

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

Details				
Company:	MicroPharm Limited	Station Road Industrial Estate, Newcastle Emlyn, Carmarthenshire SA38 9BY		YEAR: 2021
	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. LII criteria: $\leq 50\text{ m}^3$ (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: $\leq 1\text{ m}^3$ (1000 L) of trade effluent per day	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: - Review and revision of EMS documents - Completion of EMS documents including annual return
B	Aqueous waste		Up to 200 L (0.20 m³) per day Equivalent to 73 000 L (73 m³) per year	29 200 L equivalent to 80 L (0.080 m³) 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

	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.	No instances of emission during the last year		
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	Total non-hazardous waste: < 2 000 kg (2 tonnes) per year Equivalent to 5.5 kg per day Total hazardous waste: < 400 kg (0.4 tonnes) per year Equivalent to 1.1 kg per day	Recycling waste	5 650 kg	See note 2.1
				General waste	440 kg	See note 2.2
				Total non-hazardous waste	6 090 kg (6.09 tonnes) This is equivalent to ~17 kg per day See notes 2.3 and 2.4	
				Hazardous waste waste in yellow bags	1 490 kg	See note 3.1
				Hazardous waste 'sharps' containers	155 kg	See note 3.2
				Hazardous waste glass containers	165 kg	See note 3.3
				Hazardous waste chemical waste	610 kg	See note 3.4
Total hazardous waste	2 420 kg (1.35 tonnes) This is equivalent to 6.6 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)	Total annual consumption: Day = 84 766 kW-h Night = 34 412 kW-h Total = 119 178 kW-h Maximum demand = < 40 kVA			

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.	Several solutions are stored in volumes >50L; these include: • Filtered water in 200L tanks (no risk to environment) • Low molarity buffers comprising sodium salts • Sodium hydroxide, 0.1M, 0.5M, and 1M The rooms are sealed, so liquid spillages cannot enter surface, ground, or foul water. No spillages or incidents have occurred. Spillage kits are available.
H Noise	No noticeable noise from installation outside installation boundary.	Air Handling Unit is acoustically shielded (Environmental Health Department requirement at time of construction). No complaints from nearby residents.	A new external temperature-controlled unit (TCU) was installed during 2019. It comprises an insulated container and air-conditioning (A/C) unit. 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)]. The situation will be monitored during use. No complaints have been received.
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.	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. Liquid pollution – not applicable	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/m ³ as it emerges from the cleanroom air handling system into the environment (this is based on the efficiency of the HEPA filters). No large volumes are produced.



	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 2021.

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 10L 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 – there was a constant increase between 2015 and 2018 due to business expansion and increased market demands. However, volumes decreased in 2019 and again in 2020. The latter was partially caused by the COVID-19 pandemic. Volumes increased again in 2021 because manufacturing activities recommenced following temporary suspension in 2020 (due to COVID-19 pandemic). 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 is collected fortnightly by CWM. 2.2. General waste is collected by CWM and 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. Manufacturing activities recommenced in 2021 following temporary suspension in 2020 (due to COVID-19 pandemic). 2.4. Our average daily amount of 17 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.
	3.2.	Waste in 'sharps' containers is collected by 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.
	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 Summerleaze (for incineration) and recorded on hazardous waste consignment notes.
	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.) 30 L chemical bins until full. They are collected by Summerleaze when requested; details are recorded separately on hazardous waste consignment notes. In addition, quarterly waste reports are provided.
	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. Manufacturing activities recommenced in 2021 following temporary suspension in 2020 (due to COVID-19 pandemic).
	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 6.6 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 2021) 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 5kW 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 14kW for the cleanroom HVAC (heating, ventilation, and air-conditioning).
	4.4.	The electricity supplier has not provided 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	25/07/2022
------------------------------------	----------------	------------

