

Subsidiary Permit 1 with introductory note

Environment Protection Act (CAP. 549);
Industrial Emissions (Framework) Regulations, S.L.549.76;
Industrial Emissions (Integrated Pollution Prevention and Control) Regulations, S.L.549.77.

Installation	Medichem Manufacturing (Malta) Ltd & Combino Pharm (Malta) Ltd.
Operator	Medichem Manufacturing (Malta) Ltd HF-61, Hal Far Industrial Estate Hal Far BBG 3000
Approved Documents:	Permit number IP 0002/05/E – framework document Sub-permit numbers IP 0002/05/Ei– Medichem Manufacturing (Malta) Ltd. IP 0002/05/Eii – Combino Pharma (Malta) Ltd.

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Introductory note

The following Permit is issued under Regulation 7 of the Industrial Emissions (Framework) Regulations, 2013 (S.L.549.76) (“the Industrial Emissions (Framework) Regulations”) to operate an installation carrying out activities covered by the description in Section 4.5 in Schedule 1 of the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77), to the extent authorised by the Permit, i.e.

“Production on an industrial scale by chemical or biological processing of pharmaceutical products including intermediates”.

Aspects of the operation of the installation which are not specifically regulated by conditions in the Permit may also be subject to the condition implied by Regulation 8 the Industrial Emissions (IPPC) Regulations, which require the Operator to use the best available techniques for preventing or, where that is not practicable, reducing emissions from the installation.

Conditions marked with a ‘∞’ shall be construed as conditions which are to be enforced by the Authority responsible for such an issue.

Techniques include both the technology used and the way in which the installation is designed, built, maintained, managed, operated and decommissioned.

In some sections of the Permit conditions require the Operator to use Best Available Techniques (BAT), in each of the aspects of the management of the installation, to prevent and where that is not practicable to reduce emissions. These conditions do not explain what is BAT.

A non-technical description of the installation is given in the Application, but the main features of the installation are summarized as follows:

- **Production of basic pharmaceutical products (Active Pharmaceutical Ingredients – APIs).**

Note that the Permit requires the submission of certain information to the Competent Authority. In addition, the Competent Authority has the power to seek further information at any time under regulation 11 of the Industrial Emissions (Framework) Regulations, provided that it acts reasonably.

Other IPPC Permits relating to this installation		
Permit holder	Permit Number	Date of Granting
<i>Not applicable</i>		

Superseded Licences/Authorisations/Consents relating to this installation		
Holder	Reference Number	Date of Granting
<i>Medichem Manufacturing (Malta) Ltd</i>	<i>IP 0002/05/A</i>	<i>20 October 2005</i>
<i>Medichem Manufacturing (Malta) Ltd</i>	<i>IP 0002/05/B</i>	<i>12 June 2009</i>
<i>Medichem Manufacturing (Malta) Ltd</i>	<i>IP 0002/05/C</i>	<i>11 January 2010</i>
<i>Medichem Manufacturing (Malta) Ltd</i>	<i>IP 0002/05/D</i>	<i>12 December 2013</i>

Public Registers

This IPPC Permit and application is available to the public through the Competent Authority website in accordance with the requirements of the Industrial Emissions (IPPC) Regulations. Certain information may be withheld from the public where it is commercially confidential or contrary to national security. The applicant has made a request for certain information of a commercial nature to be withheld from the public. ERA has been supplied with all this information and has accepted the request of the applicant, because it was deemed to be commercially confidential.

Multiple Operator installations

As indicated in Regulation 6(3) of S.L. 549.76¹, a permit may regulate several parts of an installation operated by different Operators. The importance of integrating the operations of each technical unit stems from the definition of “installation” in the provisions of S.L. 549.76, where this is defined as “a stationary technical unit within which one or more activities listed in the regulations concerning integrated prevention and control or in the regulations concerning organic solvents are carried out, and any other directly associated activities on the same site which have a technical connection with these activities and which could have an effect on emissions and pollution”.

In accordance to guidance provided by the Commission, an activity is considered to be a directly associated activity with a Schedule 1 activity if it shares common features, for example: it is part of the same industrial complex; it operates in the same or a related sector; or operates with some collective aspects such as site security.

This installation is therefore being regarded as a multi operator installation.

Functions of the permit

This **Subsidiary Permit 1** (IP0002/05/Ei) which addresses the operations carried out by Medichem Manufacturing (Malta) Ltd., shall be regarded as part of the Permit IP00002/05/E which consists of three main parts structured as follows:

- **The Framework Permit** addressing the obligation of all Operators and coordinating these obligations due to the nature of the facility as a multi-operator installation (IP 0002/05/E).
- **Subsidiary Permit 1** addressing the operation carried out by Medichem Manufacturing (Malta) Ltd. (IP 0002/05/Ei).
- **Subsidiary Permit 2** addressing the operations carried out by Combino Pharm (Malta) Ltd. (IP 0002/05/Eii).

Variations to the Permit

This Permit may be varied at any time in the future (by the Authority serving a Variation Notice on the Operator). If the Operator wants any of the Conditions of the Permit to be changed, a formal Application must be submitted to ERA. The Status Log within the Introductory Note to any such Variation Notice will include summary details of this Permit, variations issued up to that point in time and state whether a consolidated version of the Permit has been granted.

¹ S.L 549.76 – Industrial Emissions (Framework) Regulations, 2013

Surrender of the Permit

Before this Permit can be wholly or partially surrendered, an Application to surrender the Permit has to be made to the Competent Authority by the Operator. For the application to be successful, the Permit Holder must be able to demonstrate to the Authority that there is no pollution risk and that no further steps are required to return the site to a satisfactory state.

The Permit Holder shall notify the other Operators within the installation of any such intent so as to enable these entities to assess the impact of this proposal on their operations and on any obligations arising from either the Framework Permit or the Operator specific Subsidiary Permits.

Transfer of the Permit or part of the Permit

Upon the joint application of a Permit Holder and a proposed transferee, the Permit Holder may request to transfer an environment permit. The permit shall not be transferred from the Permit Holder without prior approval from the Authority. Upon the Authority's decision to transfer the permit to the transferee, all rights, obligations, liabilities shall subsist onto the transferee.

The Permit Holder shall notify the other Operators within the installation of any such intent so as to enable these entities to assess the impact of this proposal on their operations and on any obligations arising from either the Framework Permit or the Operator specific Subsidiary Permits.

