Compliance Assessment Report CAR_NRW0046225

Permit being assessed: CB3092CA.

For: MicroPharm Limited, **held by:** MicroPharm Limited

At: MicroPharm Limited, Cnwcau, Cilgerran, SA43 2SN.

Type of assessment: Report/Data Review,

Reason: Routine.

On: 31/12/2024.

Parts of permit assessed: 2024 Annual Monitoring Returns.

NRW Lead Officer: Daren Pike.

Report sent to: Michele Gamage, Health and Safety Officer, on 11/02/2025.

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

This Compliance Assessment Report (CAR) has been issued in response to the submission of the 2024 annual monitoring returns by MicroPharm Ltd (the operator) for activities at Cnwcau Pharmaceutical Plant - Cnwcau, Cilgerran, SA43 2SN under permit EPR-CB3092CA.

This CAR was undertaken on 11 February 2025. However, to ensure that the CCS score is attributed to the correct financial year (for billing) the date on CARS shows 31 December 2024.

There are no parameters for emission that are subject to permit, so this CAR is in relation to the submission of annual reporting as per permit condition 4.2.1. This was received 11 February 2025 and was in compliance with the permit requirements.

The report can be found below and attached.

Permit Number: EPR-CB3092CA Operator: MicroPharm Limited

Facility: Cnwcau Pharmaceutical Plant Form Number: WaterUsage1 / 2024

Reporting of Water Usage for the year 2024

Water Source	Usage (m^3/year)	Specific Usage (m^3/unit output)
Mains water	469	27.14 m^3/kg of product
TOTAL WATER USAGE:	469 m^3/year	27.14 m^3/kg of product

Operator's comments:

None

Signed: Michele Gamage Michele Gamage Date: 11 Feb 2025

(authorised to sign as representative of Operator)

Permit Number: EPR-CB3092CA Operator: MicroPharm Limited

Facility: Cnwcau Pharmaceutical Plant Form Number: Energy1 / 2024

Reporting of Energy Usage for the year 2024

Energy Source	Energy Usage Quantity	Primary Energy (MWh)	Specific Usage (MWh/unit output)
Electricity *	MWh	MWh	MWh/kg of product
Manufacturing facility – day	190.4	457.0	26.4
Manufacturing facility – night	75.1	180.2	10.4
Offices, stores, labs, general areas etc.	28.2	67.8	3.9
TOTAL:	293.7	705	40.7

* Conversion factor for delivered electricity to primary energy = 2.4

Operator's comments:

None

Signed: Michele Gamage Michele Gamage Date: 11 Feb 2025
(Authorised to sign as representative of Operator)

Permit Number: EPR-CB3092CA Operator: MicroPharm Limited

Facility: Cnwcau Pharmaceutical Plant Form Number: Performance1 / 2024

Reporting of other performance indicators for the period 01/01/2024 to 31/12/2024

Parameter	Units
Production of immunotherapeutic product	17.28 kg/year

Operator's comments:

None

Signed: Michele Gamage Michele Gamage Date: 11 Feb 2025
(Authorised to sign as representative of Operator)

Please can you send any reporting forms to the South West Wales area team mailbox:
industryregulation.swwales@cyfoethnaturiolcymru.gov.uk

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 only relating to the activity assessment
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 – Emissions to water, air or 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.

What do I do if I disagree with the report or have a complaint?

If you disagree with this compliance assessment report, you should contact the lead officer without delay to discuss your concerns.

If you are unable to resolve the issue with the lead officer or their line manager you should contact our Customer Contact team on 0300 065 3000 (Monday to Friday 08:00 to 18:00), or email enquiries@naturalresourceswales.gov.uk for details of how to raise your dispute further through our Complaints and Commendations procedure.

If you are dissatisfied with our response, you can contact the Public Services Ombudsman for Wales by phone on 0300 7900203 or by email at 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.