

Natural Resources Wales permitting decisions

**MicroPharm Limited
Cnwcau Pharmaceutical Plant
Decision document**

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DRAFT

New bespoke permit

The application number is: PAN-009065

The applicant / operator is: MicroPharm Limited

The Installation is located at: MicroPharm Limited, Cnwcau, Cilgerran, SA43 2SN

We have decided to grant the permit for Cnwcau Pharmaceutical Plant operated by MicroPharm Ltd.

We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that the appropriate level of environmental protection is provided.

Purpose of this document

This decision document:

- explains how the application has been determined
- provides a record of the decision-making process
- shows how all relevant factors have been taken into account
- justifies the specific conditions in the permit other than those in our generic permit template.

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Key issues of the decision

Receipt of application

Confidential information

The Applicant made a claim for commercial confidentiality which was subsequently withdrawn on 17/08/20 by the operator following a review of the information. We have not identified any information provided as part of the application that we consider to be confidential. The decision was taken in accordance with our guidance on commercial confidentiality.

Consultation

The consultation requirements were identified and implemented. The decision was taken in accordance with RGN 6 High Profile Sites, our Public Participation Statement and our Working Together Agreements.

A copy of the Application and all other documents relevant to our determination (see below) are available for the public to view. Anyone wishing to see these documents could arrange for copies to be made.

We sent copies of the Application to the following bodies, which includes those with whom we have “Working Together Agreements”:

- **Health and Safety Executive**
- **Public Health Wales**
- **Pembrokeshire Council – planning department**
- **Pembrokeshire Council – environmental health department**

These are bodies whose expertise, democratic accountability and/or local knowledge make it appropriate for us to seek their views directly.

An advert was placed on our website, the consultation started on 04/09/2020 and ended on 04/10/2020.

Further details along with a summary of consultation comments and our response to the representations we received can be found in Annex 1. We have taken all relevant representations into consideration in reaching our determination. We are now carrying out a consultation on our draft decision. This consultation will begin on 29/01/21 and end on 26/02/21.

Operator

We are satisfied that the applicant (now the operator) is the person who will have control over the operation of the facility after the grant of the permit. The decision was taken in accordance with EPR RGN 1 Understanding the meaning of operator.

The Installation

Description of the Installation and related issues

The permitted activities

The Installation is subject to the EPR because it carries out an activity listed in Schedule 1 Part 2 of the EPR:

- Section 4.5 Part A(1) (a) Producing pharmaceutical products.

An installation may also comprise “directly associated activities”, which at this Installation includes.

- Storage of waste

Together, these listed and directly associated activities comprise the Installation.

The Legal Framework

The Permit will be granted, under Regulation 13 of the EPR. The Environmental Permitting regime is a legal vehicle which delivers most of the relevant legal requirements for activities falling within its scope. In particular, the regulated facility is:

- an *Installation* as described by the IED;
- subject to aspects of the Well-Being of Future Generations (Wales) Act 2015 and the Environment (Wales) Act 2016 which also have to be addressed.

We address the legal requirements directly where relevant in the body of this document. NRW is satisfied that this decision is consistent with its general purpose of pursuing the sustainable management of natural resources in relation to Wales, and applying the principles of sustainable management of natural resources. In particular, NRW acknowledges that it is a principle of sustainable management to take action to prevent significant damage to ecosystems. We consider that, in granting the Permit a high level of protection will be delivered for the environment and human health through the operation of the Installation in accordance with the permit conditions.

The site

The site is located in Cnwcau, Cilgerran, SA43 2SN and centred on the National Grid Reference (NGR) 220249 242714. The Installation is bound by Cilgerran Road to the north from which the Installation is accessed. The River Teifi runs north of the Installation, north of Cilgerran Road.

The Installation is 0.26km NW from the residential area of Llwynceilyn and 1.3km SW of Malgwyn Castle. The Installation is also located 1.7km SW of the village of Llechryd and is 4km SE from Cardigan Town. The location is shown in Figure 1.



Figure 1: Indicative site location, Cnwcau, Cilgerran

The operator has provided a plan which we consider is satisfactory, showing the extent of the site of the facility including emission points. A plan is included in the permit and the operator is required to carry on the permitted activities within the site boundary.

Site condition report

The operator has provided a description of the condition of the site. Site condition report ECL.066.01.01/ASCR Issue 1, was produced by the operator.

The report indicates that the Installation was previously operated as a saw mill which could have potentially been a source of contamination from the treatment and preservative chemicals which may have been used. The Installation was also operated as a builder's merchants and clothing distribution unit which are both unlikely to have been a source of contamination due to the nature of the activities and the impermeable concrete surfacing on which the activities took place.