Status Log

Detail	Date	Comment
Application IPPC 0002/05	Received November 2004	
Response to request for information	Request dated: 01-12-04 01-07-05 19-07-05 20-07-05 25-07-05 26-07-05	Response dated: 17-12-04 05-07-05 19-07-05 20-07-05 26-07-05 27-07-05
Permit determined	August 2005	Permit number: <i>IP 0002/05/A</i> Permit issued <i>20 October 2005</i>
Variation determined	26 February 2009	Changes in conditions related to air emissions, sewer discharge conditions, noise monitoring and reporting requirements. Permit number: <i>IP 0002/05/B</i> Permit issued <i>12 June 2009</i>
Renewal and variation determined	15 October 2009	Permit number: <i>IP 0002/05/C</i> A consolidated version is being issued. Permit issued <i>11 January 2010</i>

Detail	Date	Comment
Application for renewal and variation (to include a 4,000 litre reaction vessel, kilo lab and pre-fabricated HPAI lab)	Application received 10 April 2013	Application considered 'Duly Made' on 26 April 2013. Public Consultation held between 18 May – 01 June 2013.
Renewal and variation determined	5 December 2013	
Permit issued	12 December 2013	Permit expires on 12 December 2018
Permit validity extended	11 th January 2019	From 11 th January 2019 to 11 th July 2019
Permit validity extended	26 th July 2019	From 26 th July 2019 to 26 th July 2020
Permit validity extended	24 th July 2020	From 24 th July 2020 to 26 th January 2021
Application IP 0002/05/E for the relocation of QC lab from Medichem Manufacturing (Malta) Ltd. to Combino Pharm (Malta) Ltd. and the consideration of both operations as a multi-operator permit	5 March 2019	
Application duly made	17 November 2020	
Public consultation	Commenced on 18 November 2020	Concluded on 2 December 2020
Permit Determined	15 th January 2021	

End of Introductory Note

Permit

Permit number

IP 0002/05/Ei

Approved documents

- IP 0002/05/E/DOC 1
- IP 0002/05/Ei/DOC 2

The Environment and Resources Authority (hereinafter the Authority; the Competent Authority or ERA) in exercise of its powers under Regulation 7 of the Industrial Emissions (Framework) Regulations, (S.L.549.76) ("the Industrial Emissions (Framework) Regulations"), hereby authorises:

Dr. Dino Mangion obo Medichem Manufacturing (Malta) Ltd. (hereinafter "The Permit Holder"),

of/ whose Registered Office (or principal place of business) is at

HF-61, Hal Far Industrial Estate, Hal Far BBG 3000

(Company registration number: **C 33743**)

to operate an installation at

HF-61, Hal Far Industrial Estate, Hal Far BBG 3000

to the extent authorised by and subject to the conditions of this Permit.

The permit is valid for a period of four (4) years from the date of the granting. The Permit Holder is able to renew the permit upon application with the Authority expressing his/her intention at least nine (9) months prior to the expiry of this permit. The permit will be considered renewed once the official renewed permit is issued by the Authority

Environment and Resources Authority	
APPROVAL	
Board No. _____ Held on _____	
Chairman _____ Secretary _____	
Date Granted:	
24/3/2021	

Authorised to sign on behalf of the Competent Authority

Conditions

1 General

This permit shall be read in conjunction with the Regulatory framework Permit and the Subsidiary Permits issued to Medichem Manufacturing (Malta) Ltd. and Combino Pharm (Malta) Ltd., together with the Regulatory Framework Permit which together comprise permit IP 0002/05/E.

1.1 Permitted Activities

- 1.1.1 The Operator is authorised to carry out the activities and the associated activities specified in Table 1.1.1.

Table 1.1.1		
Activity listed in Schedule 1 of the Industrial Emissions (IPPC) Regulations / Associated Activity	Description of specified activity	Limits of specified activity
Section 4.5: Production of basic pharmaceutical products (Active Pharmaceutical Ingredients – APIs)	Synthesis of potent and non-potent active pharmaceutical ingredients (APIs).	From receipt of raw materials to despatch of finished product (including packing). Does not include the manufacture of any radioactive APIs.
Associated activity of research and development	Research and development laboratories for active pharmaceutical ingredients.	From receipt of raw materials to research and development of non-potent and high potency APIs. Does not include the research and development of any radioactive APIs.

Associated activity of utilities	<p>Dual fuel boiler to produce steam and hot water.</p> <p>Emergency electricity generator (gas oil) for provision of electricity in case of power failure.</p> <p>Reverse osmosis plant.</p> <p>Provision of air supplies, coolants, nitrogen, solvent/mother liquor storage tanks an external storage of raw material.</p> <p>Associated activity of mitigation of emissions including operation of a wet scrubber and condensers.</p> <p>Associated activity of incidents and runaway reactions including the operation of blow-down tanks.</p>	<p>From receipt of fuel to delivery of utility.</p> <p>From receipt of fuel to delivery of utility.</p> <p>From receipt of water to delivery of utility.</p> <p>From receipt of chemicals to delivery of utility.</p> <p>Mitigation of emissions from the installation as well as solvent recovery.</p> <p>Mitigation of emissions and incidents from the installation.</p>
Associated activity of the storage, treatment or disposal/export of waste materials	Handling, storage and treatment/disposal/export of wastes from the installation.	From generation of waste to final disposal or recycling onsite or offsite.
Associated activity of wastewater treatment plant	<p>Treatment of liquid effluents through the following physico-chemical:</p> <ul style="list-style-type: none"> - pH correction - Coagulation - Flocculation - Sedimentation - Filtration at high pressure - Sludge formation and separate disposal 	From release from the main and associated activities to final disposal offsite.

1.2 Site

- 1.2.1 The activities authorised under condition 1.1.1 shall not extend beyond the Site, as shown in the Site Plan in Schedule 2 to this Permit.
- 1.2.2 Site security systems shall be implemented at all times during the subsistence of this Permit, the objective of which shall be to prevent access which is not authorised either by the Permit Holder or under legal powers of entry. These shall be installed, operated and maintained, and shall be fully documented and recorded.

1.3 Improvement Programme

- 1.3.1 The Permit Holder shall complete the improvements specified in Table 1.3.1 by the date specified in that table, and shall send written notification of the date of completion of each requirement to the Authority on ced.facilities@era.org.mt within 10 working days of the completion of each such requirement.

Table 1.3.1: Improvement programme		
Reference	Requirement	Date
7	a) Identification of waste gas pollutants and implementation of a waste gas stream inventory in line with the requirements of BAT 2 and BAT 16 of the CID 2016/902 [Establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU for common waste water and waste gas treatment /management systems in the chemical sector	a) Within six months of the granting of the permit
	b) Depending on the outcome of item (a), a revised monitoring proposal to reflect established best available techniques, as applicable	b) Within nine months of approval of 7a)
	c) Depending on the outcome of item (a), submission of a monitoring results to reflect established best available techniques.	c) Within twelve months of 7b)
8	Submission of a noise monitoring plan in line with Schedule 2 of IP002/05/E	Within three months of granting of the permit
	Implementation of a noise monitoring exercise and submission of the report.	By end 2021
9	Submission of the monitoring proposal for a one-time air emission monitoring exercise from the fume hood exhaust vent (PS 8)	By 31 December 2021
10	Ultrasonic testing of shell thickness on tanks and pipework.	By end 2024

1.4 Operational Changes

- 1.4.1 In furtherance to condition 1.5.1 in the framework permit (IP0002/05/E), operational changes shall include but not be limited to:
- a) Installation of new reactors, centrifuges, driers and other equipment;
 - b) Inclusion of new production lines or process areas

1.5 Approval procedure for new production processes

- 1.5.1 Prior to the production of any new Active Pharmaceutical Ingredient other than those approved by the Authority, the Operator shall notify the Authority 1 month prior to the start of production and submit the following documentation:
- i. Safety Data Sheets for the raw materials, intermediates and final product.
 - ii. An Emission Diagram detailing the production process and associated mitigation measures for the identified emissions.
 - iii. A mass flow calculation in the case of the use of solvents carrying the hazard statements indicated in conditions 2.1.8 and 2.1.9.

