

ANNUAL RETURNS FORM



Details

Company:	MicroPharm Limited	Station Road Industrial Estate, Newcastle Emlyn, Carmarthenshire SA38 9BY	YEAR:	2022
	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.	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	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	Up to 200 L (0.20 m^3) per day Equivalent to 73 000 L (73 m^3) per year	16 605 L equivalent to 46 L (0.046 m^3) 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

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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.	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	6 050 kg	See note 2.1
			General waste	370 kg	See note 2.2
			Total non-hazardous waste	6 420 kg (6.42 tonnes) This is equivalent to 17.6 kg per day See notes 2.3 and 2.4	
			Hazardous waste waste in yellow bags	970 kg	See note 3.1
			Hazardous waste 'sharps' containers	140 kg	See note 3.2
			Hazardous waste glass containers	90 kg	See note 3.3
F Energy consumption	This equates to: Non-hazardous: < 365 000 kg/year Hazardous < 3 650 kg/year Energy must note be consumed at a rate greater than 3 MW (3000 kW)	0.10 MW peak consumption	Hazardous waste chemical waste	240 kg	See note 3.4
			Total hazardous waste	1 440 kg (1.35 tonnes) This is equivalent to 3.9 kg per day See notes 3.5 and 3.6	
			Total annual consumption: Day = 84 179 kW-h Night = 34 416 kW-h Total = 118 595 kW-h Maximum demand = < 40 kVA	See note 4.4	

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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 external 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)].
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	The situation will be monitored during use. No complaints have been received. 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/m³ 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.

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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 2022.

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 10 L 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; this is mainly dictated by market demands for our products. Volumes in 2022 were lower than volumes in 2021. 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. 2.4. Our average daily amount of 17.6kg is well within the terms of our permit (1000 kg per day).

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. 90% of the waste is recovered and 10% goes to landfill.
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.) 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. However, waste is directly proportional to manufacturing activities; this is mainly dictated by market demands for our products.
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 3.9 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 2022) 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 5 kW 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 14 kW for the cleanroom HVAC (heating, ventilation, and air-conditioning).
4.4.	The electricity supplier does not provide 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

Michele Gamage 26/07/23

