



To: Medichem Manufacturing (Malta) Ltd
HF-61, Hal Far Industrial Estate
Hal Far BBG 3000

20 December 2013
Our Ref: IP 0002/05/D

Application Number: IP 0002/05
Application Type: Integrated Pollution Prevention and Control Permit
Approved Documents: Document IP 0002/05/D

Location: HF-61, Hal Far Industrial Estate, Hal Far BBG 3000
Proposal: Production of basic pharmaceutical products (Active
Pharmaceutical Ingredients)

**Industrial Emissions (Integrated Pollution Prevention and Control)
Regulations (LN 10 of 2013)**

The Malta Environment and Planning Authority (MEPA) hereby grants consent in accordance with the application described above, of the operations detailed in the attached IPPC permit document (IP 0002/05/D) and associated approved documents.

This permit regulates the management and operational conduct of the site.

This permit is granted for a period of five years from its date of issue; however, it may be varied/surrendered/transferred as specified in pages 2 & 3 of the introductory note in the permit. An application for renewal of this permit is to be submitted at least six months prior to expiry of this permit and must show how the obligations in the improvement programme have been met.

This permit is granted subject to the following conditions:

1. Operations are to conform to the standards and operating conditions specified in the IPPC permit document (IP 0002/05/D) and associated approved documents as listed above.
2. Prior to issue of this permit, the applicant is to submit a financial guarantee of €14,900 to secure the obligations under this permit. This guarantee shall replace the financial guarantee requested under

previous IPPC permits (IP 0002/05/A as varied by IP 0002/05/B and renewed by IP 0002/05/C) and be maintained by the permit holder throughout the term of validity of this permit. **The financial guarantee shall only be released on surrender of the permit.**

3. Prior to issue of the permit, a contribution of €950 is to be remitted by the permit holder to cover the first year of operations after this renewal. This consists of a fixed basic annual contribution of €750, with an addition of €200 reflecting the standard costs for MEPA for inspections for the first year of operations.

Future remittances will consist of the fixed annual amount of €750 and a variable addition reflecting MEPA's cost for inspections. The fixed annual amount of €750 will be increased to €1,500 should the installation cease to be in possession of environmental management certification recognised by the Malta Competition and Consumer Affairs Authority (MCCAA). The latter variable component depends on the actual number of site inspections, which is determined by the performance of the operator. This total annual contribution has to be paid before the anniversary of the date of issue of this permit. Variations in MEPA's inspection expenditure will be reflected in the following year's contribution.

This permit is granted saving third party rights. The applicant/permit holder is not excused from obtaining any other permission, authorisation, etc., required by any other law.



David Cassar
MEPA Board Secretary



Permit with introductory note

Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (LN 10 of 2013)

Medichem Manufacturing (Malta) Ltd
HF-61, Hal Far Industrial Estate
Hal Far BBG 3000

Permit number
IP 0002/05/D

Contents

Introductory note	2
Permit	5
Conditions	6
1 General.....	6
2 Operating conditions	9
3 Records	24
4 Reporting.....	25
5 Notifications.....	25
6 Interpretation.....	28
Schedule 1 - Notification of abnormal emissions	29
Schedule 2 - Annual Environmental Report	30
Schedule 3 – Site Plan.....	39
Schedule 4 – Site layout Plan.....	40
Schedule 5 – Terms of Reference for Noise Monitoring.....	41
Schedule 6 – List of wastes authorised for acceptance from Combino Pharm.....	43

Introductory note

This introductory note does not form part of the Permit

The following Permit is issued under Regulation 7 of the Industrial Emissions (Framework) Regulations, 2013 (LN 9 of 2013) ("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 (LN 10 of 2013) ("the Industrial Emissions (IPPC) Regulations"), 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.

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 (see sections 1, 2, 4 and 5). 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 Issue
<i>Not applicable</i>		

Superseded Licences/Authorisations/Consents relating to this installation		
Holder	Reference Number	Date of Issue
<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>

Public Registers

This IPPC Permit and application is available to the public through the MEPA website in accordance with the requirements of the Industrial Emissions (IPPC) Regulations. The applicant has made a request for certain information of a commercial nature to be withheld from the public. MEPA has been supplied with all this information and has accepted the request of the applicant, because it was deemed to be commercially confidential or contrary to national security. A non technical summary has however been included in the documentation as annexes 3, 5, 6, and 10.

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 MEPA. 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 issued.

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 Operator 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. Should this be required, an application for surrender of the permit is to be submitted at least six months prior to expiry of this permit.

Transfer of the Permit or part of the Permit

Before the Permit can be wholly or partially transferred to another person, an Application to transfer the Permit has to be made to MEPA, by the existing and proposed holders jointly. A transfer will be allowed unless the Authority considers that the proposed holder will not be the person who will have control over the operation of the installation or will not comply with the conditions of the transferred Permit. If, however, the Permit authorises the carrying out of a specified waste management activity, the transfer will only be allowed if the proposed holder is also considered to be a technically competent person. Should this be required, an application for a transfer of the permit is to be submitted at least six months prior to expiry of this permit.

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>
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.

Detail	Date	Comment
Renewal and variation determined	2 December 2013	
Permit issued	20 December 2013	Permit expires on 20 December 2018 A consolidated permit is being issued.

End of Introductory Note

Permit

Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (LN 10 of 2013)

Permit number
IP 0002/05/D

The Malta Environment and Planning Authority (hereinafter the Authority; the Competent Authority or MEPA) in exercise of its powers under Regulation 7 of the Industrial Emissions (Framework) Regulations, 2013 (LN 9 of 2013) ("the Industrial Emissions (Framework) Regulations"), hereby authorises:

Medichem Manufacturing (Malta) Ltd. (hereinafter "the Operator" and "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.

Signed

Date

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Authorised to sign on behalf of MEPA

Name in Block letters

ID Number:

Malta Environment & Planning Authority

APPROVAL

Board No: PA037-13/14 held on: 5/12/13

Chairman: _____ Secretary: _____

Conditions

1 General

These permit conditions shall be read in conjunction with the IPPC Application received in November 2004, and the applications for renewal and variation as subsequently clarified and recorded in the status log above, which form an integral part of these permit conditions.

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	Gas-fired boilers to produce steam and hot water.	From receipt of fuel to delivery of utility.
	Emergency electricity generator for provision of electricity in case of power failure.	From receipt of fuel to delivery of utility.
	Reverse osmosis plant.	From receipt of water to delivery of utility.
	Provision of air supplies, coolants and nitrogen.	From receipt of chemicals to delivery of utility.
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	Plant for the physico-chemical treatment of liquid effluents.	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 3 to this Permit.
- 1.2.2 A site notice shall be erected and displayed in a prominent position such as to be readily visible by the public. The notice shall contain the following information:
- 1.2.2.1 State that the site operates under an IPPC permit issued by MEPA.
- 1.2.2.2 Provide the permit number and the name of the permit holder.
- 1.2.2.3 Provide a 24-hour emergency contact name and telephone number for the permit holder.

1.3 Overarching Management Condition

- 1.3.1 Without prejudice to the other conditions of this Permit, the Operator shall maintain an Environmental Management System (EMS), and an organisational structure and allocate resources that are sufficient to achieve compliance with the limits and conditions of this permit. The EMS shall give information on the person responsible for environmental management on site, and standard operating procedures on environmentally relevant matters. An EMS can take the form of a standardised system (e.g. EN ISO 14001:2004 or EMAS) or a non-standardised ("customised") system, provided that is properly designed and implemented.
- 1.3.2 The Permit Holder shall submit (including as part of the EMS) the following reports annually as part of the Annual Environmental Report:
- 1.3.2.1 Environmental Policy containing the installation's environmental objectives and targets;
- 1.3.2.2 Environmental Management Programme report (for the reporting year);
- 1.3.2.3 Environmental Management Programme proposal (for the following year).

1.4 Improvement Programme

- 1.4.1 The Operator shall complete the improvements specified in Table 1.4.1 by the date specified in that table, and shall send written notification of the date of completion of each requirement to the Authority within 10 working days of the completion of each such requirement.

Table 1.4.1: Improvement programme

Reference	Requirement	Date
6	Submission of a land and groundwater risk assessment, and if required, a monitoring strategy and baseline report in line with European Commission and MEPA guidance pursuant to Regulations 9(3) and 16(2) of the Industrial Emissions (IPPC) Regulations	By not later than 5 December 2016, for the submission of the land and groundwater risk assessment & monitoring strategy (if required). By not later than 30 June 2018 for the submission of baseline report.

* Requirement 6 is new in IP 0002/05/D.

1.5 Operational Changes

- 1.5.1 The Operator shall seek the Authority's written agreement to any operational change as defined in the Industrial Emissions (IPPC) Regulations by sending to the Authority: written notice of the details of the proposed change including an assessment of its possible effects (including changes in emissions and waste production) on risks to the environment and to public health from the permitted installation; any relevant supporting assessments and drawings; and the proposed implementation date.
- 1.5.2 Any such change shall not be implemented until agreed to in writing by the Authority. As from the agreed implementation date, the Operator shall operate the permitted installation in accordance with that change, and relevant provisions in the application shall be deemed to be amended.
- 1.5.3 When the qualification "unless otherwise agreed in writing" is used elsewhere in this permit, the Operator shall seek such agreement by sending to the Authority written notice of the details of the proposed method(s) or techniques.
- 1.5.4 Any such method(s) or techniques shall not be implemented until agreed in writing by the Authority. As from the agreed implementation date, the Operator shall operate the permitted installation using that method or technique, and relevant provisions in the application shall be deemed to be amended.
- 1.5.5 The Director of Environment Protection and any officials to whom this role is delegated are hereby authorised to make decisions on variations to this permit, with the exception of the following cases:
- (a) variations which could lead to significant impact on human health or the environment;
 - (b) any change in the nature or functioning or an extension of an installation where the change or extension in itself reaches the capacity thresholds set out in Schedule 1 of the Industrial Emissions (IPPC) Regulations;
 - (c) variations covered by the Environmental Impact Assessment Regulations;
 - (d) aspects of the operations specifically prohibited by this permit;
 - (e) changes to emission limit values;
 - (f) changes to fees;
 - (g) renewal of the validity of this permit.

1.6 Pre-Operational Conditions

- 1.6.1 There are no pre-operational conditions.

1.7 Off-site Conditions

- 1.7.1 The Permit holder shall ensure that all measures are in place to prevent the escape of chemicals or waste to the environment especially during transportation of such materials.

2 Operating conditions

2.1 In-Process Controls

- 2.1.1 The Permitted Installation shall, subject to the conditions of this Permit, be operated using the techniques and in the manner described in the IPPC application and in the subsequent applications for renewal and variation, or as otherwise agreed in writing by the Authority in accordance with conditions 1.5.1 and 1.5.2 of this permit.

2.2 Emissions

2.2.1 Emissions to Air, (excluding Odour, Noise or Vibration) from Specified Points

- 2.2.1.1 This Part 2.2.1 of this Permit shall not apply to releases of odour, noise or vibration.
- 2.2.1.2 Emissions to air shall only arise from the emission points specified in Table 2.2.1, as described in the IPPC application.

Table 2.2.1 : Emission points to air	
Emission point reference (Schedule 4)	Source
1	Vent scrubber
2	Vent atmospheric tanks
3	Boiler
4a	HVAC plant exhaust
4b	HVAC exhaust from laboratory
5	Cooling Towers

- 2.2.1.3 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. In all other handling and production areas, the same efficiency performance as previously agreed upon with the Authority shall be maintained.
- 2.2.1.4 The limits for emissions to air for the parameters and emission points set out in Table 2.2.2 shall not be exceeded. These limits refer to dry gas and volume flows without dilution.

Table 2.2.2 : Emission limits to air and monitoring		
Emission point reference	Parameter	Limit
1	VOC as carbon	150 mgC /Nm ³
3*	Carbon Monoxide	50 mg/m ³
3*	Particulate Matter	5 mg/m ³
3*	Oxides of Nitrogen	110mg/m ³

*All concentrations from emission point reference 3 shall be corrected to 273K, 101.3kPa and an oxygen content of 3%.