The production process shall also place due consideration to the Organic Fine chemicals BREF document in the development of such a process.

1.6 Pre-Operational Conditions

- 1.6.1 There are no pre-operational conditions.

1.7 General Conditions

- 1.7.1 The permit is granted against a Bank Guarantee of €15,025 which shall be renewed annually. This guarantee will have to be maintained throughout the validity of the permit. Following renewal and/or variations to this permit, the Authority may require amendments to the Bank Guarantee.
- 1.7.2 The Bank Guarantee shall remain in place for the duration of validity of this permit and shall only be released upon confirmation of full compliance with the permit conditions by the Authority.
- 1.7.3 The Authority may take part or all of the bank guarantee if the Permit Holder fails to take the necessary action, or fails to fulfil his legal obligations under the Act or its subsidiary legislation thereof, in cases of non-compliance with these permit conditions, or in cases where environmental integrity is threatened. This bank guarantee is without prejudice to any environmental liabilities incurred by the Permit Holder through failure to adhere with permit conditions or any other works/activity carried out on site. Should the Authority forfeit the Bank Guarantee either in part or in full, the permit holder shall ensure that this is replenished without undue delay, in any case not exceeding 2 months from the date of forfeiture.
- 1.7.4 In cases where the bank guarantee does not cover the expenses incurred by the Authority to take any remedial action on the Permit Holder's behalf, the Permit Holder is to financially reimburse the Authority of all the expenses incurred within.
- 1.7.5 The operator shall submit a fixed annual fee of €750 and a variable addition reflecting ERA's cost for inspections. The latter variable component depends on the actual number of site inspections, which is determined by the

performance of the Permit Holder. The total annual contribution has to be paid annually before the anniversary of the date of issue of this permit.

- 1.7.6 Without prejudice to condition 1.7.3 the Authority may take any action deemed necessary including but not limited to the suspension of any activity/operation until investigations are concluded.

2 Operating Conditions

2.1 Emissions to Air

- 2.1.1 Emissions to air shall only arise from the emission points specified in Table 2.1.1 and Schedule 3.

Emission point reference (PS)	Source
1	Vent scrubber
2a	Vent atmospheric tank
2b	Vent atmospheric tank
2c	Vent atmospheric tank
3	Boiler
4a	HVAC plant exhaust
4b	HVAC exhaust from laboratory
5	Cooling Towers
6	Generator
7	Blowdown Tank
8	R&D Fumehoods vent

- 2.1.2 The limits for emissions to air for the parameters and emission points set out in Table 2.1.2 shall not be exceeded. These limits refer to dry gas and volume flows without dilution. The limits for the generator (PS3) are defined at a temperature of 273,15 K, a pressure of 101,3 kPa and after correction for the water vapour content of the waste gases and at a standardised O₂ content of 3%.

Emission point reference (PS)	Parameter	Limit	Minimum Monitoring Frequency
1	VOC (total organic carbon)	150 mgC /Nm ³	As per condition 2.1.8
1	Particulate matter	5 mg/ Nm ³	
1	Ammonia	10 mg/ Nm ³	Annual
1	HCl	7.5 mg/ Nm ³	Annual
1	Cl ₂	1 mg/Nm ³	Annual
1	HBr	1 mg / Nm ³	Annual
3	NOx	200 mg / Nm ³	As per condition 2.1.13
3	SOx	200 mg / Nm ³	
3	CO	-	

API Handling

- 2.1.3 There shall be no storage or handling of APIs in dry powder form in the storage areas unless storage is carried out in double polyethylene bags, closed with seals and re-packaged in polyethylene UN approved Drums. These shall only be handled and stored outside of such storage arrangements in the enclosed process rooms having dedicated extraction and room filtration as per condition 2.2.4 in the framework permit.
- 2.1.4 Emissions to air from all areas where high potency active pharmaceutical ingredients are handled shall be exhausted through abatement equipment having at least 99.9% efficiency. Handling of the high potency active pharmaceutical ingredients shall only take place within the prefabricated modular laboratory (kilo-lab) and the employed double closed system shall be maintained at all times.

Emissions from the Scrubbers

- 2.1.5 Regarding emissions of VOCs from organic solvents, the Installation shall comply with either of the following emission limits:
- i. A total emission limit value of 5% of the solvent input, or
 - ii. The emission limit value for waste gases as defined in Table 2.1.2 for PS1 and a fugitive emission value of 5% of the solvent input
- 2.1.6 Compliance with the total emission limit value or with the fugitive emission value is to be demonstrated in accordance with the guidance provided in Schedule IV of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.79) and as may be subsequently amended, and, the VOC Reporting Template in Schedule 4. The calculations shall take account of all organic solvents used within the installation, including raw materials used in the process and solvent used for cleaning the equipment.
- 2.1.7 Compliance with the waste gas emission limit value in Table 2.1.2 shall be demonstrated through a monitoring exercise carried out in accordance with Regulations 7 and 8 of the industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.79).
- 2.1.8 Discharges of VOCs which are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F where the mass flow of the sum of the compounds causing the risk labelling (H340, H350, H350i, H360D or H360F) is greater or equal to 10 g/hour, an emission limit value of 2 mg/Nm³ shall be complied with. The emission limit value refers to the mass sum of the individual compounds causing the risk labelling and these limits relate to dry gas and volume flows without dilution. Where the Permit Holder has not used such substances during a particular year, he shall notify the Authority as part of the Annual Environmental Report, and such monitoring shall not be required during that year.
- 2.1.9 Discharges from the scrubber of halogenated VOCs which are assigned or need to carry the hazard statements H341 or H351, and where the mass flow of the sum of the compounds causing the labelling is greater than or equal to 100 g/hour, shall comply with an emission limit value of 20 mg/Nm³. The emission limit value refers to the mass sum of the individual compounds and these limits relate to dry gas and volume flows without dilution. Where the Permit Holder has not used such substances during a particular year, one shall notify the Authority as part of the Annual Environmental Report, and such monitoring shall not be required during that year.

