of delay to commissioning the facility"

It is understood that the application to vary the permit has been submitted to NRW by Ipsen Biopharm Ltd in the last few days.

NRW officers advised the EHS Senior Advisor that the queue for permit determination is currently around 12 months and reiterated that **production must not start** at the new plant until the permit variation has been determined.

Discussion was held around what is involved with the validation batch production tests, and whether or not this could go ahead before the variation is determined.

Action 1: Provide NRW with details of the specifics of the validation batch production tests by 30th April 2026.

Permission from NRW will be required prior to commencing either the production tests or permanent operation

The Operator is reminded that all emissions and fugitive emissions must be reported to Natural Resources Wales in a timely manner.

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.