- 2.2.1.4 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 2,2,2 for point source 1 and a fugitive emission value of 5% of the solvent input;
- 2.2.1.5 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 (LN 12 of 2013), and as may be subsequently amended, and 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.
- 2.2.1.6 Compliance with the waste gas emission limit value in table 2,2,2 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 (LN12 of 2013).
- 2.2.1.7 Without prejudice to the emission limit for total VOC as carbon specified in Table 2.2.2, discharges from the scrubber of VOCs from substances or preparations 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 or the risk phrases R45, R46, R49, R60, or R61, where the mass flow of the sum of the compounds causing the risk labelling is greater or equal to 10 g/hour, shall comply with an emission limit value of 2 mg/Nm³. 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 operator 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.
- 2.2.1.8 Without prejudice to the emission limit for total VOC as carbon specified in Table 2.2.2, discharges from the scrubber of halogenated VOCs that are assigned, or need to carry, the hazard statements H341 or H351 or the risk phrases R40 or R68, 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 operator 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.
- 2.2.1.9 The Operator shall monitor the parameters listed in Table 2.2.2 and in conditions 2.2.1.4 and 2.2.1.8 annually. Monitoring from the boiler shall be carried out during its operation, and monitoring from the scrubber shall be carried out during use of the substances to be monitored. Measurements of the parameters in conditions 2.2.1.4 and 2.2.1.8 shall be carried out according to regulations 6 and 8 of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (LN 12 of 2013).
- 2.2.1.10 Monitoring shall be carried out annually, provided that the limits detected are within the emission limit values specified in Table 2.2.2 and conditions 2.2.1.4 and 2.2.1.5. Otherwise, monitoring shall be carried out at six-monthly intervals.
- 2.2.1.11 The HVAC system shall be regularly maintained. A maintenance log for the HVAC system shall be kept and made available to the Authority upon request.
- 2.2.1.12 Under abnormal operating conditions such as in the case of breakdown, the Operator shall reduce or close operations as soon as practical until normal operation can be restored.

2.2.1.13 Measurements for the determination of concentrations of substances specified in this Permit shall be carried out under normal operational conditions to ensure that measurements are representative of the actual emissions.

2.2.1.14 The operational effectiveness of filters (such as HEPA filters) for the control of particulate emissions of pharmaceutical raw materials, intermediates and products shall be monitored by means of a pressure differential recorder or equally effective means. Such recorders shall be visible to operators working on the equipment such that an out of range incident can be easily and immediately identified.

2.2.1.15 When filters are found to have reached the pressure alert limit indicated by filter manufacturer, these shall be immediately replaced and where applicable, damaged filters shall be treated as hazardous waste as per LN 184 of 2011, as amended.

2.2.1.16 In the event of a local nuisance from emissions to air, the operator must, at the written request of MEPA and within 10 working days, identify the specific cause of the nuisance and examine means for its elimination or minimisation including:

2.2.1.16.1 Relocating / redesigning the stack(s) or vent(s) to a point where nuisance is minimised.

2.2.1.16.2 Replacement of fuel.

2.2.1.16.3 Preventative measures such as replacement of process materials (e.g. odorous solvents) by more environmentally sensitive compounds.

2.2.1.16.4 Improved storage of materials.

2.2.1.16.5 Use of additional abatement measures.

2.2.1.17 All abatement equipment and ducting shall be cleaned and maintained on a regular basis.

2.2.1.18 Cooling tower Registration

2.2.1.18.1 Any new cooling towers on site shall be registered with the Environmental Health Directorate, with a timeframe agreed with the Environmental Health Directorate.

2.2.1.18.2 The installation shall comply with the conditions set by the Environmental Health Directorate, (document dated 29th July 2005), with the provisions of the Control of *Legionella* Regulations, 2006 (LN 5 of 2006) and with the provisions of the Registration of Cooling Towers and Evaporative Condensers Regulations (LN 6 of 2006), as may be amended from time to time.

2.2.1.18.3 The Permit Holder and Operator 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 take a sample of the recirculating water of the cooling tower system to an accredited laboratory for testing for *Legionella* and at least every month take a sample of the recirculating water of the cooling tower system to an accredited laboratory for testing for heterotrophic colony count. The results of such tests shall be submitted as part of the Annual Environmental Report of the installation in the format specified therein.

2.2.2 Discharges to surface water

2.2.2.1 This Part 2.2.2 of this Permit shall not apply to releases of odour, noise or vibration or to releases to groundwater.

2.2.2.2 No discharges to surface water shall take place at the installation.

2.2.3 Discharges to sewers

2.2.3.1 The Operator shall be allowed to discharge effluent into the sewage system in Hal Far.

2.2.3.2 The discharge of effluent into the public sewer shall be fully compliant with the agreement entered into between the Water Services Corporation (WSC) and Medichem arising from the Sewer Discharge Control regulations (LN 139/2002 as amended by LN 378 of 2008 and as may be amended from time to time).

2.2.3.3 The operator shall not discharge any substance under Schedule A and Schedule B.

2.2.3.4 The agreement with the Water Services Corporation (WSC) will be subject to renewal on a yearly basis.

2.2.3.5 A copy of the renewed 'agreement' has to be submitted to MEPA within 2 days of approval, every time it is renewed. If this permit will not be renewed Medichem will have to find alternative ways to dispose of brine.

2.2.3.6 Discharge of effluent to sewer shall only arise from the emission point in Schedule 4.

2.2.3.7 The operator shall:

2.2.3.7.1 Monitor for the parameters found in Table 2.2.3 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.

2.2.3.7.2 Follow the conditions of the agreement entered into with the Water Services Corporation (WSC) as stated in 2.2.3.2.

2.2.3.7.3 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.

2.2.3.7.4 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 2.2.3 : Parameters to be monitored and monitoring frequency to sewer

Emission point reference	Substance or Parameter	Monitoring frequency
Discharge point	Temperature	Each batch
	pH	Each batch
	Settleable solids	Yearly
	Suspended solids	Yearly
	Total Kjeldahl Nitrogen	Yearly
	Sulphides and compounds releasing hydrogen sulphide on acidification	Yearly
	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

2.2.3.8 Only the physico-chemical waste water treatment plant is permitted in this permit.

2.2.3.9 The biological waste water treatment plant described in the IPPC application as a future project of the installation is not permitted in this IPPC permit.

2.2.3.10 The operator must apply for a variation of the IPPC permit in order to start construction and operation of the biological or other type of waste water treatment plant planned for the future.

2.2.3.11 Medichem is authorised to accept wastewaters produced by Combino Pharm (Malta) Ltd. (of HF 60 Hal Far Industrial Estate BBG 3000 Malta) by means of connecting pipes installations, provided that:

2.2.3.11.1 Transfers are only allowed if Combino Pharm is operating under a valid environmental permit issued by the Authority.

2.2.3.11.2 Wastewaters from Combino Pharm are treated in the on-site wastewater treatment plant prior to discharge, except where the wastewaters from Combino Pharm are in conformity with the limits set in the Water Services Corporation Sewer Discharge Permit and do not require treatment prior to discharge.

2.2.3.11.3 Wastewaters from Combino Pharm do not result in any exceedance of the limits set in the Water Services Corporation Sewer Discharge Permit.

2.2.3.11.4 Medichem takes all the necessary preventive measures to ensure that no leakages occur from the pipes.

2.2.3.11.5 The monitoring requirements in condition 2.2.3.7 shall also apply for these discharges. Moreover, reporting as part of the AER and the E-PRTR report shall include such discharges.

2.2.4 Emissions to groundwater

- 2.2.4.1 The permitted installation shall not allow the introduction into groundwater of any substance included in the Regulations for the Protection of Groundwater against pollution and deterioration (LN 108 of 2009). The Operator shall also not allow any discharges to groundwater for substances other than those specified in the Regulations unless specifically permitted by the Malta Resources Authority.
- 2.2.4.2 The permitted installation shall not hinder the achievement of good chemical and quantitative status of groundwater as prescribed under the Water Policy Framework Regulations, Legal Notice 194 of 2004, and as may be amended from time to time.

2.2.5 Fugitive emissions of substances to air

- 2.2.5.1 The Operator 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:
- 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 Operator shall be no less effective than those described in the Application, where relevant.
- 2.2.5.2 The Operator shall use BAT so as to prevent or where that is not practicable to reduce emissions of litter from the Permitted Installation provided always that the techniques used by the Operator shall be no less effective than those described in the Application, where relevant.
- 2.2.5.3 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 2.

2.2.6 Fugitive emissions of substances to surface water and sewer

- 2.2.6.1 Subject to condition 2.2.6.2, the Operator shall use BAT so as to prevent or where that is not practicable to reduce fugitive emissions of substances to surface water (other than groundwater) and sewer from the Permitted Installation in particular from:
- all structures under or over ground
 - surfacing
 - bunding
 - storage areas
- provided always that the techniques used by the Operator shall be no less effective than those described in the Application, where relevant.
- 2.2.6.2 There shall be no release to surface water that would cause a breach of an EQS (Environmental Quality Standard) established to implement the Dangerous Substances Directive 76/464/EEC (LN 231 of 2001) and Daughter Directives (LN 218 of 2001, LN 219 of 2001, LN 220 of 2001, LN 221 of 2001 and LN 227 of 2001) and any other Directives regulating discharges into the aquatic environment.

- 2.2.6.3 The Operator shall undertake all necessary measures and precautions to prevent spillage of raw materials, intermediates, products, waste and any other materials.
- 2.2.6.4 Catchment pits, reservoirs and bunds on site must be visually inspected and examined for odours at least once every month and maintained where necessary. Records of such inspections and maintenance are to be kept by the Operator.
- 2.2.6.5 Catchment pits, reservoirs and bunds on site are to be tested and certified to be leak-proof by an independent, warranted architect or engineer once every 5 years. Such certification shall be also submitted as part of the AER.
- 2.2.6.6 All process and storage areas must be appropriately contained. Any accidental release of substances shall be duly treated prior to discharge into the sewers, or disposed as described in the original IPPC application if treatment does not enable compliance with emission limit values. Records shall be kept of such discharges, including the volume discharged and other parameters, as agreed with the Water Services Corporation, as per the Sewer Discharge Permit.
- 2.2.6.7 The operations of the installation shall not hinder the achievement of good ecological status for surface waters as prescribed under the Water Policy Framework Regulations, LN 194 of 2004.

2.2.7 Odour

- 2.2.7.1 The Operator shall use BAT so as to prevent or where that is not practicable to reduce odorous emissions from the Permitted Installation, in particular by:
- limiting the use of odorous materials
 - restricting odorous activities
 - controlling the storage conditions of odorous materials
 - controlling processing parameters to minimise the generation of odour
 - optimising the performance of abatement systems
 - timely monitoring, inspection and maintenance
 - employing, where appropriate, an approved odour management plan
- provided always that the techniques used by the Operator shall be no less effective than those described in the Application, where relevant.
- 2.2.7.2 All emissions to air from the installation shall be free from offensive odour as perceived by an Authorised Officer of the Authority, at sensitive locations.

2.2.8 Emissions to Land

- 2.2.8.1 This Part 2.2.8 of this Permit shall not apply to emissions to groundwater.
- 2.2.8.2 No emission from the Permitted installation shall be made to land.

2.2.9 Noise and vibration

- 2.2.9.1 The Operator shall use BAT so as to prevent or where that is not practicable to reduce emissions of noise and vibration from the Permitted Installation, in particular by:
 - 2.2.9.1.1 equipment maintenance, e.g. of fans, pumps, motors, conveyors and mobile plant;
 - 2.2.9.1.2 use and maintenance of appropriate attenuation, e.g. silencers, barriers, enclosures;
 - 2.2.9.1.3 appropriate timing and location of noisy activities and vehicle movements;
 - 2.2.9.1.4 periodic checking of noise emissions, either qualitatively or quantitatively; and
 - 2.2.9.1.5 maintenance of building fabric,provided always that the techniques used by the Operator shall be no less effective than those described in the Application, where relevant.
- 2.2.9.2 Emergency generators/alarms/sirens/release valves shall only be tested between the hours of 10.00 and 17.00 Monday to Friday and not on any Public Holiday.
- 2.2.9.3 The level of noise emitted from the installation at all operational times shall not exceed 75 dB, expressed as an LAeq, 1 hour, as measured or assessed at the specified boundary locations of the installation.
- 2.2.9.4 Noise monitoring is to be carried out every 5 years, to ensure that the above limits are not exceeded. In this regard, the locations, measurements and assessment must be made according to BS 4142:1997, all the series of ISO 1996 and any other standard methodology stipulated by the Authority. Noise monitoring shall be implemented according to the Terms of Reference set out in Schedule 5 and shall be subject to the submission of a method statement and subsequent approval by the authority prior to the commencement of any monitoring.
- 2.2.9.5 As part of the AER, records of noise monitoring of the previous year shall be submitted to the Competent Authority by not later than end of March after the end of each reporting year, in the format specified in Schedule 2 of this permit. A detailed report shall also accompany such results.

