

This form will report compliance with your permit as determined by an NRW officer

Site	Blaenwaun Pharmaceutical Plant	Permit Ref	SP3338LF		
Operator/Permit holder	Protherics UK Limited				
Regime	Installations				
Date of assessment	12/02/2019	Time in	N/A	Out	N/A
Assessment type	Check Monitoring/Sampling				
Parts of the permit assessed	4.2 - Annual Reporting				
Lead officer's name	Jenkins, Nicholas				
Accompanied by					
Recipient's name/position	Elaine Davies/ EHS Lead	Date issued	13/02/2019		

Section 1 – Compliance Assessment Summary

This is based on the requirements of the permit under the Environmental Permitting Regulations or the licence under the Water Resources Act 1991 as amended by the Water Act 2003. A detailed explanation is captured in "Compliance Assessment Report Detail" (Section 2) and any actions you may need to take are given in the "Action(s)" (section 4). This summary details where we believe any non-compliance with the permit has occurred, the relevant condition and how the non-compliance has been categorised using our Compliance Classification Scheme (CCS). CCS Scores can be consolidated or suspended where appropriate, to reflect the impact of some non-compliances more accurately. For more details of our CCS scheme, contact your local office.

Permit conditions and compliance summary	CCS Category	Condition(s) breached
G4 - Monitoring and Records, Maintenance and Reporting - Reporting and notification to Natural Resources Wales	A	

KEY: See Section 5 for breach categories, suspended scores will be indicated as such.
A = Assessed or assessed in part (no evidence of non-compliance), **X** = Action only,
O = Ongoing non-compliance, not scored.

Number of breaches recorded	0	Total compliance score (see section 5 for scoring scheme)	0
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If the Number of breaches recorded is greater than zero, please see Section 3 for our proposed enforcement response

Section 2 – Compliance Assessment Report Detail

This section contains a report of our findings and will usually include information on:

- The part(s) of the permit that were assessed (eg. Maintenance, training, combustion plant, etc)
- Where the type of assessment was 'Data Review' details of the report/results triggering the assessment
- Any non-compliances identified
- Any non-compliances with directly applicable legislation
- Details of any multiple non-compliances
- Information on the compliance score accrued inc.
- Details of advice given
- Any other areas of concern
- Any actions requested
- Any examples of good practice
- A reference to photos taken

This Compliance Assessment Report form has been created to review the operator's annual submission in line with section 4.2 of its environmental permit.

Permit condition 4.2.2 of Protherics' environmental permit requires the reporting on the performance of the activities over the previous year to be submitted to Natural Resources Wales by 31 January. Protherics submitted its annual report 28 January 2019.

Protherics' report is a template that has been created based on the original permit and subsequently reviewed. As such some sections are not required and refer to conditions that were removed at the end of 2017 when the permit was varied. However, some of the data is very useful and has been used in auditing the installation i.e. waste produced and recovered.

Protherics is required to provide:

A report or reports on the performance of the activities over the previous year shall be submitted to Natural Resources Wales by 31 January (or other date agreed in writing by Natural Resources Wales) each year. The report(s) shall include as a minimum:

- (a) a review of the results of the monitoring and assessment carried out in accordance with the permit including an interpretive review of that data;**
- (b) the annual production /treatment data set out in schedule 4 table S4.2; and**
- (c) the performance parameters set out in schedule 4 table S4.3 using the forms specified in table S4.4 of that schedule.**

Having reviewed the 2018 report against the same report for 2017, the following points have been identified:

- An increase of 179.3Kgs in the production of serum, however, the annual production output in 2017 report was confirmed as 317.04Kgs not 625.8Kgs as presented in 2018 report. This will need to be clarified.
- A decrease of 3% in electricity usage
- A decrease of 62% in specific energy consumption (electrical). There is a conversion error in the figure reported. It should read 3,279kWh/Kg DS or 3.279MWh/Kg DS
- A decrease of 17% in water usage
- A decrease of 67% in specific water consumption
- A decrease of 0.05% and 11.3% in total waste produced and total waste recovered

- A decrease of 20% in the production of hazardous waste recovered

All performance parameters presented provide evidence of an improvement on 2017 data which acknowledges the work that the EHS and Site Service team has implemented. However, we will need clarification of the annual production of drug output in 2017 as there is a discrepancy between what was reported in 2017 and the comparison in the 2018 report.

