

Compliance Assessment Report CAR_NRW0046209

Permit being assessed: FP3437VK.

For: Units B1 - B3 Antur Teifi EPR/FP3437VK, **held by:** MicroPharm Ltd

At: Unit's B1, B2 and D1 Antur Teifi Business Park , Aberarad, Newcastle Emlyn, SA38 9DB.

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 Manager, 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 Unit B2 Antur Teifi Business Park, Aberarad, Newcastle Emlyn, SA38 9DB under permit EPR-FP3437VK.

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 recorded on CARS is 31 December 2024.


There are no parameters for emission that the site is subject to on the permit, so this CAR is in relation to the submission of annual reporting. This was received 29 January 2025 and was in compliance with the permit requirements.

The report can be found below and attached.


MicroPharm Environmental Management ANNUAL RETURNS FORM	Document Number: EMF 04	Version Number: e-01	
		Page 1 of 5	

Details			
Company:	MicroPharm Limited	Station Road Industrial Estate, Newcastle Emlyn, Carmarthenshire SA38 9BY	YEAR: 2024
	Site:	Unit B2, Antur Teifi Business Park, Newcastle Emlyn, Carmarthenshire, SA38 9DB	
	Environmental Permit Number:	EPR/FP3437VK	Low Impact Installation (LII) Issued 07/10/14


	Condition	Details from Appendix 1 Part B1 Guidance	Details in Original Permit Application	Actual for Year
A	Management techniques	All of the criteria described below must be met without having to rely on significant management effort. The installation must have only a low environmental impact, including under start up, shut down, or abnormal operating conditions.	Description of MicroPharm's Pharmaceutical Quality Management System (QMS). No specific Environmental Management System. SOP 8.001 describes disposition of cleanroom waste.	The EMS is being complied with. Minimum management effort is required and involves the following: <ul style="list-style-type: none"> Review and revision of EMS documents Completion of EMS documents including annual return
B	Aqueous waste	LII criteria: ≤ 50 m ³ (50 000 L) per day of water from processing activities. Characterize and quantify all aqueous effluents released and provide justification that the criteria are met. Dŵr Cymru: ≤ 1 m ³ (1000 L) of trade effluent per day	Up to 200 L (0.20 m ³) per day Equivalent to 73 000 L (73 m ³) per year	12 730 L equivalent to 35 L (0.035 m ³) per day <u>2023 data:</u> 23 320 L equivalent to 64 L (0.064 m ³) per day See note 1
C	Abatement systems/releases to air	LII criteria: There must be no active abatement. Releases to air must not be dependent on correct or continuing running of equipment, i.e. failure should not result in unacceptable external release. Abatement systems installed solely for the protection of workers (where abatement is not to attenuate external environmental releases) are excluded.	Release to air – minimal, so no system required. Air is cleaner when exhausted from cleanrooms than when taken in. Noise – see below	Still within current criteria

MicroPharm Environmental Management	Document Number: EMF 04	Version Number: e-01	
ANNUAL RETURNS FORM		Page 2 of 5	