2.3 Management and Technically Competent Person

- 2.3.1 A copy of this Permit and those parts of the application referred to in this Permit shall be available, at all times, for reference by all staff carrying out work subject to the requirements of the Permit.

Training

- 2.3.2 The Permitted Installation shall be managed, controlled, supervised and operated by staff who are suitably trained and fully conversant with the requirements of this Permit.
- 2.3.3 All staff shall be fully conversant with those aspects of the Permit conditions which are relevant to their duties and shall be provided with adequate professional technical development and training and written operating instructions to enable them to effectively carry out their duties.
- 2.3.4 The Operator shall maintain a record of the skills and training requirements for all staff whose tasks in relation to the Permitted Installation may have an impact on the environment and shall keep records of all relevant training.

Maintenance

- 2.3.5 All plant, equipment and technical means used in operating the Permitted Installation, the failure of which could lead to an adverse impact on the environment, shall be maintained in good operating condition.
- 2.3.6 The Operator shall maintain a record of relevant plant and equipment covered by condition 0 and for such plant and equipment:
- 2.3.6.1 a written or electronic maintenance programme; and
 - 2.3.6.2 records of its maintenance.

Incidents and Complaints

- 2.3.7 The Operator shall maintain and implement written procedures for:
- 2.3.7.1 taking prompt remedial action, investigating and reporting actual or potential non-compliance with operating procedures or emission limits and if such event occur;
 - 2.3.7.2 investigating incidents, (including any malfunction, breakdown or failure of plant, equipment or techniques, down time, any short term and long term remedial measures and near misses) and prompt implementation of appropriate actions; and
 - 2.3.7.3 ensuring that detailed records are made of all such actions and investigations.
- 2.3.8 The Operator shall record and investigate complaints concerning the Permitted Installation's effects or alleged effects on the environment. The record shall give the date and nature of complaint, time of complaint, name of complainant (if given), a summary of any investigation and the results of such investigation and any actions taken.

Attendance of Technically Competent Persons

- 2.3.9 Attendance of the technically competent person(s) at the Site shall be recorded in the Site diary on arrival and departure.
- 2.3.10 For the whole operational hours permitted for the Site under this Permit, the Technically Competent Person/s shall be physically in attendance at the Site. The Technically Competent Person/s has to be permanently present on site during the manufacture of APIs. The permit holder is to provide details as to how he intends to provide this coverage in order to take into account unavoidable absences due to vacation or sick leave.
- 2.3.11 Where the Site has been notified to the Authority as being either non-operational or closed, the Technically Competent Person shall be capable of attending the Site within one hour.

Changes in Technically Competent Persons

- 2.3.12 Any changes in technically competent management (Person/s) and the name of any incoming person together with evidence that such person has the required technical competence shall be submitted to the Authority in writing within 5 working days of the change in management.
- 2.3.13 In the event of the death, dismissal, resignation, leave, or of extended sick leave of the Technically Competent Management of the Site, the Permit Holder shall immediately inform the Authority, and prove to the Authority that the Permit Holder is actively seeking a replacement.

Setting up of a Monitoring Committee

- 2.3.14 A monitoring committee made up of representatives from MEPA, Medichem Ltd. and the Birzebbuga Local Council with the aim of monitoring the permit conditions within the permit is hereby setup.
- 2.3.15 The monitoring committee shall be made up of two representatives from each entity and another technical advisor when necessary.
- 2.3.16 The Committee shall be chaired by MEPA representatives who shall convene meeting on an annual basis.
- 2.3.17 The Operator shall provide secretarial assistance for taking minutes during the Committee Meetings.

2.4 Solvents

- 2.4.1 A monthly inventory of solvent usage shall be maintained on site.
- 2.4.2 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, or the risk phrases R45, R46, R49, R60, or R61, shall be replaced as far as possible and as soon as possible. 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.
- 2.4.3 The operator shall, annually as part of the Annual Environmental Report report progress on substitution of substances referred to in condition 2.4.2.

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

2.5 Storage

- 2.5.1 No storage of equipment or materials is permitted on property outside the site premises.
- 2.5.2 All storage areas for liquid hazardous materials shall be provided with an adequately designed bund system with an impermeable base and walls. The capacity of the bund shall be a minimum of 110% of the largest tank within the bund or 25% of the total capacity of all the tanks within the bund, whichever is the greater. Filling and off-take points shall be located within the bund.
- 2.5.3 Spillages of hazardous material shall receive immediate attention to prevent escape to drain, surface water or land. Spilled material shall be disposed of in an appropriate manner. Kits for the collection of liquid and powder spills shall be available on site at sensitive locations.

2.6 Efficient use of raw materials

- 2.6.1 The Operator shall:
- 2.6.1.1 maintain the raw materials table or description submitted in response to Section 2.2 and 2.4 of the original Application and in particular consider on a periodic basis whether there are suitable alternative materials to reduce environmental impact;
 - 2.6.1.2 Submission of waste minimisation audits and water use efficiency audits carried out at the installation..
 - 2.6.1.3 ensure that incoming water use is directly measured and recorded.
- 2.6.2 The Operator shall notify MEPA of any change in the raw materials, if a new family of chemicals that is not found in the list supplied on pages 18 and 19 of the IPPC application, is going to be introduced.
- 2.6.3 Such a notification shall reach MEPA once it is in the final phases of the research and development phase. No production shall start, until it is ascertained by the Operator that there are no environmental or public health impacts.

2.7 Waste

2.7.1 Waste Storage and Handling

2.7.1.1 No storage of waste is permitted on property outside the site premises

2.7.1.2 The Operator shall use BAT in the design, maintenance and operation of all facilities for the storage and handling of waste on site such that there are no releases to surface water or land during normal operation and that emissions to air and risk of accidental release to surface water or land are minimised, as listed in the document entitled 'Responses to Waste Management Team' and dated 20th July 2005.

2.7.2 Waste recovery or disposal

2.7.2.1 The Operator shall be committed to reduce waste generation where possible.

2.7.2.2 Waste produced at the Permitted Installation shall be recycled or recovered unless technically and/or economically impossible.

2.7.2.3 The Operator shall keep up to date records of all wastes. Such a system of record keeping should include records of:

- 2.7.2.3.1 quantities of waste;
- 2.7.2.3.2 the date of removal from site;
- 2.7.2.3.3 European Waste Catalogue (EWC) code of the waste;
- 2.7.2.3.4 consignment note number, in the case of hazardous wastes;
- 2.7.2.3.5 description of the waste;
- 2.7.2.3.6 the mode of transport and the names of the agent and transporter of the waste (quoting GBR registration numbers for waste carriers),
- 2.7.2.3.7 where such wastes are deposited and the name of the Installation responsible for ultimate disposal or recovery;
- 2.7.2.3.8 whether wastes are recovered or disposed, and if they are recovered,;
- 2.7.2.3.9 information on any treatment/s applied before disposal/recovery.

2.7.2.4 Without prejudice to condition 2.7.2.2, disposal of wastes including rejects, expired products or pharmaceutical wastes are to be managed in accordance with the legal obligations of the Waste Regulations 2011, as published by Legal Notice 184 of 2011 and as amended by LN 441 of 2001, or any statutory provisions or regulations amending or replacing them.

2.7.2.5 Off-site disposal or recovery of wastes may only take place at a facility licensed for that purpose.

2.7.2.6 Without prejudice to condition 2.7.2.2, movement of hazardous waste to authorised facilities shall be covered by a valid consignment permit obtainable from the Competent Authority. Each movement shall also be covered by a consignment note obtainable from the authority.

2.7.2.7 Disposal certificates should be kept on record and made available for inspection for a period of at least 5 years from date of their issue.

2.7.2.8 Without prejudice to condition 2.7.2.2, shipment of hazardous waste abroad is to follow the obligations listed in Council Regulation (EC) 1013/2006 of the European Parliament and of The Council of 14 June 2006 on shipments of waste.

2.7.2.9 Medichem is authorised to accept and export wastes covered by the EWC Codes specified in Schedule 6 produced by Combino Pharm (Malta) Ltd. (of HF 60 Hal Far Industrial Estate BBG 3000 Malta), provided that:

- 2.7.2.9.1 Medichem only accepts wastes if these follow the hazardous waste consignment note procedure and are delivered by registered waste carriers (according to L.N. 106/07). Medichem shall ensure that the waste is adequately described on the waste consignment notes.
- 2.7.2.9.2 Medichem only accepts waste that has been produced and packaged on the site of production.
- 2.7.2.9.3 Such wastes are only accepted if these can be exported within fifteen (15) days from date of acceptance.
- 2.7.2.9.4 Medichem abides by the provisions of L.N. 184/11.
- 2.7.2.9.5 Medichem ensures that waste is safely stored and presented for collection in appropriate and secure containment/packaging and labelled in accordance with international and national standards.
- 2.7.2.9.6 Medichem inform MEPA of their intention to export waste at least one week prior to export by sending an email to wastebrokers.notification@mepa.org.mt.
- 2.7.2.9.7 Transfers are only allowed if Combino Pharm is operating under a valid environmental permit issued by the Authority.
- 2.7.2.9.8 Acceptance of such wastes and removal from site shall be included in the Annual Environmental Report and export of such wastes shall be included in the E-PRTR report.
- 2.7.2.9.9 As part of the Annual Environmental Report for the installation, the Operator shall produce a report on the off-site transfers of waste from the Permitted Installation over the previous calendar year, providing the information listed in Schedule 2.

2.8 Energy Efficiency

- 2.8.1 The Operator shall produce a report on the energy (electricity and fuel) consumed at the Permitted Installation over the previous calendar year, by the end of the first quarter of each year, providing the information listed in Schedule 2.
- 2.8.2 The Operator shall design, maintain and operate the Permitted Installation so as to secure energy efficiency, in particular by:
 - ensuring that the appropriate operating and maintenance systems are in place;
 - ensuring that all plant is adequately insulated to minimise energy loss or gain;
 - ensuring that the type of lighting used is energy-efficient;
 - ensuring that all appropriate containment methods, (e.g. seals and self-closing doors) are employed and maintained to minimise energy loss;
 - employing appropriate basic controls, such as simple sensors and timers, to avoid unnecessary discharge of heated water or air;
 - maintaining and implementing an energy efficiency plan which identifies energy saving techniques that are applicable to the activities and their associated environmental benefit and prioritises them.

2.9 Accident prevention and control

- 2.9.1 In the case of an accident, the Operator shall follow the Emergency Plan as approved by the Civil Protection Department.
- 2.9.2 The plan shall be reviewed at least every 2 years or as soon as practicable after an accident, whichever is the earlier, and the Authority notified of the results of the review within 2 months of its completion.
- 2.9.3 The Operator shall maintain and implement all health and safety measures in compliance with ACT XXVII of 2000; Occupational Health and Safety Authority Chapter 424 and all relevant subsidiary legislation.
- 2.9.4 The Operator and Permit Holder shall have sufficient employees trained to deal with any emergency that may arise, e.g. fire-fighting and first aid.
- 2.9.5 The Operator and Permit Holder are to keep the Authority updated on any major changes in operations that may impact on the health and safety of the employees.
- 2.9.6 The Operator and Permit Holder are to keep available Health and Safety documentation upon request by Occupational Health and Safety Officers.