During the initial site walkover survey no visual or olfactory evidence of contamination was observed. No signs of cracks or depressions were identified during the site walk over. All concrete hardstanding is considered to be in good condition.

We consider this description is satisfactory. The decision was taken in accordance with our guidance on site condition reports – guidance and templates (H5).

Biodiversity, Heritage, Landscape and Nature Conservation

The Installation is within the relevant screening distance criteria for protected conservation sites. An assessment of the application and its potential to affect any of the sites has been carried out as part of the permit determination process. Natura 2000/Ramsar sites, SSSIs and local nature sites will be discussed in detail separately below.

Natura 2000/Ramsar sites

The following Natura 2000/Ramsar sites are located within 10 km of the installation:

- West Wales Marine Site Special Area of Conservation (SAC)
- Preseli Mountain SAC
- North Pembrokeshire SAC
- Cardigan Bay SAC
- River Teifi SAC

The Installation is not located within 10km of any Special Protection Areas (SPA) or Ramsar sites.

There is only one process related emission point (A1) which will only occur in an emergency situation. Nitrogen gas could be released from the pressure relief valve in the unlikely event of a catastrophic failure of the vessel or fittings.

An OGN 200 Form 1 (Habitats Regulation Assessment) was completed to assess the potential to affect the Natura 2000 site, this is available on the public register. We consider that the application will not affect the features of the sites.

SSSI and Non-statutory site assessment

Site checks concluded that there were none of the following sensitive land uses located within 2km:

- Areas of Outstanding Natural Beauty (AONB);
- Groundwater Source Protection Zones;
- Marine Conservation Zones;
- National Parks; or
- Nitrate Vulnerability Zones.

The installation is located within 2km of one National Nature Reserve (NNR) and three Sites of Specific Scientific Interest (SSSI). No Local Nature Reserves (LNR) or Local Wildlife Sites (LWS) were identified within 2km of the installation.

The following NNR and SSSI are located within 2 km of the installation:

- Coedmor NNR
- River Teifi SSSI

- Teifi Estuary Woodlands and Marshes SSSI
- Gwaun Pen-Lan SSSI

An Appendix 4 Form (CRoW Act Assessment) was completed to assess the potential to affect the SSSI sites, this is available on the public register. We consider that the application will not affect the features of the sites.

There are 63 areas of Ancient Woodland (restored and semi natural) within 2km of the Installation. We consider that the application will not affect the features of the sites due to a limited impact pathway.

Environmental Risk Assessment

Air

There will be one point source to air on site (A1). A1 is associated with the storage and use of liquid nitrogen and will only occur in an emergency situation. Nitrogen gas will only be released in the unlikely event of vessel or fittings failure. Given the release of nitrogen gas is not routine and will only occur during an emergency we have concluded that the environmental risk from A1 is very low. We have decided not to set emission limits for A1. Tank maintenance is included in the Planned Preventive Maintenance Regime (PPMR), operating techniques are discussed in detail in the sections below.

Water

There will be a direct process-related point source emission to foul sewer (S1). The point source emission has been authorised under a Trade Effluent Consent granted by Welsh Water. Trade effluent consent No. SW659/2019 MicroPharm Ltd issued 20 July 2020.

There will be no direct process-related releases i.e. process contributions to surface water from the activities that will be undertaken at the proposed facility. Only clean uncontaminated storm water run-off from the building and areas of hardstanding will

pass through the sites drainage system into emission points W1 and W2 as shown on the site plan in the permit. No limits have been set for these emission points.

Any fuel oil spillage will be captured within the bund and will be subsequently tankered off site to an appropriately licensed Facility or Installation for disposal or re-use. Any accidental spillage will be dealt with in accordance with the Installation's emergency spillage response procedure which forms part of the installations EMS.

Based upon the information in the application we are satisfied that the appropriate measures will be in place to prevent pollution of ground and surface water.

Odour

The process is not odorous in nature and therefore, an assessment of odour and the requirement for an Odour Management Plan is not considered relevant.

Noise

The closest residential receptor is located <30m from the east installation boundary. A noise risk assessment has been completed by the applicant. The risk assessment concluded that even with the Installation operating twenty four hours a day, the risk of noise nuisance is not considered to be significant. Normal operating hours will be 8.00am to 6pm Monday to Friday. Where possible all major items of plant have been placed inside the building. The main external sources of noise are from the condenser and the fresh air unit.

A condition of the Installation's Planning Permission (Application number 18/0988/PA) states that noise generated by the condenser and fresh air unit will not exceed the background noise level by more than 5dB (A) at the nearest residential property to the development site at any time when measured (and shall be assessed in accordance with BS4142:2014). The permit also contains conditions 3.4.1 and 3.4.2 ensuring emissions from site are free from noise and vibration at levels likely to cause pollution outside the site.

