Compliance Assessment Report

Report ID: CAR_NRW0036305

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	07/02/2020	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	Bacon-Weekes, Liane				
Accompanied by					
Recipient's name/position	Elaine Davies/ EHS & Site Services Manager	Date issued	10/02/2020		

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

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

The objective of this Compliance Assessment Report (CAR) is to record our review of the annual reporting submissions to NRW, in line with condition 4.2 of the environmental permit

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Condition 4.2.1 states:

> *The operator shall send all reports and notifications required by the permit to Natural Resources Wales using the contact details supplied in writing by Natural Resources Wales*

Condition 4.2.2 states:

> *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.*

Schedule 4 of the permit provides the parameters, for which reports shall be made, in accordance with conditions of the permit. No emission monitoring is required.

Table S4.1 Reporting of monitoring data

Parameter	Emission or monitoring point/reference	Reporting period	Period begins
None	-	-	-

Table S4.2: Annual production/treatment

Parameter	Units
Production of serum	Kg/year

Table S4.3 Performance parameters

Parameter	Frequency of assessment	Units
Water usage	Annually	tonnes
Energy usage	Annually	MWh
Specific water consumption	Annually	m^3 water / kg serumkg serum
Specific energy consumption	Annually	MWh energy / kg serum

Table S4.4 Reporting forms

Media/parameter	Reporting format	Date of form
Water usage	Form water usage 1 or other form as agreed in writing by Natural Resources Wales	01/11/06
Energy usage	Form energy 1 or other form as agreed in writing by Natural Resources Wales	01/11/06
Other performance indicators	Form performance 1 or other form as agreed in writing by Natural Resources Wales	01/11/06

The 2019 Annual Report was submitted on 20th January 2020, and compliant with the 31st January 2020 deadline. The annual report (Ref: WAL-SP-19.022-F01) provides details on the following:

Production of Serum

During the 2019 production period, there was an increase of 18.6 % in the manufacturing productivity in comparison to 2018 figures

Annual production output of drug substance (Kg) for 2018	805.1 Kg
Annual production output of drug substance (Kg) for 2019	988.5 Kg
Percentage change from previous year:	18.6 % Increase
Comments	The production output between 2018 and 2019 increased by 183.4 Kg in 2019.

Water Usage

The water usage for 2019 has been retrieved from the two Welsh Water meters servicing the site. In 2018, Protherics / BTG implemented a water saving initiative on the site, to date several projects have been completed. The water saving initiative remains ongoing and future projects have been identified.

Water Source	Usage (M^3/Year)	Percentage change over previous year	Specific Usage (m^3/Kg serum)
Mains Water	17,242.2 M^3	4.2% **Reduction**	17.44 m^3/kg DS
Total Water Usage	17,242.2 M^3		

Energy usage

The energy usage on site continues to show a decrease in comparison to 2018 figures by 6%. The decrease in electrical usage may be attributable to the implementation of energy saving devises introduced throughout site during this review period. The site introduced several lighting PIR's to walkway and offices and exchanged several lighting areas with energy efficient systems.

There has been a 12% reduction in the Gas Oil figures in comparison with 2018 figures per (2019 - 287.6L compared with 2018 - 400.1 L) per Kg of OS. The economical steam generators are attributable for the reduced oil usage while initiatives continue to review and reduce in all areas of the energy usage.

LPG is no longer utilised on site and the storage tank has been removed.

Energy Source	Quantity	Specific Usage	Percentage change over previous year
LPG	N/A	N/A	N/A
Electricity	2,480,139 kWh	2509.0 MWh /Kg DS	6% Reduction
Gas Oil	284,265 Litres	287.6 Litres/Kg DS	12% Reduction

Waste Comparison 2019

Waste Comparison for 2019 table shows variances in the waste produced between the two reporting periods however; the percentage of waste recovered shows a slight increase from the 2018 period with 4.9% higher production in 2019.
In addition, the comparisons between 2018 and 2019 shows an increase in Hazardous waste and reduction in Trade Effluent production. The information regarding the trade effluent has been determined via the amounts tankered away in 2019.

Previous Year	2018	Percentage change from previous year
Total Waste Produced (kg)	98,905 Kg	0.05% less than 2017
Total Waste recovered (kg)	50,230 kg	11.30 % higher than 2017
Recovery percentage (kg)	56.55 %	11.36 % higher than 2017
Total Hazardous Waste	25,636 Kg	(2017 total 32,386.00 Kg) 20.1 % less than 2017
Total Liquid Trade Effluent Produced	7,810,194 Kg	(2017 total 9,355,604 Kg) 17 % less than 2017

Current Year	2019	Percentage change from previous year
Total Waste Produced (kg)	103,917 Kg	4.9 % higher than 2018
Total Waste recovered (kg)	66,250 kg	15.6 % higher than 2018
Recovery percentage (kg)	65.69 %	13.9 % higher than 2018
Total Hazardous Waste	34,957 kg	26.7 % higher than 2018
Total Liquid Trade Effluent Produced	5,822,205 kg	25.5 % **lower** than 2018

I have reviewed the above figures and unsure if the percentage increase/decrease results are correct. The percentage increase / decrease is established using the previous 2018 figure and not the latest from 2019. Please can you clarify how these figures have been calculated and amend if required.

It is positive to see that there have been continued improvements in 2019.

END.

Cyfoeth Naturiol Cymru Natural Resources Wales	**EPR Compliance Assessment Report**	**Report ID: CAR_NRW0036305**

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Site	Blaenwaun Pharmaceutical Plant	Permit Ref	SP3338LF
Operator/Permit holder	Protherics UK Limited	Date	07/02/2020

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.