2.10 Monitoring

- 2.10.1 The Operator shall maintain and implement an emissions monitoring programme which ensures that emissions are monitored as specified in this Permit, and that the results of such monitoring are assessed. The programme shall ensure that monitoring is carried out under an appropriate range of operating conditions, and that measurements for the determination of concentrations of substances specified in this permit is carried out representatively.
- 2.10.2 Sampling and analysis of all pollutants, as well as reference measurement methods to calibrate automated, continuous, measurement systems shall be carried out as specified by the appropriate CEN standards. If CEN standards are not available, ISO standards, national or international standards, which will ensure the provision of data of an equivalent scientific quality, as agreed in writing with the Authority, shall apply. VOC discharges shall be measured and assessed according to Regulation 8(2) of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations. Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme in condition 2.10.1 of this Permit shall be from a laboratory accredited to at least EN ISO 17025/Corr 1:2006 or in the process of accreditation, as confirmed by the National Accreditation Body (NAB-Malta). As part of the Annual Environmental Report, the operator shall provide evidence of certification or accreditation of laboratories used for the emissions monitoring programme. The Operator shall notify the Authority at least 10 working days in advance of undertaking monitoring and/ or spot sampling.
- 2.10.3 The Operator shall maintain records of all monitoring taken or carried out (this includes records of the taking and analysis of samples instrument measurements (periodic and continual), calibrations, examinations, tests and surveys) and any assessment or evaluation made on the basis of such data, for at least a period of 5 years. Such records may be requested at any time by the Authority.
- 2.10.4 There shall be provided safe and permanent means of access to enable sampling/monitoring to be carried out in relation to the emission points already mentioned in this Permit; and safe means of access to other sampling/monitoring points when required by the Authority.

- 2.10.5 The Operator shall provide MEPA with monitoring reports as indicated in section 4 of this permit.

2.11 Transport

- 2.11.1 Independent of any Environment Management System, the Operator shall be responsible for making use of the services of an ADR (The European Agreement concerning the International Carriage of Dangerous Goods by Road) certified carrier for transport of chemicals and hazardous wastes on land.
- 2.11.2 The Operator shall make use of the services of a registered waste carrier for the transport of waste from the site in accordance with LN 106 of 2007, or any other subsequent amendments.

2.12 Ozone Depleting Substances and F Gases

- 2.12.1 No new equipment or components containing substances falling within the scope of EC Regulation No. 1005/2009 on substances that deplete the Ozone Layer & L.N. 280 of 2010 on substances that deplete the Ozone Layer, regulations 2007, shall be installed within the site.
- 2.12.2 All installation, maintenance and servicing of equipment containing Fluorinated Greenhouse Gases shall abide by the requirements of EC Regulation No. 842/2006 on Certain Fluorinated Greenhouse Gases, Commission Regulation (EC) Nos 1493/2007, 1516/2007, 1494/2007, 1497/2007, 303/2008, 304/2008, 305/2008, 306/2008, 308/2008 and L.N. 93 of 2010 on Certain Fluorinated Greenhouse Gases, Regulations 2010.
- 2.12.3 For all equipment installed on site utilising Ozone Depleting Substances or Fluorinated Greenhouse Gases, information pertaining to installation, maintenance and servicing shall be provided as part of the AER in format specified in Schedule 2.
- 2.12.4 Upon decommissioning of all equipment containing foam and insulation panels containing substances falling within the scope of EC Regulation No. 1005/09 on substances that deplete the Ozone Layer & L.N. 280 of 2010 on substances that deplete the ozone Layer, regulations 2007, together with EC Regulation No. 842/2006 on certain Fluorinated Greenhouse Gases, the waste gas should be treated as hazardous waste and any foam containing components need to be disposed of at specialised facilities where possible ODS/F gas can be extracted prior to disposal.

2.13 Closure and Decommissioning

- 2.13.1 The Operator shall maintain and operate the Permitted Installation so as to prevent or minimise any pollution and public health risk, including the generation of waste, on closure and decommissioning in particular by:-
- 2.13.1.1 attention to the design of new plant or equipment;
- 2.13.1.2 the maintenance of a record of any events which have, or might have, impacted on the condition of the site along with any further investigation or remediation work carried out; and

- 2.13.1.3 the maintenance of a site closure plan to demonstrate that the installation can be decommissioned avoiding any pollution risk and returning the site of operation to a satisfactory state.
- 2.13.2 Notwithstanding condition 2.12.1 of this Permit, the Operator shall carry out a full review of the Site Closure Plan at least every 4 years.
- 2.13.3 The Operator shall notify the Authority immediately upon a decision being taken to decommission the site.
- 2.13.4 A finalised version of the Site Closure Plan shall be submitted to the Authority for approval not later than 10 days after the Authority is notified of the intention to decommission the site.
- 2.13.5 The approved Site Closure Plan shall be implemented within 12 months of final cessation or decommissioning of the Permitted activities or part thereof or according to a timeframe as may be agreed with the Authority.

2.14 Multiple Operator installations

- 2.14.1 This is not a multi-Operator installation.

2.15 Transfer to effluent treatment plant

- 2.15.1 No transfer whatsoever of effluent from the Permitted Installation shall be made to any off-site effluent treatment plant without the written consent of the authority.

3 Records

- 3.1 The Operator shall ensure that all records required to be made by this Permit and any other records made by it in relation to the operation of the Permitted Installation shall:-
 - 3.1.1 be made available for inspection by the Authority at any reasonable time;
 - 3.1.2 be supplied to the Authority on demand and without charge and in the format requested;
 - 3.1.3 be legible;
 - 3.1.4 be made as soon as reasonably practicable;
 - 3.1.5 indicate any amendments which have been made and shall include the original record wherever possible; and
 - 3.1.6 be retained at the Permitted Installation, or other location agreed by the Authority in writing, for a minimum period of 5 years from the date when the records were made, unless otherwise agreed in writing.

4 Reporting

- 4.1.1 All reports and written and or oral notifications required by this Permit and notifications required by Regulation 7 of the Industrial Emissions (IPPC) Regulations shall be made or sent to the Authority using the contact details notified in writing to the Operator by the Authority.
- 4.1.2 The Operator shall submit to the Authority an Annual Environmental Report (AER) of the previous year by not later than end of March of each year, providing the information listed in Schedule 2 of this Permit and in the format specified therein.
- 4.1.3 The European Pollutant Release and Transfer Register (E-PRTR) report for the installation shall be submitted as part of the Annual Environment Report, by end of March of each year, or as required by Legislation. All quantities shall be reported, even when these do not exceed the thresholds mentioned in EC Regulation 166/2006. The format used for reporting shall be that established by legislation, notably Legal Notice 152 of 2007, as may be amended from time to time.
- 4.1.4 The Operator 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 Operator, that may provide environmental improvement.

5 Notifications

- 5.1 The Operator shall notify the Authority **without delay** of:-
 - 5.1.1 the detection of an emission of any substance which exceeds any limit or criterion in this Permit specified in relation to the substance;
 - 5.1.2 the detection of any fugitive emission which has caused, is causing or may cause significant pollution unless the quantity emitted is so trivial that it would be incapable of causing significant pollution;
 - 5.1.3 the detection of any malfunction, breakdown or failure of plant or techniques which has caused, is causing or has the potential to cause significant pollution; and
 - 5.1.4 any accident which has caused, is causing or has the potential to cause significant pollution.
- 5.2 The Operator shall submit written confirmation to the Authority of any notification under condition 5.1.1, by sending:-
 - 5.2.1 the information listed in Part A of Schedule 1 to this Permit within 24 hours of such notification;
 - 5.2.2 the more detailed information listed in Part B of that Schedule as soon as practicable thereafter; and
 - 5.2.3 the information required by Schedule 2;
and such information shall be in accordance with that Schedule.
- 5.3 The Operator shall give written notification as soon as practicable prior to any of the following:-
 - 5.3.1 permanent cessation of the operation of part or all of the Permitted Installation;
 - 5.3.2 cessation of operation of part or all of the Permitted Installation for a period likely

- 5.3.3 to exceed 1 year; and
resumption of the operation of part or all of the Permitted Installation after a cessation notified under condition 5.1.3.2.
- 5.4 The Operator shall notify the Authority, as soon as practicable, of any information concerning the state of the site which affects or updates that provided to the Authority as part of the Site Report submitted with the application for this Permit.
- 5.5 The Operator shall notify the following matters to the Authority in writing within 10 working days of their occurrence:-
- 5.5.1 where the Operator is a registered company:-
- 5.5.1.1 any change in the Operator's trading name, registered name or registered office address;
- 5.5.1.2 any change to particulars of the Operator's ultimate holding company (including details of an ultimate holding company where an Operator has become a subsidiary); and
- 5.5.1.3 any steps taken with a view to the Operator going into administration, entering into a company voluntary arrangement or being wound up.
- 5.5.2 where the Operator is a corporate body other than a registered company:
- 5.5.2.1 any change in the Operator's name or address; and
- 5.5.2.2 any steps taken with a view to the dissolution of the Operator.
- 5.5.3 In any other case: -
- 5.5.3.1 the death of any of the named Operators (where the Operator consists of more than one named individual);
- 5.5.3.2 any change in the Operator's name(s) or address(es);
- 5.5.3.3 any steps taken with a view to the Operator, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case them being in a partnership, dissolving the partnership.

6 Interpretation

- 6.1 In this Permit, the following expressions shall have the following meanings:-

"AER" means the Annual Environmental Report.

"Application" means the application for this Permit, together with any response to a notice served under Regulation 5 to the Industrial Emissions (IPPC) Regulations and any operational change agreed under the conditions of this Permit.

"Authorised Officer" means any officer of the Authority;

"Background concentration" means such concentration of that substance as is present in:

- water supplied to the site; or
- where more than 50% of the water used at the site is directly abstracted from ground or surface water on site, the abstracted water; or
- where the Permitted Installation uses no significant amount of supplied or abstracted water, the precipitation on to the site.

“BAT” means best available techniques means the most effective and advanced stage of development of activities and their methods of operation which indicates the practical suitability of particular techniques for providing the basis for emission limit values and other permit conditions designed to prevent and where that is not practicable to reduce emissions and the impact on the environment as a whole. For these purposes: “techniques” includes both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned; “available techniques” means “those techniques which have been developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the costs and advantages, whether or not the techniques are used or produced in Malta, as long as they are reasonably accessible to the operator” and “best” means “most effective in achieving a high general level of protection of the environment as a whole”.

“Engineer” for engineering works specified in these conditions, means a person who works in the relevant branch of engineering and possesses a warrant to carry out the profession of an engineer in Malta.

“Fugitive emission” means an emission to air or water (including sewer) from the Permitted Installation which is not controlled by an emission or background concentration limit under conditions 2.2.1, 2.2.2, 2.2.3 or 2.2.4 of this Permit.

“Groundwater” means all water which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

“Hazardous Waste” means hazardous waste as defined in The Waste Regulations, 2011 (LN 184 of 2011 as amended by L.N. 441 of 2011), and any statutory provisions or regulations amending or replacing them.

“Industrial Emissions (IPPC) Regulations” means the *Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (LN 10 of 2013)* and words and expressions defined in the *Industrial Emissions (IPPC) Regulations* shall have the same meanings when used in this Permit save to the extent they are specifically defined in this Permit. It shall include any future amendments or superseding legislation.

“Malta” means the Island of Malta, the Island of Gozo and the other islands of the Maltese Archipelago, including the territorial waters thereof.

“Monitoring” includes the taking and analysis of samples, instrumental measurements (periodic and continual), calibrations, examinations, tests and surveys.

“Permitted Installation” means the activities and the limits to those activities described in Table 1.1.1 of this Permit.

“Sewer” means sewer within the meaning of section 219(1) of the Water Industry Act 1991.

“Staff” includes employees, directors or other officers of the Operator, and any other person under the Operator’s direct or indirect control, including contractors.

“Surface water” means inland waters, except groundwater; transitional waters and coastal waters.

“Technically Competent Person” means a person possessing the qualifications, experience and technical competence to abide by the conditions of the Permit.

“Technically Competent Management” means the Technically Competent Person or Persons in control of the day-to-day activities authorised by the Permit and carried on at the Site.

“The Authority” or *“the Competent Authority”* or *“MEPA”* means the Malta Environment and Planning Authority or such other body or person as the Minister responsible for the environment may by order in the Gazette prescribe.

“The Permit Holder” means the Permit Holder specified in the Permit or other person to whom the Permit has been transferred in accordance with the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (LN 10 of 2013), and any statutory provisions or regulations amending or replacing them.

“The Operator” means a person who is in occupation of the Site and has responsibility for carrying out day to day activities at the Site.

“The Regulations” means the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (LN 10 of 2013), and any statutory provisions or regulations amending or replacing them.

“The Site” means the land, structures, plant and equipment to which this Permit relates.

“VOC” means Volatile Organic Compound as defined by the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (LN 12 of 2013, as may be amended from time to time).

“VOC Solvents Regulations” means the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (LN 12 of 2013, as may be amended from time to time).

“Year” means calendar year ending 31 December.