Condition	Details from Appendix 1 Part B1 Guidance	Details in Original Permit Application	Actual for Year																								
D	Groundwater	No planned or fugitive emission from the permitted installation into the ground, or any soakaway. This does not preclude the discharge of clean rain water run-off into soakaways.	No planned or gas or vapour emissions into the ground or any soakaway (clean rain water into soakaways not included). No discharge to groundwater other than from building gutters and surrounding roads/parking areas.																								
E	Waste production	Not more than 1000 kg (1 tonne) of Directive waste or 10 kg of hazardous waste to be generated/day (yearly average) with not more than 20 000 kg (20 tonnes) of Directive or 200 kg of hazardous waste to be released in one day Information on the proposed recovery and disposal of waste streams arising from the installation is not required. This equates to: Non-hazardous: < 365 000 kg/year Hazardous < 3 650 kg/year	<p>Total non-hazardous waste: < 2 000 kg (2 tonnes) per year Equivalent to 5.5 kg per day</p> <p>Total hazardous waste: < 400 kg (0.4 tonnes) per year Equivalent to 1.1 kg per day</p> <table border="1"> <tr> <td>Recycling waste</td> <td>1 880 kg</td> <td>See note 2.1</td> </tr> <tr> <td>General waste</td> <td>520 kg</td> <td>See note 2.2</td> </tr> <tr> <td>Total non-hazardous waste</td> <td>2 400 kg (2.4 tonnes)</td> <td>This is equivalent to 6.6 kg per day See notes 2.3 and 2.4</td> </tr> <tr> <td>Hazardous waste waste in yellow bags</td> <td>955 kg</td> <td>See note 3.1</td> </tr> <tr> <td>Hazardous waste 'sharps' containers</td> <td>46 kg</td> <td>See note 3.2</td> </tr> <tr> <td>Hazardous waste glass containers</td> <td>196 kg</td> <td>See note 3.3</td> </tr> <tr> <td>Hazardous waste chemical waste</td> <td>80 kg</td> <td>See note 3.4</td> </tr> <tr> <td>Total hazardous waste</td> <td>1 277 kg (1.28 tonnes)</td> <td>This is equivalent to 3.5 kg per day See notes 3.5 and 3.6</td> </tr> </table>	Recycling waste	1 880 kg	See note 2.1	General waste	520 kg	See note 2.2	Total non-hazardous waste	2 400 kg (2.4 tonnes)	This is equivalent to 6.6 kg per day See notes 2.3 and 2.4	Hazardous waste waste in yellow bags	955 kg	See note 3.1	Hazardous waste 'sharps' containers	46 kg	See note 3.2	Hazardous waste glass containers	196 kg	See note 3.3	Hazardous waste chemical waste	80 kg	See note 3.4	Total hazardous waste	1 277 kg (1.28 tonnes)	This is equivalent to 3.5 kg per day See notes 3.5 and 3.6
Recycling waste	1 880 kg	See note 2.1																									
General waste	520 kg	See note 2.2																									
Total non-hazardous waste	2 400 kg (2.4 tonnes)	This is equivalent to 6.6 kg per day See notes 2.3 and 2.4																									
Hazardous waste waste in yellow bags	955 kg	See note 3.1																									
Hazardous waste 'sharps' containers	46 kg	See note 3.2																									
Hazardous waste glass containers	196 kg	See note 3.3																									
Hazardous waste chemical waste	80 kg	See note 3.4																									
Total hazardous waste	1 277 kg (1.28 tonnes)	This is equivalent to 3.5 kg per day See notes 3.5 and 3.6																									
F	Energy consumption	Energy must not be consumed at a rate greater than 3 MW (3000 kW)	0.10 MW peak consumption																								
			<p>Total annual consumption:</p> <p>Day = 91 493 kW-h Night = 36 776 kW-h Total = 128 269 kW-h Maximum demand = < 40 kVA</p> <p>See note 4.4</p>																								


MicroPharm Environmental Management	Document Number: EMF 04	Version Number: e-01	
ANNUAL RETURNS FORM		Page 3 of 5	

Condition	Details from Appendix 1 Part B1 Guidance	Details in Original Permit Application	Actual for Year
G	Accident prevention	Satisfactory containment measures must be in place to prevent fugitive emissions to surface water, sewer, and/or land; they must be adequately maintained. This requirement applies to all substances present onsite and in any quantity.	Measures for spills and releases. Containment of environment achieves EU Grade C conditions, >1000x cleaner than surrounding air. No individual liquid volumes >50L stored so even a complete rupture of a container would not produce significant depth of spill in any room.
H	Noise	No noticeable noise from installation outside installation boundary.	<p>Air Handling Unit is acoustically shielded (Environmental Health Department requirement at time of construction). No complaints from nearby residents.</p> <p>A new external temperature-controlled unit (TCU) was installed during 2019. It comprises an insulated container and air-conditioning (A/C) unit.</p> <p>Ambient noise level (underlying): 43.4 to 56.6 dB(A) Noise level with A/C unit running: 43.3 to 55.1 dB(A). This indicates that the noise level does not change significantly when the A/C unit is running. Maximum difference from average ambient noise is + 1.9 dB(A); therefore, the noise falls within permitted levels, i.e. less than 10 dB(A) above the underlying level of noise [when it exceeds 24 dB(A)].</p> <p>The situation will be monitored during use. No complaints have been received.</p>
I	Emissions of polluting substances	Justify there will be no likelihood of a release to the environment. Describe the nature, quantities, and sources of foreseeable emissions from the installation.	<p>To air – no credible risk MicroPharm’s process depends on liquid manufacturing. Only 7% of the air used in the facility is released to the environment the rest is recirculated.</p> <p>Estimated maximum contamination of air by chemical dust would be low (chemicals generating dust are not generally used in the facility), e.g. 0.5 mg/m³ as it emerges from the cleanroom air handling system into the environment (this is based on the efficiency of the HEPA filters).</p> <p>Liquid pollution – not applicable No large volumes are produced.</p>

MicroPharm Environmental Management	Document Number: EMF 04	Version Number: e-01	
ANNUAL RETURNS FORM		Page 4 of 5	

	Condition	Details from Appendix 1 Part B1 Guidance	Details in Original Permit Application	Actual for Year
J	Odour	Low potential for giving offence due to odour outside installation boundary	No solvents used. Products are low bioburden/sterile so microbiological breakdown is avoided. Product and processing solutions must be protected from air.	Within criteria, no solvents are used in the facility. Products are sterile so microbiological breakdown is avoided. No complaints received.
K	Compliance history	Absence of prosecution, formal caution, suspension notice, enforcement notice relating to actual or potential environment incident	Absence of prosecution, formal cautions, suspension notices, enforcement, or notice relating to actual or potential environmental incidents.	There have been no prosecutions, cautions, suspensions notices/enforcements, or notices during 2024.