- 2.1.10 The Permit Holder shall monitor the parameters VOC (total organic carbon), Particulate matter listed in Table 2.1.2 and in Conditions 2.1.7 – 2.1.8 annually provided that the limits detected are within the emission limit values specified in Table 2.1.2 and Conditions 2.1.7– 2.1.8. Otherwise, monitoring shall be carried out at six-monthly intervals.
- 2.1.11 Discharges from the scrubber for chlorine, ammonia, hydrogen bromide and hydrogen chloride shall comply with an emission limit value listed in table 2.1.2. Where the Permit Holder has not used such substances or such parameters are not emitted as by-product waste gas streams from the production during a particular year, one shall notify the Authority as part of the Annual Environmental Report, and such monitoring shall not be required during that year.
- 2.1.12 Monitoring from the scrubber shall be carried out during production and should reflect the operational mode of the plant. Measurements for the parameters from PS1 shall be carried out according to Regulations 7 and 8 of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (549.79).

Combustion Plants

- 2.1.13 The Permit Holder shall ensure that the boiler (PS3) referred to in Table 2.1.2 is certified every 3 years by an independent warranted engineer or an accredited laboratory. The certification shall be submitted as part of the Annual Environmental Report (AER) with the first measurement taken within four months of the granting of the permit. The data shall at the least be kept for a period of six years.
- 2.1.14 Further to condition 2.1.13, the certification shall include measurement of Nitrogen oxides, Sulphur oxides and carbon monoxide.
- 2.1.15 Only LPG or diesel shall be utilised as a source of fuel for the boilers. The co-incineration of any material or additional fuel including engine or other waste oil is strictly prohibited. Any change in fuel type shall require the notification and approval of the Authority prior to commencement of its utilisation.
- 2.1.16 Should secondary abatement equipment be installed in order to meet the emission limit values indicated in Table 2.1.2, the Permit Holder is to keep a record proving the effective continuous operation of that equipment.
- 2.1.17 The Permit Holder shall submit certification for PS6, by an independent warranted engineer showing that the boilers are in good working condition every four years. The certifications shall be submitted as part of the Annual Environmental Report (AER).

Monitoring Provisions and Emergency considerations

- 2.1.18 The Permit Holder shall keep a record of and process all monitoring results in such a way as to enable the verification of compliance with the emission limit values set out in Table 2.1.2.
- 2.1.19 Further to conditions 2.1.10 - 2.1.13, the Authority may request that the frequency of monitoring increases.
- 2.1.20 The Permit Holder is allowed to analyse for the parameters in Table 2.1.2 using equivalent standard methods, unless an EN, EN ISO or ISO method is available for the relevant analyses. In case methods other than EN, EN ISO or ISO are intended to be used for the analyses listed in this table, the Permit

Holder shall seek the Authority's prior written approval in order to analyse for a particular parameter using any standard method.

- 2.1.21 All analysis shall be conducted by a laboratory accredited to at least EN ISO 17025:2017 and preferably for each and every test listed or alternatively, with a suitably calibrated measuring instrument. Copy of the laboratory's accreditation certificate or a valid instrument calibration certificate are to be provided to the Authority as part of the AER
- 2.1.22 For the emission monitoring of medium combustion plants, during each measurement, the plant shall be operating under stable conditions at a representative even load. In this context, start-up and shut-down periods shall be excluded.
- 2.1.23 For PS3 the Operator shall keep a record of annual operating hours and provide the Authority with such information in the format specified in the AER.

Fugitive emissions of substances to air

- 2.1.24 The Permit Holder shall use BAT so as to prevent or where that is not practicable to reduce fugitive emissions of substances to air from the Permitted Installation in particular from:
- process areas
 - storage areas including tank farms
 - buildings
 - pipes, valves and other transfer systems
 - open surfaces
 - solvent storage
 - process utilities plant
 - fire fighting water reception
 -
- provided always that the techniques used by the Permit Holder shall be no less effective than those described in the Application, where relevant.
- 2.1.25 A summary report on fugitive solvent emissions shall be submitted annually as part of the Annual Environmental Report of the installation and in the format specified in Schedule 1.

2.2 Cooling Tower Registration [∞]

- 2.2.1 Any new cooling tower on site shall be registered with the Environmental Health Directorate, within a timeframe agreed with the Environmental Health Directorate
- 2.2.2 The installation shall comply with the conditions set by the Environmental Health Directorate and with the provisions of the Control of Legionella Regulations, (S.L.465.03).
- 2.2.3 The Permit Holder shall abide to the following Minimum Disinfection and water monitoring conditions for cooling towers:
- a) Water of the cooling tower should be continuously treated with one or more biocides to effectively control the growth of micro-organisms including Legionella and with chemical or other agents to minimise scale formation, corrosion and fouling.
 - b) A chlorine-compatible bio-dispersant is added to the recirculating water of the cooling tower system and, that the system is then disinfected, cleaned and re-disinfected;

- i. immediately prior to initial start-up following commissioning, or any shut down period of greater than one month;
 - ii. at intervals not exceeding 6 months;
- c) At least every 6 months a sample of the recirculating water of the cooling tower system shall be tested for *Legionella* and at least every month for heterotrophic colony count, at a laboratory accredited for such tests (or other laboratory providing the equivalent performance and reliability). The results of such tests shall be submitted as part of the Annual Environmental Report of the installation in the format specified therein.

2.3 Discharges to the sewer [∞]

2.3.1 Emissions shall only arise from the emission point specified in Table 2.3.3, as described in the IPPC application.

2.3.2 Emissions of trade effluent to sewer shall only arise from the emission point specified in Table 2.3.2. Discharge of effluent to sewer shall only arise from the emission point in Schedule 3.

Table 2.3.2: Emission point to sewer		
Emission reference	point	Location of emission point
EM4b	Sewer discharge connection	Sewer discharge point

2.3.3 The Permit Holder shall:

- a. Monitor for the parameters found in Table 2.3.3 below and according to the frequency found in the same table, or as may be directed by the Water Services Corporation from time to time.
- b. Inform the Authority of any changes to the Sewer Discharge Permit of the installation or changes made by the Water Services Corporation to monitoring requirements or frequency of monitoring.
- c. Report discharges to the sewer as part of the Annual Environmental Report of the installation, in addition to any other reporting requirements set by the Water Services Corporation.

Table 2.3.3 : Parameters to be monitored and monitoring frequency to sewer				
Emission point reference	Substance Parameter	or	Monitoring frequency	Standard
Discharge point	Volume per year		Yearly	-
	Temperature		Each batch	-
	pH		Each batch	-
	Settleable solids		Yearly	-
	Suspended solids		Yearly	EN 872
	Total Kjeldahl Nitrogen		Yearly	EN 12260
	Sulphides and compounds releasing hydrogen sulphide on		Yearly	-

	acidification		
	Free and emulsified grease	Yearly	-
	Free Chlorine	Yearly	-
	Chloride	Each batch	-
	Total Sulphates	Yearly	-
	Total Boron	Yearly	-
	Chemical Oxygen Demand	Quarterly	-
	Biological Oxygen Demand	Quarterly	--
	Total Phosphorous	Yearly	

2.3.4 The Permit Holder shall collect waste water during other than normal operating conditions prior to the introduction of the waste water treatment plant

2.4 Noise

2.4.1 The level of noise emitted from the installation at all operational times shall not exceed the background noise level by more than 5dB.