- 6.2 Where a minimum limit is set for pH reference to exceeding the limit shall mean that the parameter shall not be less than that limit.
- 6.3 Unless otherwise stated, any references in this Permit to concentrations of substances in emissions into air means:-
- 6.3.1 in relation to gases from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or
- 6.3.2 in relation to gases from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content.
- 6.4 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 document(s) with the most recent date shall prevail to the extent of such conflict.

Schedule 1

Notification of abnormal emissions and significant adverse environmental effects

This page outlines the information that the Operator must provide to satisfy conditions 5.1.1 and 5.1.2 of this Permit.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the Industrial Emissions (IPPC) Regulations.

Part A

Permit Number	
Name of Operator	
Location of Installation	
Location of the emission	
Time and date of the emission	

Substance(s) emitted	Media (e.g. air, groundwater)	Best estimate of the quantity or the rate of emission (include units)	Time during which the emission took place

Measures taken, or intended to be taken, to stop the emission	
---	--

Part B

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident.	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment or harm which has been or may be caused by the emission.	
The dates of any unauthorised emissions from the installation in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of Operator

Schedule 2

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.

S2.1 Introduction

IPPC Permit Number	
Reporting Year	
Name and location of Site	
Brief description of activities at the site	

S2.2 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 4.1.3).

Tick (✓)

S2.3 Process Data**S2.3.1 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		

S2.3.2 Fuel consumption

	Units	Sulphur Content ¹	Consumption	
			Previous Year	Current Year
Propane	m ³			
Diesel	m ³			

¹ Specify units (e.g. as percentage, or mg/kg)

S2.3.3 List of Raw Materials

Raw Material	Risk phrase	Annual Quantity Used (kg)

S2.3.4 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)								
Actions taken to eliminate such leakages								
Quantity and nature of the substances involved								
Serial number of the personnel involved								
Quantities added and/or recovered (in Kg).								

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.

S2.4 Monitoring Data

S2.4.1 Emissions to air

Parameter	Emission point reference	Limit Value	Total annual number of exceedances ¹		Concentration (Annual Average)			Total Annual Load		
			Previous year ⁴	Present year ⁴	Unit	Previous report	Current report	Unit	Previous report	Current report
VOC as carbon	1	150 mgC/Nm ³		4	mgC/ m ³			kg		
VOCs: R45, R46, R49, R60, or R61 (H340, H350, H350i, H360D or H360F) where mass flow of sum of compounds ≥10 g/h ^{2,3}	1	2 mg/Nm ³		4						
Halogenated VOCs: R40 or R68 (H341or H351) where mass flow of sum of compounds ≥100 g/h ^{5,3}	1	20 mg/Nm ³	4	4	mgC/Nm ³			kg		
Carbon Monoxide	3	50 mg/m ³			g/m ³			kg		
Particulate Matter	3	5 mg/m ³			mg/m ³			kg		
Oxides of Nitrogen	3	110 mg/m ³			g/m ³			kg		

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"/>

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.

² Where mass flow is $< 10 \text{ g/h}$, 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 $< 100 \text{ g/h}$, appropriate calculations are required to confirm this.

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 (✓)

S2.4.2 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			
Legionella	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 (✓)

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S2.4.4 VOC solvents**S2.4.4.1 Total/Fugitive emissions of solvents¹ (tick and fill as applicable)****Total Emission Limit Value Option**

Tick (✓)

	Annual quantity	Units
VOC solvent input		
Total VOC solvent emissions		
% total VOC solvent emissions		%

Fugitive and Waste gas Emission Limit Value Option

Tick (✓)

	Annual quantity	Units
VOC solvent input		
Fugitive VOC solvent emissions		
% fugitive VOC solvent emissions		%

S2.4.4.2 VOCs used in the installation with specific risk phrases:

Phrase	Name of VOC substance(s) used
R45 (H340)	
R46 (H350)	
R49 (H350i)	
R60 (H360D)	
R61 (H360F)	

Additional documentation to be submitted:

Tick (✓)

Mass balance for total/fugitive emissions

Progress on substitution of above VOC substances

S2.4.5 Noise monitoring

Year when noise monitoring was last carried out

Testing due in (year)

Additional documentation submitted	Attached
Noise monitoring report according to BS4142:1997	

¹ The calculation methodology used shall be according to Schedule IV of LN 12 of 2013, as may be amended from time to time.

S2.5 Waste**S2.5.1 Wastes produced by Combino Pharm and accepted on site**

EWC Code¹	Quantity of waste accepted on site	Quantity of wastes removed from site	Disposal/ Recovery	Location of disposal/recovery
TOTAL				

¹ Hazardous waste codes must be indicated by an asterisk (*).

S2.5.2 Wastes produced by Medichem and removed from site¹

[illegible]

¹ For non-hazardous waste, only categories of non-hazardous waste in which the quantity exceeds 10 tonnes per annum need to be reported.

² European Waste Catalogue Code (Reference: Commission Decision 2000/532/EC; <http://www.mepa.org.mt/file.aspx?f=6289>)

³ For hazardous waste only. If waste is not hazardous, please write "n/a".

S2.6 Testing of catchment pits, reservoirs and bunds

Number of catchment pits on site	
Number of reservoirs on site	
Number of bunds on site	
Date of last test	
Testing due on (date)	

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

Tick (✓)

Certification by warranted architect or engineer

☐
S2.7 Environmental Incidents and Complaints**S2.7.1 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:	

S2.7.2 Complaints made by the public to Medichem

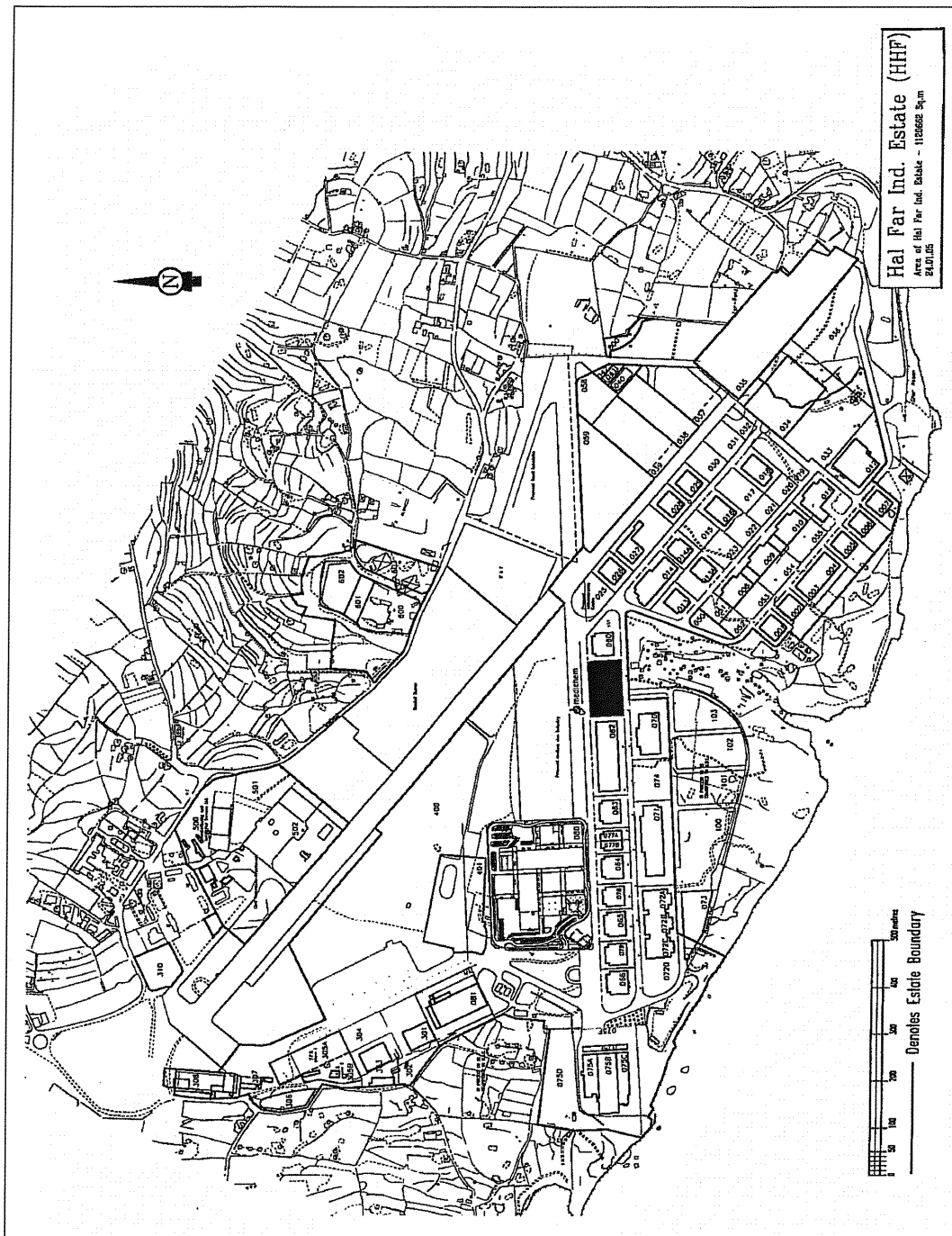
Date of complaint	Description of complaint	Actions taken

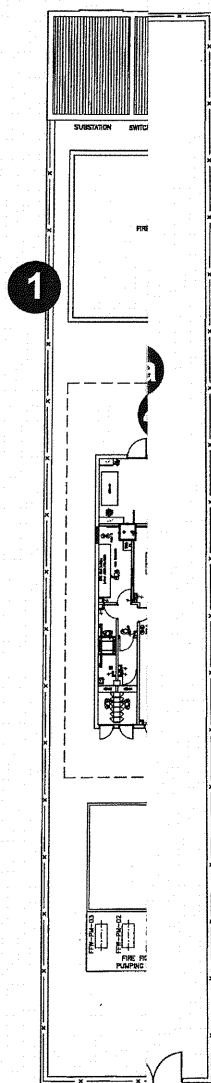
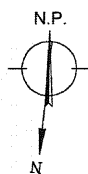
Total number of complaints for previous year:	
Total number of complaints for current reporting year:	

S2.8 Transport

Name of registered waste carrier used during reporting year	Waste type(s) transported

Schedule 3 Site Plan





Schedule 5

Terms of Reference for Noise Monitoring

1. Introduction

The noise monitoring shall be carried out by the Operator. A consultant approved by MEPA on the basis of the requirements of points (a.) & (b.), shall be commissioned and propose a monitoring procedure for measuring noise levels within and around the installation as described in section 2 below.

The person(s) undertaking the “on field monitoring” shall be in possession of a certification for the collection of data.

The noise monitoring survey and report shall be reviewed by a person who is in possession of a:

- (a) Bachelors degree in Acoustics, or
- (b) Bachelors degree in Physics, Architecture, Civil Engineering or Engineering, Environmental Health, Environmental Science/Management, Occupational Health and Safety **and** a specialisation Masters degree in Acoustics, **or**
- (c) Have any recognised certification in Acoustics and be at least an associate member of the Institute of Acoustics or equivalent grade of Membership of a professional body for those working in acoustics, noise and vibration in any one of the EU member states.

The consultant, in collaboration with MEPA, shall seek advice from the Local Council during the selection of the sensitive receptors.

2. Content of monitoring study

The monitoring study should address the following issues:

1. A description of the installation – this shall include a description of all processes carried out on site and related equipment and infrastructures.
2. A description of the surrounding areas – this shall include identification of the types of activities, whether residential or commercial, roads and other amenities. These shall be location-specific taking into account their location with respect to the site.
3. Identification of the main sources of noise – this shall include all processes on site, including aspects such as transport noise on site, plant equipment, mechanical operations, etc (amongst others).
4. Identification of the closest noise sensitive receptors – this shall be carried out after assessing the noise levels in the plant's perimeter and in the other locations identified in point 2 above under normal operating conditions of the plant (including grit blasting operations). The various monitoring points shall be identified with a unique code and an analyses of the ambient noise to which each monitoring point is subjected to.
5. Environmental Noise Survey – this shall include details of the standards used for measurements, equipment used including calibration details, resultant measurement data, assessment methods and complaints significance scale. The survey is to be carried out according to the latest revisions of ISO1996 and the rating of industrial noise affecting residential areas shall be according to BS4142:1997. The survey should include perimeter noise levels, baseline noise survey of sensitive receptor sites, noise impact on site sensitive receipts including day and night background levels.
6. The monitoring shall be performed exclusively using type 1 sound level meter. The use of type 2 sound level metres or less is not considered acceptable and will not be considered.