Routine noise inspections will be undertaken at the EP boundary by MicroPharm Ltd personnel during site walkabouts, with findings reported to management and

scheduled maintenance carried out on all equipment in accordance with manufacturer's specifications to ensure that equipment is kept at optimal operational conditions.

Based upon the information in the application and the conditions in the permit we are satisfied that the appropriate measures will be in place to prevent or where not practicable to minimise the effects of noise.

Fugitive emissions

Raw materials storage and processing areas are located within the installation main building. Any accidental spillages within the building would not be able to enter the surface water drainage system without travelling a considerable distance. All site activities take place on impermeable concrete hardstanding.

There is a fuel oil tank which is used for the purposes of fuelling the central heating system. The tank is housed in a concrete impermeable bund with capacity for 110% of the tank. The tank filling coupling and all associated pipework is located within the bund to ensure any small leaks are captured. The integrity of the tank and bund will be regularly checked by MicroPharm Ltd, all site personnel are trained in spill response procedure outlined in the EMS.

Based upon the information in the application we are satisfied that the appropriate measures will be in place to prevent or where that is not practicable to minimise fugitive emissions and to prevent pollution from fugitive emissions.

Reporting

We have specified the reporting requirements in Schedule 4 of the Permit to ensure data is reported to enable timely review by Natural Resources Wales to ensure compliance with permit conditions and to monitor the efficiency of material use at the installation.

Operating techniques

We have specified that the Installation must be operated in accordance with the techniques set out in table S1.2 of the Permit. The details referred to in that table describe the techniques that will be used for the operation of the Installation that have been assessed by Natural Resources Wales as BAT; they form part of the Permit through condition 2.3.1 and Table S1.2 in the Permit Schedules.

We have reviewed the techniques used by the operator and compared these with the relevant guidance notes. The relevant guidance notes for this installation are:

- How to comply with your environmental permit;
- How to comply with your environmental permit, Additional Guidance for: Speciality Organic Chemicals Sector; and
- BRef document – Manufacture of Organic Fine Chemicals (OFC).

The Installation is designed, constructed and operated using Best Available Techniques (BAT) for the Manufacture of Organic Fine Chemicals. We are satisfied that the operating techniques being employed are BAT.

The production process involves the following eight functional phases;

1. Plasma pooling;
2. Removal of unwanted proteins;
3. Chromatography step #1;
4. Peptidic hydrolysis;
5. Chromatography step #2;
6. Pooling of sub-batches;
7. Pasteurisation; and
8. Formulation of active compound.

Some process stages, such as purification by chromatography will be automated using programmable chromatography systems (rigs). However, a MicroPharm Operator will be present to supervise all operations until the methods become established.

We are satisfied that appropriate management systems and management structures will be in place for this Installation, and that sufficient resources are available to the Operator to ensure compliance with all the permit conditions.

Accident Management Plan

There will be two liquid nitrogen tanks installed on site, each holding approx. 240-250L of liquid nitrogen. Both tanks have pressure relief valves and rupture disks to prevent explosions. The tanks will be installed to the following standards:

- British Compressed Gases Association (BCGA) Code of Practice 30;
- Pressure Systems Safety Regulations 20; and
- Pressure Equipment Directive.

The Applicant has submitted an Accident and Pollution Incident Management Plan with the Application. Considering this with other information submitted, we are satisfied that appropriate measures will be in place to ensure that accidents that have the potential to cause pollution are prevented, but that if they should occur their consequences are sufficiently minimised.

To ensure that the management system proposed by the applicant sufficiently manages the residual risk of accidents, permit condition 1.1.1(a) requires the implementation of a written management system which addresses the pollution risks associated with, amongst other things, accidents.

Site Security

The site has a large lockable entrance gate and perimeter fence installed to prevent unauthorised access. The nitrogen storage area will have a security fence and lockable gate to prevent any untrained personnel accessing the liquid nitrogen.

Having considered the information submitted in the Application, we are satisfied that appropriate infrastructure and procedures will be in place to ensure that the site remains secure.

Efficient use of raw materials, water and energy

The Operator cannot rework or recycle product as it would jeopardise patient safety. The Operator is required to report energy and water usage under condition 4.2 and Schedule 4. The following parameters are required to be reported: energy usage and consumption (per kg of product) and water usage and consumption (per kg of product). This will enable Natural Resources Wales to monitor energy recovery efficiency at the Installation.