2.4.2 Noise monitoring is to be carried out every 5 years, to ensure that the above limits are not exceeded. Noise monitoring shall also be carried out upon commissioning of any new equipment which in the opinion of the Authority has the potential to significantly increase noise emissions from the installation. The Permit Holder shall submit to the Authority a method statement for carrying out a Noise Monitoring Survey in line with the Terms of Reference provided in Schedule 2 of the Framework Permit (IP0002/05/E). Once the method statement is approved by the Authority, the noise monitoring survey shall be initiated.

2.4.3 Without prejudice to the requirements stipulated in Table 1.3.1, the next noise monitoring exercise shall be carried out by not later than 31 December 2021 or as agreed with the Authority.

2.5 Solvents

2.5.1 A monthly inventory of solvent usage shall be maintained on site, and be available for review by an authorised officer of the Competent Authority where requested.

2.5.2 This permit does not authorise the use of substances and preparations which because of their content of volatile organic compounds, are classified as carcinogens, mutagens, or toxic to reproduction, and are assigned or need to carry the hazard statements H340, H341, H350, H350i, H351, H360D or H360F other than those included in the submitted IPPC Application.

2.5.3 The Permit Holder shall submit to the Competent Authority, a plan for the replacement, as far as reasonably practicable for the process & relevant installation, of substances or preparations that are used in the installation and which, because of their content of VOCs are classified as carcinogens, mutagens or toxic to reproduction and are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F, shall be replaced by less harmful substances / preparations. Details of the substances that shall be used as replacements and timeframes for substitution shall be submitted to the Competent Authority for approval prior to substitution. A reduction programme shall be submitted to the Competent Authority on an annual basis together with the submission of the Annual Environmental Report.

2.5.4 The Permit Holder shall and examine options to replace substances or preparations listed in condition 2.5.2, a report of which shall be submitted to the Authority annually, together with the AER.

2.5.5 The Permit Holder shall, annually as part of the Annual Environmental Reports submit an updated list of the raw materials and generated waste streams being produced.

3 Reporting

3.1 The Permit Holder shall, within 6 months of receipt of written notice from the Authority, submit to the Authority a report assessing whether all appropriate preventive measures continue to be taken against pollution, in particular through the application of the best available techniques, at the installation. The report shall consider any relevant published technical guidance current at the time of the notice which is either supplied with or referred to in the notice, and shall assess the costs and benefits of applying techniques described in that guidance, or otherwise identified by the Permit Holder, that may provide environmental improvement.

4 Records

4.1 The Operator shall :

2.5.1.1 Maintain the raw materials list which shall be reported annually as per Schedule 1. As assessment of the production processes for suitable alternative materials to reduce environmental impact shall take place every four years prior to the renewal of the permit..

2.5.1.2 Submit waste minimisation audits and water use efficiency audits carried out at the installation every four years prior to the renewal of the permit..

2.5.1.3 Ensure that incoming water use is directly measured and recorded.

5 Interpretation

5.1 The interpretation and relevant expressions as defined in Section 6 of the Framework Permit (IP0002/5/E) shall also apply to this Subsidiary Permit.

5.2 Where any condition of this Permit refers to the whole or parts of different documents, in the event of any conflict between the wording of such documents, the wording of the Framework Permit shall prevail to the extent of such conflict.

Schedule 1
Annual Environmental Report

Important note

By this submission, you confirm that you give your explicit consent for the entire contents of this Annual Environment Report to be made available on the Authority's public website.

S1.1 Introduction

IPPC Permit Number	
Reporting Year (Calendar Year: January to 31 December)	1
Name and location of Site	
Brief description of activities at the site	

S1.2 Environment Management System

Please attach a supporting document with the following:

1. A summary of the installation's Environmental Policy containing the installation's environmental objectives and targets;
2. Summary of the Environmental Management Programme report (for the reporting year);
3. Summary of the Environmental Management Programme proposal (for the following year);
4. European Pollutant Release and Transfer Register Report (as per Condition 4.3 of the Framework Permit).¹

Tick (✓)

S1.3 Process Data**S1.3.1 Annual Summary**

	Units	Previous reporting year	Current reporting year
Quantity of product	tonnes		
Total Annual Energy Consumption (from electricity and other sources)	MWh		
Energy consumption per unit product	MWh/tonne of product		
Annual water consumption	m ³		
Water consumption per unit product	m ³ /tonne of product		
Annual quantity of waste produced	tonnes		
Waste produced per unit product	tonne waste/tonne product		

S1.3.2 Fuel consumption

	Units	Sulphur Content ²	Consumption	
			Previous Year	Current Year
Propane	m ³			
Diesel	m ³			

¹ The format used for reporting shall be that published in the Government Gazette (<http://www.doi.gov.mt/EN/gazetteonline/2007/07/gazts/GG%2013.7.pdf>)

² Specify units (e.g. as percentage, or mg/kg)

S1.3.3 List of Raw Materials

Raw Material	Risk phrase	Annual Quantity Used (kg)

S1.3.4 Data on ozone depleting substances and fluorinated greenhouse gases**Table 1: Registration of equipment**

Equipment code	Type of equipment	Use	Charge (kg)	Type of substance
EQ 1				
EQ 2				
EQ 3				
EQ 4				

Table 2: Maintenance Schedule¹

Data Submitted for each scheduled inspection ²	Equipment Code							
	EQ 1	EQ 2	EQ 3	EQ 4	EQ 5	EQ 6	EQ 7	Continue as required
Date of inspection								
All amounts of leakages detected (in Kg/ CO ₂ equiv ³)								
Actions taken to eliminate such leakages								
Quantity and nature of the substances involved								
Serial number of the personnel involved								
Quantities added ⁴ and/or recovered (in Kg/ CO ₂ equiv).								

¹ To note that equipment containing more than 3 kgs shall be inspected at least every 12 months, equipment containing more than 30 kgs shall be inspected at least every 6 months and equipment containing more than 300 kgs shall be inspected at least every 12 months.

² Table to be repeated for every scheduled inspection as per 'footnote 1' above.

³ Carbon Dioxide equivalent – use Annex 1 and Annex IV of EC517/2014 for calculation.