Impact assessment of noise events on noise sensitive receptor site – this shall include an assessment according to the guidelines BS 4142:1997, ISO1996 and ISO9613 or any other standard and any other standard methodology stipulated by the Authority. A summary of the data obtained after the survey has been carried out in relation to the noise sensitive receptors identified above shall be submitted.

7. Conclusions and Mitigation measures – this shall include a summary report of findings from the noise monitoring survey and any remedial action and/or mitigation measures to be implemented by the operator in order to reduce impacts resulting from the site of operation.

Schedule 6

List of wastes authorised for acceptance from Combino Pharm.

06	WASTES FROM INORGANIC CHEMICAL PROCESSES
06 01 06*	other acids
06 03 13*	solid salts and solutions containing heavy metals
06 04 04*	wastes containing mercury
07	WASTES FROM ORGANIC CHEMICAL PROCESSES
07 01 01*	aqueous washing liquids and mother liquors
07 05 01*	aqueous washing liquids and mother liquors
07 05 03*	organic halogenated solvents, washing liquids and mother liquors
07 05 04*	other organic solvents, washing liquids and mother liquors
07 05 09*	halogenated filter cakes and spent absorbents
07 05 10*	other filter cakes and spent absorbents
07 05 13*	solid wastes containing dangerous substances
07 07 01*	aqueous washing liquids and mother liquors
07 07 03*	organic halogenated solvents, washing liquids and mother liquors
07 07 04*	other organic solvents, washing liquids and mother liquors
07 07 09*	halogenated filter cakes and spent absorbents
07 07 10*	other filter cakes and spent absorbents
13	OIL WASTES AND WASTES OF LIQUID FUELS (except edible oils, and those in chapters 05, 12 and 19)
13 02 05*	mineral-based non-chlorinated engine, gear and lubricating oils
13 08 02*	other emulsions
14	WASTE ORGANIC SOLVENTS, REFRIGERANTS AND PROPELLANTS (except 07 and 08)
14 06 02*	other halogenated solvents and solvent mixtures
15	WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED
15 01 10*	packaging containing residues of or contaminated by dangerous substances
15 02 02*	absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances
16	WASTES NOT OTHERWISE SPECIFIED IN THE LIST
16 03 05*	organic wastes containing dangerous substances
16 05 06*	laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals
16 05 07*	discarded inorganic chemicals consisting of or containing dangerous substances
16 05 08*	discarded organic chemicals consisting of or containing dangerous substances
18	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 01 08*	cytotoxic and cytostatic medicines
18 02 05*	chemicals consisting of or containing dangerous substances
18 02 07*	cytotoxic and cytostatic medicines

END OF PERMIT

Environmental Permit

Environment Protection Act (CAP. 549)

Permit number
EP 0102/20

The Environment and Resources Authority (hereinafter the Authority; the Competent Authority) in exercise of its powers under the Environment Protection Act (CAP. 549), hereby authorises:

Dr. Dino Mangion o.b.o.

Combino Pharm (Malta) Ltd. (hereinafter "the Operator" or "the Permit Holder"),

Of / Whose Registered Office (or principal place of business) is at
HHF60

Hal Far Industrial Park

Birżebbuġa BBG 3000

(Company registration number: **C 34302**)

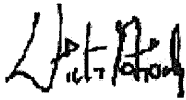
to operate an installation at:

Combino Pharm (Malta) Ltd.

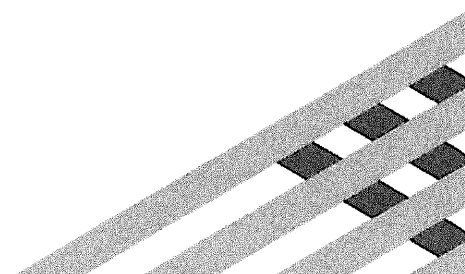
HHF60, Hal Far Industrial Park

Birżebbuġa BBG 3000

This permit is valid for six (6) months from the date of issue below.

Signed	Date
 Prof. Victor Axiak Chairman	 28/07/2020

Authorised to sign on behalf of the Competent Authority



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Conditions

1 General

The Permitted Installation shall, subject to the conditions of this Permit, be managed, controlled and operated as described in the EP Application, or as otherwise previously agreed in writing by the Authority.

1.1 Status Log

Detail	Date
<i>EP application</i>	11 September 2009
<i>Permit Issued</i>	19 July 2010
<i>Variation Request</i>	22 March 2013
<i>Permit Variation Issued</i>	06 May 2013
<i>Renewal Requested</i>	21 January 2014
<i>Renewal Issued</i>	17 December 2014
<i>Renewal Request</i>	17 July 2020
<i>Renewal determined by ERA board</i>	26 July 2020

1.2 Permitted Activities

1.2.1 The Operator is authorised to carry out the activities and the associated activities specified in Table 1.2.1.

Table 1.2.1		
Activity	Description of specified activity	Limits of specified activity
Manufacture of pharmaceutical preparations	Manufacture of pharmaceutical products (non-sterile solid dosage forms: tablets and capsules)	From receipt of raw materials and associated chemicals to dispatch of finished product (including packing and testing). Includes the manufacture of cytostatic/cytotoxic products. Does not include the preparation of any APIs (including intermediates) using a chemical/biological reaction. Does not include the manufacture of hormones or injectables.
Associated activity of utilities	LPG boiler to produce steam and hot water. Emergency diesel generator to produce energy.	From receipt of fuel to delivery of utility. From receipt of fuel to delivery of energy.

	Reverse osmosis for water purification.	From receipt of water to delivery of utility.
Associated activity of storage, treatment and disposal/recycling of waste materials	Handling, storage, treatment and containment of wastes from installation prior to disposal.	From generation of waste to disposal or recycling (including recovery) offsite at permitted facilities.

1.3 Site

- 1.3.1 The activities authorised under condition 1.1.1 shall not extend beyond the Site, as shown on the Site Map in Schedule 2 to this Permit.

1.4 General Conditions

- 1.4.1 The conditions and obligations of this permit are without prejudice to any other regulation, code of practice, conditions or requirements requested by other Authorities or entities, including but not limited to, the Planning Authority, the Occupational Health and Safety Authority, Transport Malta, the Regulator for Energy and Water Services (REWS) and the Environmental Health Directorate.
- 1.4.2 This permit is granted saving third party rights. The Permit Holder is not excused from obtaining any other permission required by law.
- 1.4.3 A copy of this Permit shall be available at all times on site at the permitted facility, including any Variation Notices or amendments to it.
- 1.4.4 In these conditions and their interpretation, all terms shall have the same meaning as that assigned to them in CAP 549 the Environment Protection Act and its subsidiary legislation.
- 1.4.5 The Permit Holder has the sole responsibility to ascertain compliance with legal obligations, permit conditions and to undertake activities on and off site in line with good environmental practices at all times.
- 1.4.6 The company shall maintain a register of third party complaints. The register shall record the name and address of the complainant(s), the date, location, source and nature of the complaint and the corrective action undertaken, where such action proves necessary.
- 1.4.7 All plant, equipment and technical means used in operating the Permitted Installation shall be maintained in good operating condition and without causing polluting emissions, leaks and spillages. The Permit Holder shall keep maintenance records as per Section 2.8 of this Permit.
- 1.4.8 The Permitted Installation shall be managed, controlled, supervised and operated by staff who are aware of the importance of environmental protection and suitably trained on the requirements of this Permit. All staff shall be provided with adequate training and written operating instructions to enable them to effectively carry out their duties. Such training shall be recorded and maintained in line with conditions in section 3.3. Subcontractors who enter the site shall also be made aware of any obligations arising from the permit which might affect their duties.
- 1.4.9 The permit is valid for a period of six months from the date of the granting. The permit will be considered renewed once the official renewed permit is granted by

the Authority.

- 1.4.10 The Authority may request monitoring and/or review of operational practices and/or commission audits on the installation as deemed necessary to address any circumstances that may affect quality of the surrounding environment.
- 1.4.11 In case of any monitoring requirements specified in this permit, there shall be provided safe means of access to enable sampling/monitoring to be carried out by the Authority or by a third party if deemed if necessary.
- 1.4.12 Without prejudice to condition 1.4.10, the Authority may take any action deemed necessary including but not limited to the suspension of any activity/operation until investigations are concluded.
- 1.4.13 The Authority may carry out pre-set or unannounced compliance checks that vary in frequency according to the site's compliance with the permit conditions. Any such checks and audits carried out by the Authority are to be made at the Permit Holder's financial expense at the rate and arrangement communicated by ERA's Compliance and Enforcement Directorate.
- 1.4.14 The Authority's representatives may inspect and photograph any part of the site and ask for any closed or locked areas to be opened and may demand to be provided with any proof, documentation, plans, receipts or any other records.
- 1.4.15 The Authority may add, amend, delete or substitute any of the conditions of this permit after notifying the Permit Holder of its intention and after describing the changes to the Permit Holder. This is without prejudice to any prevailing circumstances that would preclude the Authority from following such a procedure.
- 1.4.16 The Authority may suspend or revoke this environmental permit in line with the provisions of CAP 549.
- 1.4.17 The Permit Holder shall undertake all reasonable measures and precautions to prevent spillage of raw materials, intermediates, products, waste and any other materials.

1.5 Operational Changes

- 1.5.1 The Permit Holder may apply for a variation in permit and shall seek the Authority's written agreement prior to any operational changes, by sending to the Authority;
 - a. Written notice of the details of the proposed change, including an assessment of its possible effects (including changes in emissions and waste production) on risks to the environment from the Permitted installation
 - b. Any relevant supporting information (e.g. chemical/fuel consumption, technical details, changes in the type/use of substances/mixtures, etc.);
 - c. Any relevant supporting assessments and drawings, and;
 - d. The proposed implementation date

Any such change shall only be implemented following the granting of a variation of the permit by the Authority.

- 1.5.2 The Permit Holder shall notify the following matters to the Authority in writing at

least within 10 working days prior to their occurrence:

- a) Any change in the Permit Holder's trading name, registered name or registered office address;
- b) Any change to particulars of the Permit Holder's corporate identity

1.6 Improvement Programme

1.6.1 There are no improvement programme conditions

2 Operating Conditions

2.1 Emissions to Air

- 2.1.1 All processes which generate significant levels of airborne contaminants (such as dusts, toxic gases, odorous chemicals) shall have effective local collection and shall discharge (after treatment where necessary) through a stack or vent located and/or designed in such a way as to avoid a local nuisance effect.
- 2.1.2 The exhaust from general building ventilation (e.g. extractors or fans in walls or roofs) shall be vented in such a way as to avoid adverse environmental effects and in accordance with applicable legislation in this regard.
- 2.1.3 The Operator shall prevent or where that is not practicable reduce fugitive emissions of substances to air from the Permitted Installation.
- 2.1.4 Emissions to air shall only arise from the emission points specified in Table 2.1.4, as described Schedule 3.

Table 2.1.4 : Emission points to air	
Emission point references (Schedule 3)	Source
PS1	Boiler
PS2	Generator
PS3	Fluid-bed drier
PS4	Coater
PS5	HVAC exhausts

- 2.1.5 Should the Permit Holder intend to install equipment, which could lead to additional emissions to air (e.g. an additional boiler, etc.), a variation of this Permit must be secured prior to installation and operation of this equipment

API Handling areas

- 2.1.6 Emissions to air from all areas where active pharmaceutical ingredients are handled (including weighed, processed, compacted and dried) shall be exhausted through abatement equipment having at least 99.9% efficiency.
- 2.1.7 The operational effectiveness of filters (such as HEPA filters) for the control of particulate emissions of pharmaceutical raw materials, intermediates and products shall be monitored by means of a pressure differential recorder or equally effective means. Such recorders shall be visible to operators working on the equipment such that an out of range incident can be easily and immediately identified.