Avoidance, recovery or disposal of wastes produced by the activities

A small amount of hazardous waste is produced and primarily includes yellow bag waste, sharps and glass. The wastes are stored appropriately on site awaiting collection by a licensed waste contractor. To reduce the amount of non-hazardous municipal waste produced, recycling will be encouraged and waste reduction targets will be incorporated into the EMS.

We are satisfied that waste from the Installation that cannot be recovered will be disposed of using a method that minimises any impact on the environment. Permit condition 1.4.1 will ensure that this position is maintained.

Operator Competence

MicroPharm operate a similar site in Newcastle Emlyn, Carmarthenshire (EPR/FP3437VK). MicroPharm Ltd has extensive understanding of the manufacture of anti-venom products. The application confirms that experienced personnel will be involved in the risk assessment, commissioning and training of employees at the proposed Installation.

There is no known reason to consider that the operator will not have the management systems to enable it to comply with the permit conditions. The decision was taken in accordance with RGN 5 on Operator Competence.

Relevant convictions

Our Enforcement Database has been checked to ensure that all relevant convictions have been declared. No relevant convictions were found. The operator satisfies the criteria in RGN 5 on Operator Competence.

Financial provision

There is no known reason to consider that the operator will not be financially able to comply with the permit conditions. The decision was taken in accordance with RGN 5 on Operator Competence.

OPRA

The OPRA score at permit issue is 65.

ANNEX 1: Consultation Responses

A) Advertising and Consultation on the Application

The Application has been advertised and consulted upon in accordance with Natural Resources Wales Public Participation Statement. The way in which this has been carried out along with the results of our consultation and how we have taken consultation responses into account in reaching our draft decision is summarised in this Annex. Copies of all consultation responses have been placed on Natural Resources Wales public register.

1) Consultation Responses from Statutory and Non-Statutory Bodies

Response Received from Public Health Wales	
Brief summary of issues raised:	Summary of action taken / how this has been covered
The Regulator should be satisfied that the relevant health and safety management controls and an annual assessment is satisfactory for the safe storage and management of liquid nitrogen. The risk of explosion and fire through inadequate management could be potentially fatal in the event of an emergency.	<p>There will be two liquid nitrogen tanks installed on site, each holding approx. 240-250L of liquid nitrogen. Both tanks have pressure relief valves and rupture disks to prevent explosions. The tanks will be installed to the following standards:</p> <ul style="list-style-type: none">• British Compressed Gases Association (BCGA) Code of Practice 30;• Pressure Systems Safety Regulations 20; and• Pressure Equipment Directive.

<p>We recommend that the site continue to work to current FRS guidance to ensure all measures within the EMS are up-to-date to prevent emergency situations.</p> <p>The site is within 2.5km of residential properties, with the closest property being 31m to the east, so the regulator should be satisfied that suitable management controls are included for all operations to ensure mitigation of noise and that procedures are adequate to investigate and respond to any complaints that may arise.</p>	<p>The nitrogen storage area will have a security fence and lockable gate to prevent any untrained personnel accessing the liquid nitrogen.</p> <p>The operator has provided a copy of their environmental policy. One of the main policy aims is to “Monitor environmental performance with the aim to continually improve”. The operator also has a preventative management plan to prevent emergency situations.</p> <p>The Permit contains condition 3.4.1 and 3.4.2 to prevent noise pollution outside the site. Where possible all relevant equipment is located within the main building.</p>
Response Received from Pembrokeshire County Council	
Brief summary of issues raised:	Summary of action taken / how this has been covered
<p><u>Noise proforma returned - Informed of planning condition at site.</u></p> <p>Condition 3 on planning permission 18/0988/PA</p> <p>The noise generated by the condenser and fresh air units shall not exceed the background noise level by more than 5 dB (A) at the nearest residential property to the development site at any time when measured and assessed in accordance with BS4142:2014.</p>	<p>The Permit contains condition 3.4.1 and 3.4.2 to prevent noise pollution outside the site.</p>

Methods for rating and assessing industrial and commercial sound.	
Reason: In the interest of amenity and to satisfy the relevant requirements of policy GN.1 from the Pembrokeshire Local Development Plan, adopted February 2013.	

2) Consultation Responses from Members of the Public and Community Organisations

a) Representations from Local MP, Assembly Member (AM), Councillors and Parish / Town / Community Councils

Response Received from	
Brief summary of issues raised:	Summary of action taken / how this has been covered
None	N/A

b) Representations from Community and Other Organisations

Response Received from	
Brief summary of issues raised:	Summary of action taken / how this has been covered
None	N/A

c) Representations from Individual Members of the Public

Response Received from	
Brief summary of issues raised:	Summary of action taken / how this has been covered
None	N/A