⁴ The quantities of added fluorinated greenhouse gases are from recycled or reclaimed stocks, please include the name and address of the recycling or reclamation facility and, where applicable, the certificate number

S1.4 Monitoring Data

S1.4.1 Emissions to air (PS1)

Parameter	Emission point reference	Limit Value	Total annual number of exceedances ¹		Concentration (Annual Average)			Total Annual Load		
			Previous year	Present year	Unit	Previous report	Current report	Unit	Previous report	Current report
Flow rate	1									
Total VOC (total organic carbon)	1	150 mgC/Nm ³	4	4	mgC/ m ³			kg		
VOCs: H340, H350, H350i, H360D or H360F where mass flow of sum of compounds ≥10 g/h ^{2,3}	1	2 mg/Nm ³	4	11	mg/ Nm ³					
Halogenated VOCs: H341 or H351 where mass flow of sum of compounds ≥100 g/h ^{5,10}	1	20 mg/Nm ³	11	11	mgC/Nm ³			kg		
Particulate matter	1	5 mg/ Nm ³			mg/ Nm ³					
Ammonia ⁶	1	10 mg/ Nm ³			mg/ Nm ³					
HCl	1	7.5 mg/ Nm ³			mg/ Nm ³					
Cl ₂	1	1 mg/Nm ³			mg/ Nm ³					
HBr	1	1 mg / Nm ³			mg/ Nm ³					

Name of laboratory where tests in this section have been carried out

¹ If the total number of exceedances exceeds 0, the value of each of these exceedances (for the reporting year) must be submitted in a separate report, together with action taken to regularise the situation. Where only one measurement was required to be made during the year, the total annual number of exceedances is taken to be zero if the measurement indicates compliance with the limit value.

² Where mass flow is <10g/h, appropriate calculations are required to confirm this.

³ Where the operator has not used such substances during a particular reporting period, a notification to this effect is required.

⁴ For these VOCs only, do any of the hourly averages exceed the emission limit value by more than a factor of 1.5? Only such values are considered as exceedances.

⁵ Where mass flow is <100g/h, appropriate calculations are required to confirm this.

⁶ Monitoring is required as per condition 2.1.16, where the operator has not used such substances or generated such substances during a particular reporting period, a notification to this effect is required.

Is this laboratory accredited (certified) for the above tests?	Yes <input type="checkbox"/> No <input type="checkbox"/>
--	--

Additional documentation to be submitted:

Accreditation certificate(s) of laboratory
 Calculations showing mass flow of VOCs with risk phrases R45, R46, R49, R60, or R61 (H340, H350, H350i, H360D or H360F) where mass flow of sum of compounds <10 g/h
 Calculations showing mass flow of halogenated VOCs with risk phrases R40 or R68 (H341 or H351) where mass flow of sum of compounds <100 g/h

Tick (✓)

S1.4.2 Emissions to air from PS3¹

Parameter	Emission point reference	Limit Value	Standard methodology used	Total annual number of exceedances ²		Concentration (Annual Average)			Flow rate	Total Annual Load (kg)	
				Previous reporting period ³	Present reporting period	Unit	Previous reporting period	Present reporting period	Nm ³ /h	Previous reporting year (kg)	Present reporting year (kg)
Carbon Monoxide	PS3	-				mgC/m ³					
Oxides of Nitrogen	PS3	200 mg/Nm ³				mg/Nm ³					
Oxides of Sulphur	PS3	200 mg/Nm ³				mg/Nm ³					

¹ Monitoring within 4 months of first issue of the permit, and every three years thereafter.

² If the total number of exceedances exceeds 0, the value of each of these exceedances (for the reporting year) must be submitted in a separate report, together with action taken to regularise the situation.

³ "Previous reporting period" is not applicable for the first reporting period.

Name of laboratory where tests in this section have been carried out	
Is this laboratory accredited (certified) for the above tests?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Additional documentation to be submitted:

Accreditation certificate(s) of laboratory	Tick (✓)

S1.4.3 Operating hours for boiler

Point Sources	Operating Hours during previous reporting year	Operating Hours during reporting year
PS3 (boiler)		

S1.4.4 HEPA Filter Integrity Monitoring

Date of Inspection	Differential Pressure							Continue as required
	HF1	HF2	HF3	HF4	HF5	HF6	HF7	
Week 1								
Week 2								
Week 3								
Continue as required								

Additional documentation to be submitted:

Efficiency certification	Tick (✓)
HF1	
HF2	
HF3	
HF4	
HF5	
Continue as required	

S1.4.5 Cooling tower monitoring

Parameter	Timeframe	Standard methodology used	Previous year	Current year
Heterotrophic colony count	1 st month			
	2 nd month			
	3 rd month			
	4 th month			
	5 th month			
	6 th month			
	7 th month			
	8 th month			
	9 th month			
	10 th month			
	11 th month			
	12 th month			
<i>Legionella</i>	1 st half			
	2 nd half			

Name of laboratory where tests in this section have been carried out	
Is this laboratory accredited (certified) for the above tests?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Additional documentation to be submitted:

Accreditation certificate(s) of laboratory Tick (✓)

S1.4.6 Discharges to sewer

Parameter ¹	Limit ¹⁷	Standard methodology used	Total annual number of exceedances ²		Concentration (Annual Average)			Total Annual Mass Emissions		
			Previous year	Present year	Units	Previous year	Present year	Units	Previous Year	Present Year
Volume			-	-	-	-	-	m ³		
Temperature										
pH										
Settleable solids										
Suspended solids										
Total Kjeldahl Nitrogen										
Sulphides and compounds releasing hydrogen sulphide on acidification										
Free and emulsified grease										
Free Chlorine										
Chloride										
Total Sulphates										
Total Boron										
Chemical Oxygen Demand										
Biological Oxygen Demand										
Total Phosphorous										

¹ As agreed with the Water Services Corporation, according to the Sewer Discharge Permit.

² If the total number of exceedances exceeds 0, the value of each of these exceedances (for the reporting year) must be submitted in a separate report, together with action taken to regularise the situation.

Describe any changes to the Sewer Discharge Permit of the installation or changes made by the Water Services Corporation to monitoring requirements or frequency of monitoring as per condition 2.3.3 of this subsidiary permit. Include and refer to any associated documentation as required.	
Name of laboratory where tests in this section have been carried out	
Is this laboratory accredited (certified) for the above tests?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Additional documentation to be submitted:

Accreditation certificate(s) of laboratory Tick (✓)

S1.4.7 Noise monitoring

Year when noise monitoring was last carried out	
Testing due in (year)	

Additional documentation to be submitted if test was carried out during previous reporting year:

Noise monitoring report according to BS 4142:2014 Tick (✓)

S1.6 Testing of site containment and drainage systems, and fuel transfer system

	Number on site	Date of last test	Certification submitted (Tick ✓)	Testing due on (date)
Catchment pits				
Bunds				
Pipes				
Pumps				
Valves				
Flanges				
Others: (specify)				

Additional documentation to be submitted if test was carried out during previous reporting year:

Certification by warranted architect or engineer Tick (✓)

S1.7 Environmental Incidents and Complaints

S1.7.1 Environmental Non-Compliance Incidents during Reporting Year

Date of incident	Brief description of incident	Cause	Corrective action

Total number of non-compliance incidents for previous year:	
Total number of non-compliance incidents for current reporting year:	

S1.7.2 Complaints made by the public to Medichem Manufacturing (Malta) Ltd.