Combustion Plants

- 2.1.8 ERA recommends that diesel (gas oil) used for generators or boilers shall have a sulphur content not greater than 0.1%.
- 2.1.9 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.
- 2.1.9 The Authority may request monitoring of emissions to air listed in table 2.1.4 which shall be undertaken in accordance to the terms of reference provided by the Authority.
- 2.1.10 During each measurement, as specified in condition 2.1.9, 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.
- 2.1.11 The Permit Holder shall submit certification for the combustion equipment (PS1 and PS2) referred to in table 2.1.4, by an independent warranted engineer showing that the generator is in good working condition every four (4) years. The certification shall be submitted as part of the Environmental Report (ER) in Schedule 1. The certification and the monitoring results shall be submitted as part of the Annual Environmental Report. The Authority may request the right to require an increase in the frequency of such measurements

Volatile Organic Compounds

- 2.1.12 In the event that the VOC solvent consumption threshold exceeds 50 tonnes/year as per Activity 20 in Schedule II of S.L.549.79 (the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations), the operator is to notify the Authority, and the provisions of S.L.549.79 shall apply.
- 2.1.13 The Permit Holder shall inform the Authority in advance should there be an intention to use any VOC solvents as per S.L. 549.79 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 (or the risk phrases R40, R45, R46, R49, R60, R61 or R68). In this case, the Authority may set emission limits for these substances and monitoring requirements.

Emergency Considerations

- 2.1.14 In the event of malfunction or breakdown leading to abnormal emissions from equipment, the Permit Holder must:
- a. Investigate immediately and undertake corrective action,
 - b. Adjust the process or activity to minimise those emissions, and
 - c. Record the events and actions taken
- 2.1.15 Further to condition 2.1.14, the Permit Holder shall provide ERA with details of the specific cause of the malfunction and the remedial steps taken or to be taken to address the malfunction.
- 2.1.16 All abatement equipment and ducting shall be maintained on a regular basis (as per manufacturer specifications). Records of such maintenance shall be kept in line with Section 3.3 of this Permit.
- 2.1.7 Under abnormal operating conditions such as in the case of breakdown, the Operator shall reduce or close operations as soon as practical until normal operation can be restored.

- 2.1.18 Operation of the fluid bed drier emergency stack may only take place if the fluid bed drier is in an operational state that might otherwise cause danger to human beings or severe damage to the plant, e.g. acute danger of explosion. In the case of installation of new fluid bed driers, the operator shall endeavour to install and utilise alternative techniques, which in the case of an emergency, do not require use of an emergency stack.
- 2.1.19 The operator shall take all possible precautions (including maintenance, risk assessment, use of suitable materials in relation to the limitations of the fluid bed drier, etc.) to ensure that the likelihood of emergency stack use is minimised.
- 2.1.20 In case of emergency stack operation, the process occurring in the fluid bed drier must be stopped immediately and automatically. The duration of emergency stack operation must be reduced to the utmost minimum.
- 2.1.21 The Permit Holder shall maintain an emergency procedure that is specific to the use of the fluid bed drier emergency stack. The procedure shall include actions to be taken to minimise the release, and immediate notification of ERA, the Civil Protection Department and neighbours in case of an incident.
- 2.1.22 In the event of emergency stack operation, a report shall be submitted to ERA within two working days describing:
- a) the cause of emergency stack operation;
 - b) the duration of emergency stack operation;
 - c) the quantity of emissions resulting from emergency stack operation;
 - d) measures being implemented by the operator to minimise the probability of recurrence of such an incident.
- 2.1.23 The emergency stack vent shall be directed in such a way as to minimise impact to the surroundings in case of emissions.
- 2.2 Effluent discharges**
- 2.2.1 No discharges to surface water or groundwater shall take place from the permitted installation.
- 2.2.2 Foul sewer drains must be strictly segregated from stormwater drains.
- 2.2.3 Rainwater shall be segregated from all process areas that are potentially contaminated with raw materials, intermediates and/or products. If this is not possible, rainwater from areas where contamination by oil or chemicals is likely (such as loading/unloading and bunded areas) shall pass through an adequately sized interceptor.
- 2.2.4 All discharges to the foul sewer (other than from domestic sewage or equivalent), including reverse osmosis reject water, shall comply with the requirements of a Water Services Corporation Sewer Discharge Permit
- 2.2.5 Process effluents shall not be diluted prior to discharge to sewer or transfer off-site.
- 2.2.6 The Operator is allowed to discharge process water to the wastewater treatment plant and second reservoir of Medichem Manufacturing (Malta) Ltd (of HF-61, Hal Far Industrial Estate, Malta), provided that:
- a) Wastewaters from Combino Pharm are treated in Medichem's on-site wastewater treatment plant prior to discharge, except where the wastewaters from Combino Pharm are in conformity with the limits set in the Water Services Corporation Sewer Discharge Permit for Medichem and do not require treatment prior to discharge.

- b) Wastewaters from Combino Pharm do not result in any exceedance of the limits set in the Water Services Corporation Sewer Discharge Permit for Medichem.

2.3 Emissions to Land

- 2.3.1 No emission from the Permitted Installation shall be made to land.

2.4 Odour

- 2.4.1 The Operator shall prevent or where that is not practicable reduce odorous emissions from the Permitted Installation, in particular by:

- limiting the use of odorous materials;
- restricting odorous activities;
- controlling the storage conditions of odorous materials;
- controlling processing parameters to minimise the generation of odour;
- optimising the performance of abatement systems;
- timely monitoring, inspection and maintenance;
- employing, where appropriate, an approved odour management plan.

provided always that the techniques used by the Permit Holder shall be no less effective than those described in the Application, and where relevant approved by the Authority prior to their implementation.

- 2.4.2 There shall be no significant offensive odour as perceived by an Authorised Officer of the Competent Authority, outside the boundary of the permitted installation.

2.5 Noise and Vibration

- 2.5.1 The Operator shall prevent or where that is not practicable reduce emissions of noise and vibration from the Permitted Installation.

- 2.5.2 Emergency generators/alarms/sirens/release valves shall only be tested between the hours of 10.00 and 17.00 Monday to Friday and not on any Public Holiday.

- 2.5.3 The Authority shall reserve the right to request noise monitoring analysis, at the expense of the Permit Holder. In this regard, the locations, measurements and assessment must be made according to BS 4142:2014 and Terms of Reference issued by the Authority.

2.6 Waste

Waste storage and handling

- 2.6.1 All operations concerning the management of waste are subject to the Waste Management Regulations (S.L.549.63) and the Waste Management (Activity Registration) Regulations (S.L. 549.45).

- 2.6.2 All wastes shall be stored within a designated and controlled storage area(s) prior to ultimate disposal. Wastes to be recycled shall be stored in a designated container or area and shall not be mixed with other wastes.

- 2.6.3 Liquid and hazardous wastes shall be stored in a labelled, closed container(s) within a designated and controlled storage area(s) prior to ultimate disposal. Wastes of different natures and having different European Waste Catalogue codes as established by Commission Decision 2000/532/EC shall not be mixed in the same container.

- 2.6.4 Packaging and containers which came into contact with hazardous substances shall be regarded as hazardous waste and shall be disposed of in an appropriate manner.
- 2.6.5 No storage of waste, equipment or materials permitted on property outside the site boundary referred to in condition 1.3.1
- 2.6.6 All storage of materials or waste shall take place only in locations where thorough clean-up and site reinstatement can be readily undertaken.
- 2.6.7 No storage of waste destined for disposal is permitted for a period exceeding 12 months. No storage of waste destined for recovery is permitted for a period exceeding 3 years.
- 2.6.8 The Operator shall ensure that waste transferred to another person is packaged and labelled in accordance with national, European and any other standards which are in force in relation to such labelling. While awaiting collection, recovery or disposal all waste shall be stored in designated areas protected, as may be appropriate, against spillage, leachate run-off and accidental damage. The waste is to be clearly labelled and appropriately segregated.

Waste recovery or disposal

- 2.6.9 No treatment, dismantling or recovery of waste is allowed on site.
- 2.6.10 The Permit Holder shall be committed to reduce waste generation where possible.
- 2.6.11 The operator is to prevent litter or other wastes escaping from the site boundaries, particularly during loading/unloading. Any such escape of waste shall be collected immediately upon detection.
- 2.6.12 On-site disposal of wastes by any means including burning, disposal to drain or surface water, burying or deposition on land is prohibited.
- 2.6.13 Off-site disposal or recovery of wastes may only take place at a facility licensed for that purpose.

Transport

- 2.6.14 In the case of waste that is sent for treatment or recovery to another facility locally or abroad, the audit trail shall cover all waste from the point of generation or collection to the end recovery or disposal facility.
- 2.6.15 The Operator shall ensure that no waste escape to the environment especially when transporting such materials offsite or onsite.
- 2.6.16 All wastes leaving the site after storage and/or processing must only be sent to facilities licensed to accept the individual waste stream, either locally or abroad.
- 2.6.17 The transboundary movement of waste shall be carried out in accordance with the following regulations, as amended from time to time:
- i. Regulation (EC) N° 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste as implemented through SL 549.65;
 - ii. Commission Regulation (EC) N° 1418/2007 of 29 November 2007 concerning the export for recovery of certain waste listed in Annex III or IIIA to Regulation (EC) N° 1013/2006 of the European Parliament and of the Council to certain countries to which the OECD Decision on the control

of transboundary movements of waste does not apply; and

iii. Any other applicable legislation.

- 2.6.18 The Permit Holder shall make use of the services of a registered waste carrier for the transport of waste from the site in accordance activity 38 of schedule 1 of Subsidiary Legislation 549.45, the Waste Management (Activity Registration) Regulations. Where the company removes wastes using its own transport the vehicle(s) must also be registered as a waste carrier in accordance with S.L. 549.45 or any statutory provisions or regulations amending or replacing them.
- 2.6.19 Movement of hazardous waste to authorised facilities shall be covered by a valid consignment permit obtainable from the Competent Authority. Each movement shall also be covered by a consignment note obtainable from the Authority.
- 2.6.20 Should the operator require the services of a waste broker, it shall be ensured that any such broker is a duly registered waste broker in accordance with S.L. 549.45.
- 2.6.21 In the case of waste that is sent for treatment or recovery to another facility locally or abroad, the audit trail shall cover all waste from the point of generation or collection to the end recovery or disposal facility.

Waste Records

- 2.6.22 The Permit Holder shall ensure to keep records for every consignment of hazardous wastes, or other wastes, as deemed necessary by the Authority, removed from the Site indicating the EWC Code, description, quantities, date of removal, contractor name (including for transport), consignment note number (where applicable) and manner and place of final disposal/recovery.
- 2.6.23 Disposal certificates shall be kept on record and made available for inspection for a period of at least 3 years from date of their issue.

2.7 Storage

- 2.7.1 All bulk oil storage tanks shall be provided with an adequately designed bund system with an impermeable base and walls. The capacity of the bund shall be at least 110% of the largest tank within the bund or 25% of the total volume of all the tanks within the bund, whichever is the greater. Filling and off-take points shall be located within the bund.
- 2.7.3 Containers for bulk storage of liquids (including waste liquids) shall be properly designed, located, labelled, banded and maintained so as to prevent accidental spillage. The capacity of retention pallets shall be a minimum of 110% of the largest container within the bund or 25% of the total volume of all the containers within the bund, whichever is the greater. Incompatible chemicals shall not be stored within the same bund.
- 2.7.4 Drums and containers of solvents, oils or any other chemicals shall be stored in designated and secure storage areas. Storage areas shall be designed so that surface and ground waters cannot be contaminated by spillages.
- 2.7.5 The storage of flammable, toxic and hazardous substances shall be in line with the measures specified in the Material Safety Data Sheets (SDS) for that substance and the maintenance of safety critical equipment shall correspond to manufacturer specifications.
- 2.7.6 Chemicals of different properties shall be stored as specified in respective SDS sheets. Such sheets shall be made available and accessible to personnel responsible for the management of the storage areas and for inspection by the

Competent Authority. Incompatible chemicals shall not be stored within the same bund.

- 2.7.7 Storage and handling of cytotoxic/cytostatic materials shall be to the satisfaction of the Occupational Health and Safety Authority.

2.8 Maintenance

- 2.8.1 All plant and equipment used in operating the Permitted Installation shall be maintained in good operating condition.

- 2.8.2 The Permit Holder shall maintain a record of plant and equipment covered by section 3.3, and for such plant and equipment:

- i. a written or electronic maintenance programme;
- ii. Records of its maintenance.

2.9 Ozone depleting substances and Fluorinated greenhouse gases

- 2.9.1 All installation, maintenance and servicing of equipment containing Fluorinated Greenhouse Gases shall abide by the requirements of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/06, Commission Regulation (EC) Nos 1516/07, 304/08, 306/08 and S.L.427.94, Fluorinated Greenhouse Gases (implementing) Regulations.

