

Natural Resources Wales permitting decisions

**Protherics UK Limited -
Pharmaceutical Plant Blaenwaun,
Variation Application**

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Variation

The variation number is: **EPR/SP3338LF/V002**

The applicant /operator is: **Protherics UK Ltd**

The Installation is located at: **Blaenwaun, Ffostrasol, Llandysul, Ceredigion, SA44 5JT**

We have decided to issue the variation for Pharmaceutical Plant Blaenwaun operated by Protherics UK 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

The facility

The regulated facility is an installation which comprises the following activities listed in Part 2 of Schedule 1 to the Environmental Permitting Regulations and the following directly associated activities (DAA).

- S4.5 A1 (a) - Production of polyclonal antibody products and the manufacture of materials for clinical development.
- Steam supply Two 600 kW boilers fired on gas oil
- Purification of potable water for use in manufacturing process.

This variation is required to add the DAA for water purification and the associated discharge to surface water. Discharge to sewer was considered, however the nearest connection was >5 km away therefore it was cost prohibitive.

The site

The operator has provided a plan which we consider is satisfactory, showing the extent of the site of the facility including discharge points. The site plan differs slightly from what was originally permitted, this has been described as an administrative oversight and confirmation has been provided that this land is within the ownership of Protherics UK Ltd. As the discharge is already permitted this discharge has been incorporated within the wider Installation boundary.

A plan is included in the permit and the operator is required to carry on the permitted activities within the site boundary.

Biodiversity, Heritage, Landscape and Nature Conservation

The application is within the relevant distance criteria of a site of heritage, landscape or nature conservation, and/or protected species or habitat .

A full assessment of the application and its potential to affect the Natura 2000 designated Special Area of Conservation Afon Teifi SAC has been carried out as part of the permitting process. We consider that the application will not affect the features of the Afon Teifi SAC. An OGN 200 form 1 was completed and sent for consultation with the protected sites advisor for the Afon Teifi SAC, as a result we concluded that there is a direct pathway to the Afon Teifi SAC via a discharge to the Afon Chwechyr of mains water used in the water purification plant. A H1 screening assessment has been undertaken, all substances pass test 1 except for cadmium, chromium, copper, mercury and zinc. These five substances screen out at Test 2.

The tests used as part of the screening assessment are as follows:

Test 1: Does the concentration of the substance in the discharge exceed 10% of the Environmental Quality Standards (EQS)?

This test is devised to quickly screen out substances. If the concentration of the substance in the discharge is <10% EQS Annual Average (AA) and/or maximum allowable concentration (MAC), depending on which EQS(s) the substance has), the substance cannot cause more than 10% deterioration in the watercourse, even if it receives no dilution. This test can be carried out without needing to know upstream quality or flow information.

If the concentration of the substance in the effluent exceeds 10% of the EQS, it is potentially significant and should be carried forward to Test 2. If it does not, the substance is insignificant and is “screened out” i.e. it is not liable to cause pollution and requires no control.

Test 2: Does the Process Contribution (PC) exceed 4% of the EQS?

This step introduces the dilution available in the receiving watercourse.

Process Contribution (PC) is a test currently used when permitting installations which will now be used by all permitting regimes. PC is the concentration of a discharged substance in the receiving water after dilution. River flow data and the daily discharge volume are therefore required for this calculation.

The PC is calculated as follows:

$$PC = (EFR \times RC) / (EFR + RFR)$$

Where:

PC = Process Contribution (µg/l)

EFR = Effluent Flow Rate (m3/s)

For AA EQS use mean, for MAC EQS use maximum

RC = Release Concentration of the pollutant in the effluent ($\mu\text{g/l}$)

For AA EQS use mean concentration, for MAC EQS use maximum concentration.

RFR = Q95 River Flow Rate (m^3/s) (95% exceeded/low flow rate).

If the PC exceeds 4% of the EQS, it is potentially significant and should be carried forward to Test 3. If it does not, the substance is insignificant and is screened out i.e. it is not liable to cause pollution and requires no control.

As all substances screen out at both tests 1 and 2 they are considered insignificant and therefore not liable to cause pollution.

The project is not likely to have a significant effect on any Natura 2000 sites when considered alone, the possibility of significant effects in combination with other plans and projects were considered, however there were no other plans/projects that could act in combination with this discharge as all other discharges that could have an in-combination effect were to land and of inconsequential scale.

It was therefore concluded that the project would not have an adverse effect on the integrity of the SAC.

Environmental Risk Assessment

Water

A H1 assessment was carried out which showed that all parameters screened out after test two. NRW therefore have no concerns with regards to the parameters in the discharge. A generic risk assessment considering potential accidents, breakdowns and abnormal operations which could potentially have harmful effects was also provided. 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. We have therefore decided not to impose emission limits for this permit.

Operating techniques

Mains water is not sufficiently purified for use directly in the pharmaceutical manufacturing process and therefore treatment is required to ensure suitability of use. Treatment consists of filtration and distillation. The purified water (PFW) system produces a maximum of 2,000 litres per hour and has a holding capacity of 20,000 litres. Mains water is pumped via a sand filter and 5 micron filter into a polypropylene storage tank. It is then pumped through an Organic Scavenger unit, a 1µm filter and a 0.5 µm filter into the Purified Water Generation System. The water then passes through softener and two carbon cartridge filters into the break tank T35. It is then pumped into a reverse osmosis unit. From the reverse osmosis unit, the water is passed to a continuous electro-deionisation unit to two polypropylene 10,000 litre storage tanks fitted with hydrophobic vent filters via an ultraviolet light unit. The PFW is pumped from each tank, through another ultraviolet light unit and around two distribution loops (at a flowrate of approximately 12 m³ per hour) and returned to the storage tanks at approximately 19°C. Distribution loop A distributes PFW to the appropriate user points. Excess water not used in the purification process is discharged offsite into a surface water ditch that connects with the Afon Cwerchyr. This will reduce the volume of waste water by 21 m³ per day. Discharged water has no contact with any part of the production process other than the water purification plant. Flow is restricted to a maximum of 0.6 litres/second which will be diverted to an existing drainage ditch prior to release. Effluent sludge will be pumped out and removed via tanker.

We have reviewed the techniques used by the operator and compared these with the relevant guidance notes. The Operator has considered Best Available Techniques for Common Waste Water and Waste Gas Treatment/Management in the Chemical Sector 2003.

The Operator considered:

- Detailed assessment of the options to connect to local treatment facilities in conjunction with Welsh Water.
- Detailed assessment of water electrolysis options,
- Detailed assessment of the possibilities of segregating the most polluting waste streams at source.

The Operator has considered connecting to the nearest sewer treatment works at Ffostrasol, however this facility was too small to take the site effluent and requires phosphate to be removed on site. The next nearest treatment works at Llandysul was also considered, however this connection would require intermediate pumping stations.

Assessment of the electrolysis options concluded that it would not be technically feasible to reduce effluent contamination without additional treatment to directly discharge to the Afon Cwerchyr.

We consider the proposed techniques to represent appropriate techniques for the facility.

The permit conditions

Updating permit conditions during consolidation

We have updated previous permit conditions to those in the new generic permit template as part of permit consolidation. The new conditions have the same meaning as those in the previous permit.

The operator has agreed that the new conditions are acceptable.

OPRA

The OPRA score at permit issue is 90. This score will be used to derive future subsistence charges for the site.