Date of complaint	Description of complaint	Actions taken

Total number of complaints for previous year:	
Total number of complaints for current reporting year:	

S1.8 Submission of Certifications and Documentation

Submission	Tick (✓)
Good-working order certificate for generator and boiler prior to the renewal of the permit	<input type="checkbox"/>
Engineers certification of process pipes, valves and flanges prior to the renewal of the permit	<input type="checkbox"/>
VOC Replacement/ Reduction plan as specified in condition 2.5.3	<input type="checkbox"/>

Applicant's declaration

I declare that, to the best of my knowledge, all the above information is correct and substantiated.

.....
Name
(in block letters)

.....
ID Card Number

.....
on behalf of / in my own name
(in block letters)

.....
Signature

.....
Date

Schedule 2
Site Plan

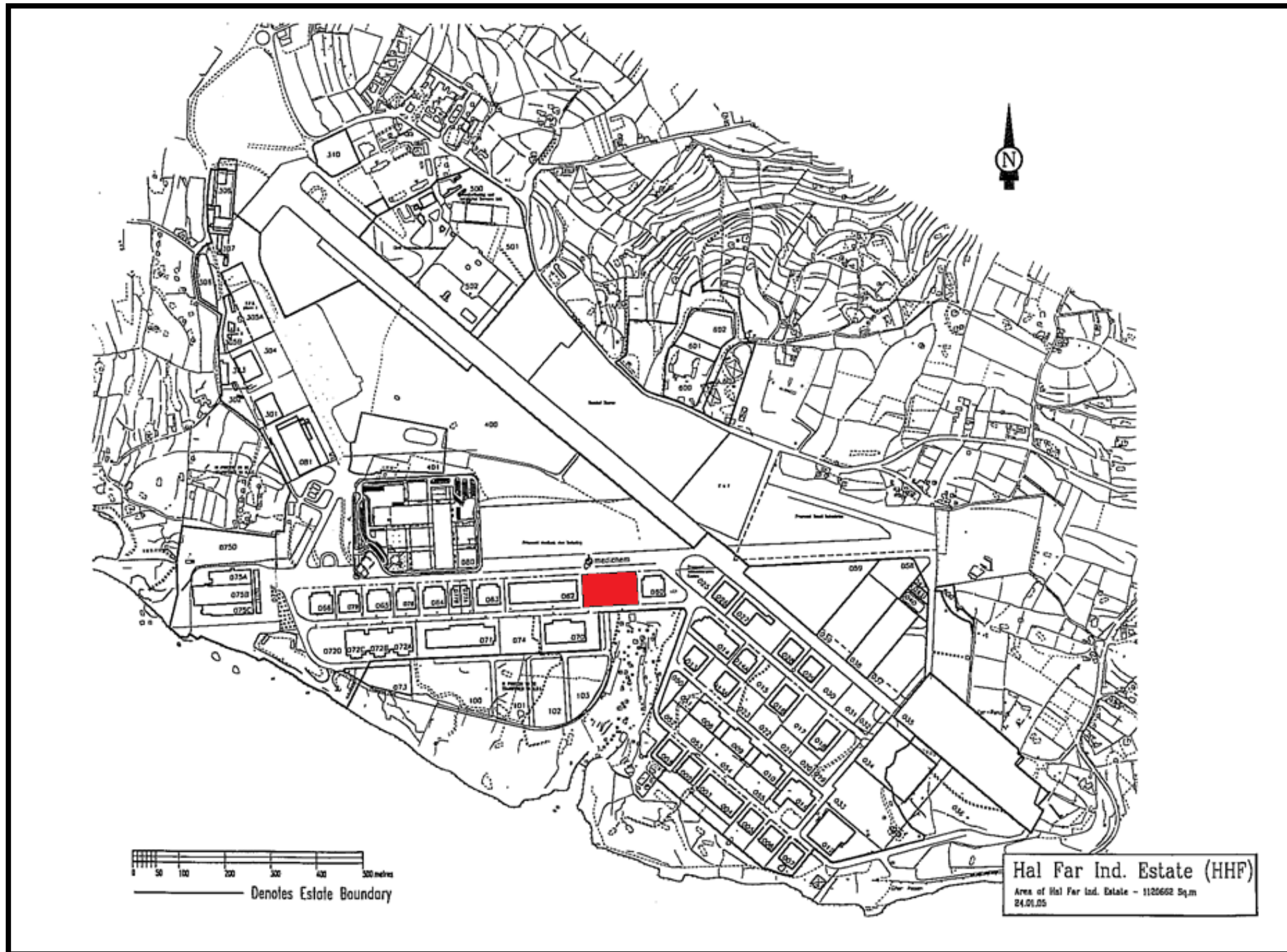
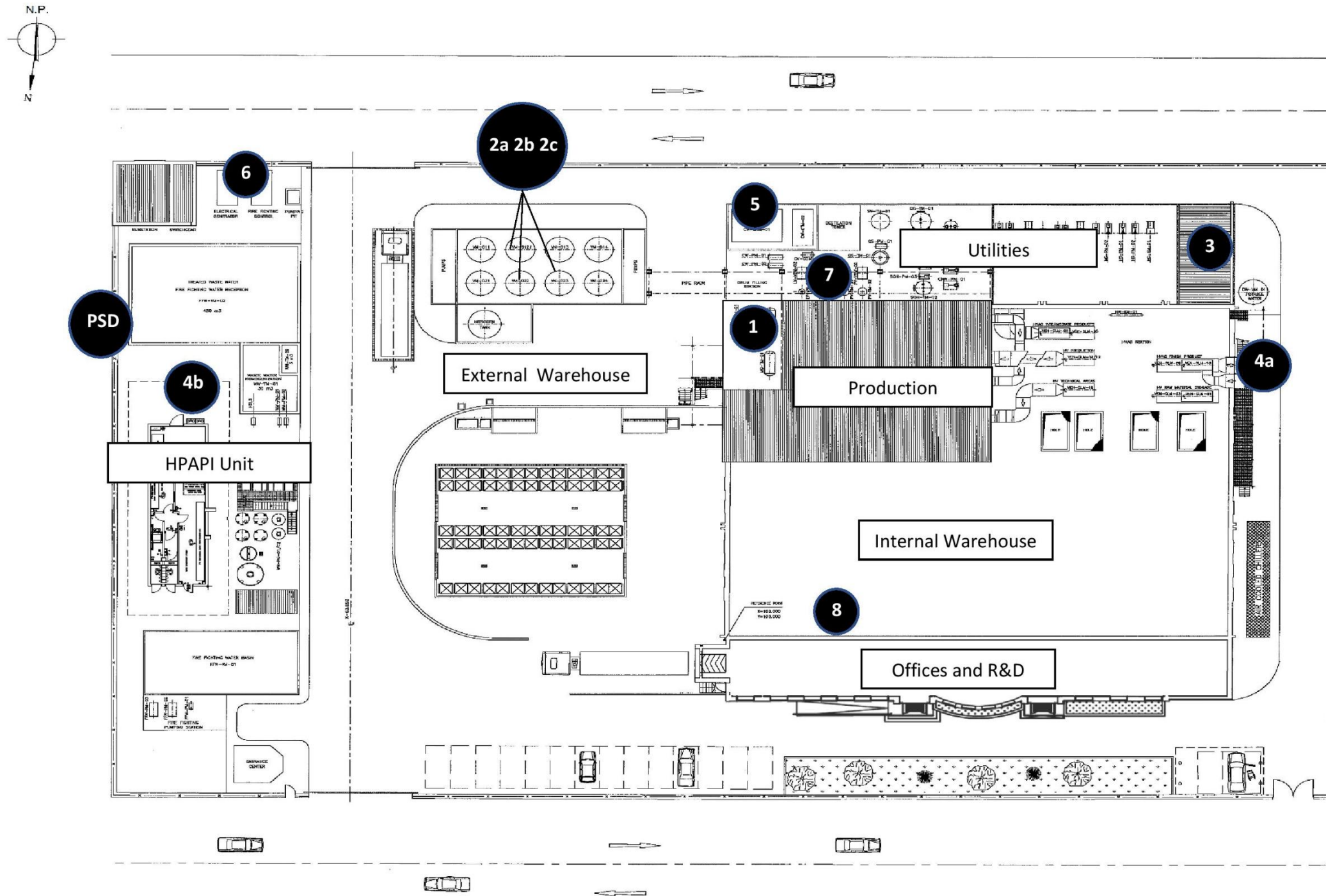