Notes:	1.	This is an estimated volume of liquid waste from manufacturing discharged into the main sewer system. 1.1. It is calculated based on the water used in the manufacturing process and trade effluent. The input of any other liquids, and the volumes of products produced are considered negligible in comparison with this. 1.2. The type of liquid discharged routinely is waste from the manufacturing process, cleaning and washing equipment. 1.3. Low volumes of non-hazardous liquid waste are discarded intermittently. 1.4. The volumes discharged at any one time are in the tens of litres. 1.5. A single sink is installed in the facility which discharges at a maximum rate of ~33 L/min. 1.6. In addition, there is a sink in the laboratory; a maximum of 10 L liquid waste would be moved to the sink for discharge at any one time, so the discharge rate will always be low. 1.7. The volume varies each year; this is mainly dictated by market demands for our products. Volumes in 2024 were lower than volumes in 2023. We have not exceeded the volumes specified in our original application. 1.8. Note that Dŵr Cymru allow us to discharge 1000 L (1 cubic metre) of trade effluent per day; this is significantly less than the Low Impact Installation (LII) allowance of 50 000 L (50 cubic metres) per day. Currently, we are well inside Dŵr Cymru restrictions.
	2.	Non-hazardous waste 2.1. Recycling waste was collected fortnightly by CWM until end of March 2024; it is now collected weekly by LAS in 2x separate waste streams – paper + card and plastic + cans + cartons. 2.2. General waste was collected by CWM until end of March 2024; it is now collected weekly by LAS. This waste includes general office waste and other items that cannot be recycled. 2.3. The amounts have increased from our original application due to a significant business expansion; this includes increased production activities and higher staffing levels. 2.4. Our average daily amount of 6.6 kg is well within the terms of our permit (1000 kg per day).

MicroPharm Environmental Management	Document Number: EMF 04	Version Number: e-01	
ANNUAL RETURNS FORM		Page 5 of 5	

Notes Cont.	3.	Hazardous waste 3.1. Waste in yellow bags is collected by LAS for incineration; it includes product contact disposables such as tubing, filters, plastic consumables, and gloves etc. These are all recorded on hazardous waste consignment notes. 90% of the waste is recovered and 10% goes to landfill. 3.2. Waste in 'sharps' containers is collected by PCS (Summerleaze) for incineration; it includes product contact disposables such as glass vials, pipette tips, and needles etc. These are all recorded on hazardous waste consignment notes; these are now available via a portal (from 29 October 2024). 3.3. Waste in this category includes glass containers (empty chemical bottles, unused ampoules, and ampoules containing non-cytotoxic material) in 60 L bins. It is collected by PCS (Summerleaze) for incineration. Details are recorded on hazardous waste consignment notes; these are now available via a portal (from 29 October 2024). 3.4. Waste in this category includes chemicals (liquid, solutions, solids, and plastic consumables that have been in contact with the chemicals) that cannot be discarded into the drainage system. They are stored in labelled (EWC, UN, HP etc.) chemical bins until full. They are collected by PCS (Summerleaze) when requested; details are recorded separately on hazardous waste consignment notes (now available via a portal). 3.5. The amounts have increased from our original application due to a significant business expansion; this includes increased production activities and higher staffing levels. However, waste is directly proportional to manufacturing activities; this is mainly dictated by market demands for our products. 3.6. The maximum LII allowance is 10 kg of hazardous waste per day (yearly average) with not more than 200 kg of hazardous waste to be released in one day. Our average daily amount of 3.5 kg is well within the terms of our permit.
	4.	Energy usage is restricted to electricity. 4.1. The figures given are for twelve months (from January to December 2024) usage in kW/hr. 4.2. There are only a few pieces of larger manufacturing equipment which are rarely used at the same time. These are very unlikely to cause a spike in demand. For instance, there are three centrifuges that have a power rating of 5 kW each; so, their initial power demand is very low. 4.3. The cleanroom air handling unit circulation fans run continuously. The thermostatically controlled heating and cooling units operate to maintain cleanroom air temperature within the range of 18 – 22°C so there are no sudden surges in heating or cooling as it is constant and maintained. The highest demand for heating is approximately 14 kW for the cleanroom HVAC (heating, ventilation, and air-conditioning). 4.4. The electricity supplier does not provide details on 'maximum demand.' However, as there have been no changes to large items of equipment, the maximum demand will be similar to previous years, i.e. < 40 kVA. 4.5. On this basis of the points above, it is very unlikely that a peak demand of 0.1 MW will ever be reached.

Completed by (signature and date):	Michele Gamage <i>Michele Gamage</i> 29/01/25
------------------------------------	---

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.