Action – Protherics to confirm the total drug substance output for 2017 by the end of February 2019.

[END]

EPR Compliance Assessment Report

**Report ID:
CAR_NRW0034640**

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Section 3 – Enforcement Response

You must take immediate action to rectify any non-compliance and prevent repetition. Non-compliance with your permit conditions constitutes an offence and can result in criminal prosecutions and/or suspension or revocation of a permit. Please read the detailed assessment in Section 2 and the steps you need to take in Section 4 below.

Section 4 – Action(s)

This section summarises the actions identified during the assessment along with the timescales for when they will need to be completed.

Criteria Ref.	CCS Category	Action required/advised	Due Date
See Section 1 above			

Section 5 – Compliance notes for the Operator

To ensure you correct actual or potential non-compliance we may

- Advise on corrective actions verbally or in writing
- Require you to take specific actions verbally or in writing
- Issue a notice
- Require you to review your procedures or management system
- Change some of the conditions of your permit
- Decide to undertake a full review of your permit

Any breach of a permit condition is an offence and we may take legal action against you

- We will normally provide advice and guidance to assist you to come back into compliance either after an offence is committed or where we consider that an offence is likely to be committed. This is without prejudice to any other enforcement response that we consider may be required.
- Enforcement action can include the issue of a formal caution, prosecution, the service of a notice and/or suspension or revocation of the permit.

See our Enforcement and Civil Sanctions guidance for further information

This report does not relieve the site operator of the responsibility to

- Ensure you comply with the conditions of the permit at all times and prevent pollution of the environment
- Ensure you comply with other legislative provisions which may apply

Non-compliance scores and categories

CCS category	Description	Score
C1	A non-compliance that could have a major environmental effect	60
C2	A non-compliance which could have a significant environmental effect	31
C3	A non-compliance which could have a minor environmental effect	4
C4	A non-compliance which has no potential environmental effect	0.1

Operational Risk Appraisal (Opra) - Compliance assessment findings may affect your Opra score and/or your charges. This score influences the resource we use to assess permit compliance.

Section 6 – General information

Data protection notice

The information on this form will be processed by the Natural Resources Wales (NRW) to fulfil its regulatory and monitoring functions and to maintain the relevant public register(s). The NRW may also use and/or disclose it in connection with:

- Offering/providing you with its literature/services relating to environmental matters
- Consulting with the public, public bodies and other organisations (eg. 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 its service
- Freedom of Information Act/Environmental Regulations request

The NRW may pass it on to its agents/representatives to do these things on its behalf. You should ensure that any persons named on this form are informed of the contents of this data protection notice.

Disclosure of information

The NRW will provide a copy of this report to the public register(s). However, if you consider that any information contained in this report should not be released to the public register(s) on the grounds of commercial confidentiality, you must write to your local area office within fifteen working days of receipt of this form indicating which information it concerns and why it should not be released, giving your reasons in full.

Customer charter

What can I do if I disagree with this compliance assessment report?

If you are unable to resolve the issue with your site officer, you should firstly discuss the matter with officer's line managers using the informal appeals procedure. If you wish to raise your dispute further through our official Complaints and Commendations procedure, phone our general enquiry number 0300 065 3000 (Mon to Fri 08.00 – 18.00) and ask for the Customer Contact team or send an email to enquiries@naturalresourceswales.gov.uk. If you are still dissatisfied you can make a complaint to the Public Services Ombudsman for Wales. For advice on how to complain to the Ombudsman phone their helpline on 0845 607 0987.

Welsh Language

If you would like this form in Welsh please contact your Regulatory Officer.