Figure 1: Site of permitted installation, showing extent of the permitted installation area in red, for the carrying out of the activities specified in condition 1.1.1. The extent of the site boundary is indicative and should not be used for interpretation purpose

Schedule 3
Site layout plan



Schedule 4
VOC Report

Kindly fill in the questionnaire with the information requested below. This information is being requested for the reporting period detailed below, in accordance with the installation's IPPC permit.

Permit Number	IP 0002/05/Ei
Installation	Medichem Manufacturing (Malta) Ltd.
Activity	Manufacturing of Pharmaceutical Products
Reporting Period	Day Month Year – Day Month Year

Solvents VOC emissions calculation is based on the guidance provided in the Solvent Management Plan in Schedule IV of S.L.549.79)

1	Solvent Input and Consumption calculation			
a	New Solvent Input = The quantity of organic solvents or their quantity in mixtures purchased which are used as input into the process in the time frame over which the mass balance is being calculated	I1		Kg VOC
b	Recovered Solvent Input = The quantity of organic solvents or their quantity in mixtures recovered and reused as solvent input into the process. The recycled solvent is counted every time it is used to carry out the activity	I2		Kg VOC
c	Sum of solvent input (cells 1a+1b)	$\Sigma I = I1+I2$		Kg VOC
2	Fugitive Emissions calculation			
	Fugitive Emissions (F) is determined by subtraction of other measured emissions (i.e. $F = I - O1 - O5 - O6 - O7 - O8$):			
a	Quantity of organic solvents in Waste gases (annual load) <i>Information / calculation to be submitted as part of ER – Section 1.5 Table 2.</i>	O1		Kg VOC
b	Quantity of organic solvents and/or organic compounds lost due to chemical or physical reactions (including those that are destroyed by incineration or other waste gas or waste water treatments, or captured, as long as they are not counted under O6, O7 or O8).	O5		Kg VOC
c	Quantity of organic solvents contained in disposed waste <i>Only solvents in waste that was produced and disposed of during the reporting period should be included as O6. VOC content in waste needs to be verified by sampling and analysis in an accredited lab and copy of test result to be submitted together with this report¹.</i>	O6		Kg VOC

¹ In case waste load (and type) can be considered to be constant, a one-time sampling and analysis would be sufficient.

d	Organic solvents, or organic solvents contained in mixtures, which are sold or are intended to be sold as a commercially valuable product.	O7		Kg VOC
e	Organic solvents contained in mixtures recovered for reuse but not as input into the process, as long as not counted under O7. This includes waste solvent treated on site which has not yet been inputted into the process.	O8		Kg VOC
f	Sum of above Emissions (Total output of organic solvents) <i>(cells 2a+2b+2c+2d+2e)</i>	$\Sigma O =$ O1+O5+O6 +O7+O8		Kg VOC
g	Fugitive Emissions = Input – (Total output of organic solvents) <i>(cells 1a – 2f)</i>	F = Ii - ΣO		Kg VOC
h	Fugitive Emissions as a % of Total Solvent Input <i>(cells 2e / 1c) x 100</i>	= F / ΣI X 100	_____	%
e	Quantity of waste containing solvents that was present on site at the end of the reporting period pending disposal	/	_____	Kg
<p>If the fugitive emission value in row 2h has exceeded the Emission Limit Value as stipulated in Condition 2.1.5 of IP 0002/05/Ei, you are requested to provide further information on:</p> <ul style="list-style-type: none"> ▪ Timeframe during which the emission Limit value and/or the fugitive emission value was exceeded; ▪ Reasons identified for non-compliance; ▪ Corrective actions taken; ▪ Emissions performance following the corrective actions <p>This information is to be submitted as a signed and dated document together with this report, referenced in the appropriate field on the right.</p>			<p>Attached Document</p> <p>_____</p> <p><i>(Name or Number reference)</i></p>	
3	During the reporting period, did the installation make use of substances or preparations which, because of their content of VOCs classified as carcinogens, mutagens or toxic to reproduction, are assigned or need to carry the risk phrases R45, R46, R49, R60, and/or R61 (or the hazard statements H340, H350, H350i, H360D or H360F)?			
<p>If YES, please submit the documentation required in accordance with permit Condition 2.1.8 of IP 0002/05/Ei</p>				
4	During the reporting period, did the installation make use of halogenated VOCs which are assigned or need to carry the risk phrases R40 or R68 (or the hazard statements H341 and H351)?			
<p>If YES, please submit the documentation required in accordance with permit Condition 2.1.9 of IP 0002/05/Ei</p>				
<p>1.1.1 Applicant's declaration <i>I declare that, to the best of my knowledge, all the above information is correct and substantiated.</i></p>				
<p>..... Name <i>(in block letters)</i></p>		<p>..... ID Card Number</p>		<p>..... on behalf of / in my own name <i>(in block letters)</i></p>

..... Signature Date
---------------------------	----------------------

END OF PERMIT