- 2.9.2 The use of HCFCs in the maintenance and servicing, in particular refilling, or products and equipment whose function relies on such substances shall be prohibited.

- 2.9.3 All installation, maintenance and servicing of equipment containing Fluorinated Greenhouse Gases shall abide by the requirements of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/06, Commission Regulation (EC) Nos 1516/07, 304/08, 306/08 and S.L.427.94, Fluorinated Greenhouse Gases (implementing) Regulations.

- 2.9.4 For all equipment installed on site utilising Ozone Depleting Substances or Fluorinated Greenhouse Gases, information pertaining to installation, maintenance and servicing shall be provided as prescribed in Schedule 1. When any equipment is replaced by new equipment, The Authority shall be notified in this regard and details provided on the new equipment installed.

- 2.9.5 Upon decommissioning of all equipment containing foam and insulation panels containing substances falling within the scope of EC Regulation No. 1005/09 on substances that deplete the Ozone Layer & S.L. 549.58 on substances that deplete the ozone Layer, together with Regulation (EU) No. 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No.842/2006, or containing foam and insulation panels utilising such substances the waste gas should be treated as hazardous waste and any foam containing components need to be disposed of at specialised facilities where possible ODS/F gas can be extracted prior to disposal.

- 2.9.6 No new equipment or components containing substances falling within the scope of EC Regulation No. 1005/2009 on Substances that Deplete the Ozone Layer & S.L. 549.58 on Substances that Deplete the Ozone Layer, shall be installed within the site.

- 2.9.7 Where required, leak detection systems as per the legal provisions of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/2006 shall be installed and well maintained.

3 Site Management

3.1 Staff obligations and Responsibilities

- 3.1.1 One member of the staff shall be nominated as the Technically Competent Person (TCP) of the site, whereby this person is to physically represent the Permit Holder during the times when the Permit Holder will not be available.
- 3.1.2 In the event of any short or long periods of leave of absence taken by the TCP for a period exceeding 10 days or change in the TCP, the Permit Holder is obliged to find a replacement for that member of staff without delay and the Authority informed accordingly.
- 3.1.3 The TCP is responsible for the implementation of all the obligations stipulated in this permit, must supervise the rest of the staff on site and is completely responsible to ascertain that all permit conditions are being adhered to.
- 3.1.4 All the staff on site shall be fully aware of the procedures to be taken in the event of an accidental spill of any liquids other than water and how to contain the environmental hazard.
- 3.1.5 Any changes in technically competent management (person/s) and the name of any incoming person together with evidence that such person has the required technical competence shall be submitted to the Authority in writing within 5 working days of the change in management.

3.2 Accident prevention and control

- 3.2.1 An Emergency Response Plan shall be maintained containing details of the location, nature and quantity of chemicals, oils and fuels stored, any special hazards, a drawing showing location of drains and the emergency phone numbers of the Permit Holder and relevant authorities. It shall also include actions to be taken in the case of incidents which could affect the environment, such as fires, chemical/fuel spills, failure of abatement equipment and use of the emergency stack. The emergency plan shall indicate that accidental releases of chemicals and fires caused by chemicals are to be managed as specified in the respective SDS sheets
- 3.2.2 In the case of an accident (including chemical spills, etc.), the Permit Holder shall follow the Emergency Response Plan referred to in Condition 3.2.1 and shall notify the Authority within 24 hours.
- 3.2.3 Spillages of chemicals or other hazardous material shall receive immediate attention to prevent escape to drain, surface water or land. Spilled material shall be disposed of in an appropriate manner. Kits for the collection of liquid and powder spills shall be available on site at strategic locations.
- 3.2.4 Small leaks or spills shall be cleared up immediately by the application of absorbent materials. All used absorbent materials shall be disposed of as hazardous waste at facilities permitted to accept such waste. Transfer of this waste shall be carried out as per conditions specified in Section 2.6 of this permit.
- 3.2.5 The Permit Holder shall have in storage an adequate supply of suitable absorbent material to absorb any spillage.
- 3.2.6 The emergency procedure shall be updated whenever necessary and the updated version sent to ERA and the Civil Protection Department.

3.3 Records

3.3.1 The Permit Holder shall ensure that all records required to be made by this Permit and any other records made by it in relation to the operation of the Permitted Installation shall:

- a) Be made available for inspection by the Authority at any reasonable time;
- b) Be supplied to the Authority on demand and without charge and in the format requested;
- c) Be legible;
- d) Be made as soon as reasonably practicable;
- e) Indicate any amendments which have been made and shall include the original record wherever possible; and
- f) Be retained at the Permitted Installation, or other location agreed by the Authority in writing, for a minimum period of 3 years from the date when the records were made, unless otherwise agreed in writing.

3.3.2 A site operations log shall be made in a legible manner and kept on site and be made available for inspection by the Authority at any reasonable time. The following information shall be recorded and retained for 5 years:

- i. Total amount of waste in kilos removed from site for disposal or further treatment
- ii. Any incidents that took place on site such as mechanical faults in the machinery or equipment used on site, any spills, fires, etc and the remedial action taken
- iii. Any other incidents that the Permit Holder deems important to record in the Site operations log.

3.3.3 Each record shall be compiled within 24 hours of the relevant event. The records kept in the site daily operational log shall be available for inspection at any time when the Authority representatives request to inspect them.

3.4 Closure and Decommissioning

3.4.1 The Permit Holder shall notify the Authority prior to ceasing operations permanently in part or full, whereby an application for cessation of operations shall be made to the Authority and shall include a decommissioning plan.

3.4.2 In the event of cessation of operations on the site, the Permit Holder shall remain responsible for all wastes and hazardous materials on site, which shall be removed from the site in accordance to good environmental practice and in such a manner that minimises environmental risks

3.4.3 The Decommissioning Plan shall be implemented once approved by the Authority and within 12 months of final cessation of operations or as agreed with the Authority in writing.

3.4.4 The obligations arising from this permit shall subsist until the Authority confirms in writing that the decommissioning plan has been implemented to its satisfaction.

3.4.5 When deemed necessary, the Authority may require the Permit Holder to take such additional measures as it considers necessary with respect to after care obligations in relation, but not limited to the remedial action, rehabilitation, and monitoring of the waste management or waste production site.

4 Reporting

- 4.1 The Permit Holder shall submit to the Authority an Annual Environmental Report (AER) of the previous year by not later than end of March of each year, providing the information listed in Schedule 1 of this Permit and in the format specified therein. It shall also be ensured that all certification and documentation as per Schedule 3 are submitted.
- 4.2 In the event where operations cease temporarily (2 weeks or more), the TCP or Permit Holder are obliged to notify the Authority within two (2) days and are also to inform the Authority with regards to when the works are intended to resume.

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

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

S1.2 Fuel Consumption Data

Equipment ¹	Fuel type	Sulphur Content of Fuel ²	Fuel Consumption	Units
				tonnes
				tonnes

S1.3 Off-site transfers and exports of hazardous waste

Date of transfer	EWC Code ³	Quantity of waste (in kg)	Consignment note number and/or TFS (Transfrontier Shipment of waste) reference number	Ultimate destination

S1.4 Off-site transfers of non-hazardous Waste

Date of transfer	EWC Code ³	Quantity of waste (in kg)	Ultimate destination	Name(s) of registered waste carrier used during reporting year

¹ E.g. Boiler, generator, vehicles, etc.

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

³ European Waste Catalogue Code (Reference: Commission decision 2000/532/EC establishing a list of wastes)

S1.5 Data on Ozone depleting substances and Fluorinated greenhouse gases

S1.5.1 registration of equipment

Equipment code	Type of equipment	Use	Charge		Type of substance
			Kg	CO ₂ (eq)	
EQ 1					
EQ 2					
EQ 3					
EQ 4					
Continue as required					

S1.5.2. 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 (a) for equipment that contains fluorinated greenhouse gases in quantities of 5 tonnes of CO₂ equivalent or more, but of less than 50 tonnes of CO₂ equivalent: at least every 12 months; or where a leakage detection system is installed, at least every 24 months; (b) for equipment that contains fluorinated greenhouse gases in quantities of 50 tonnes of CO₂ equivalent or more, but of less than 500 tonnes of CO₂ equivalent: at least every six months or, where a leakage detection system is installed, at least every 12 months; (c) for equipment that contains fluorinated greenhouse gases in quantities of 500 tonnes of CO₂ equivalent or more: at least every three months or, where a leakage detection system is installed, at least every six 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

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 Map

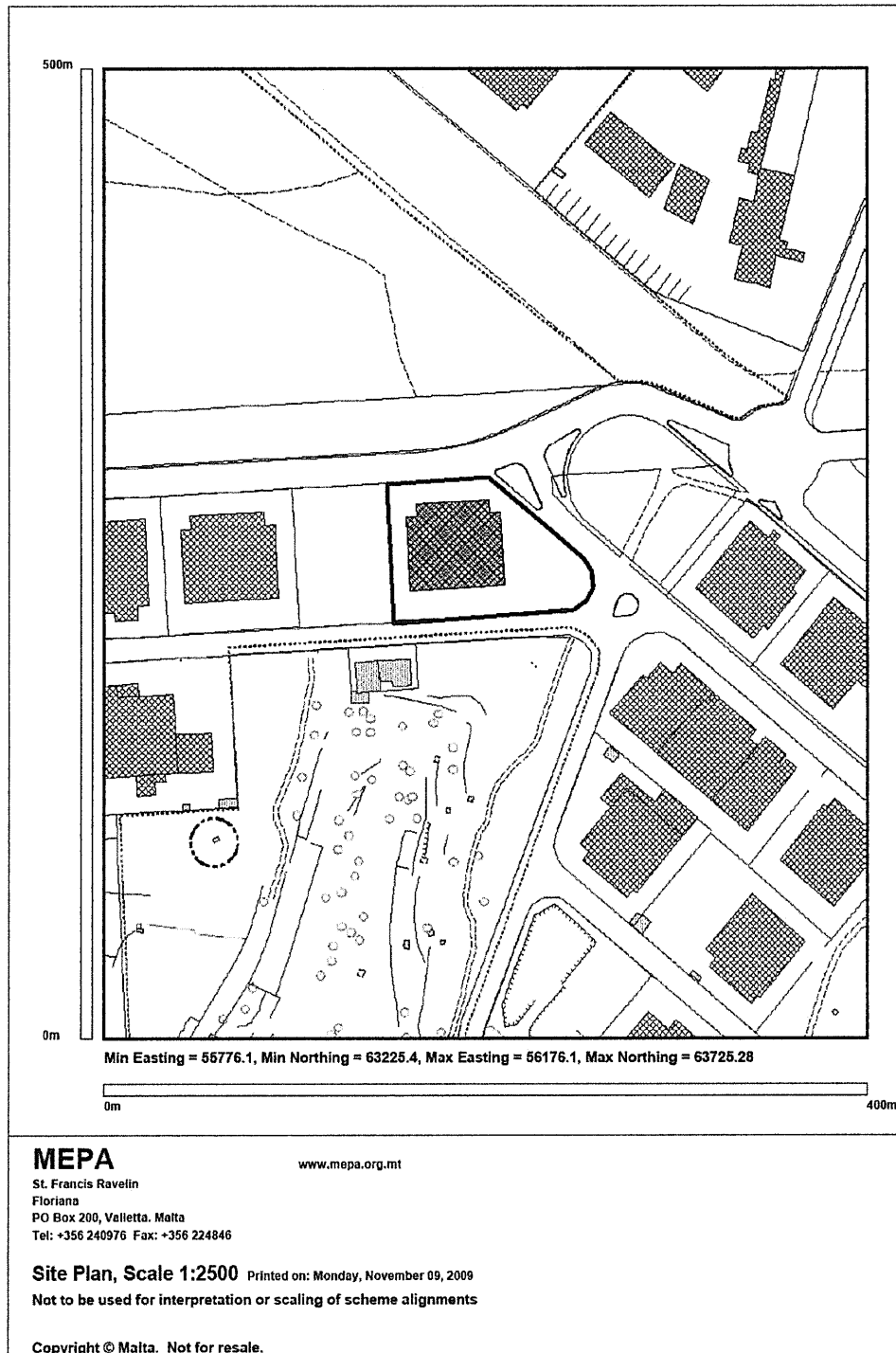
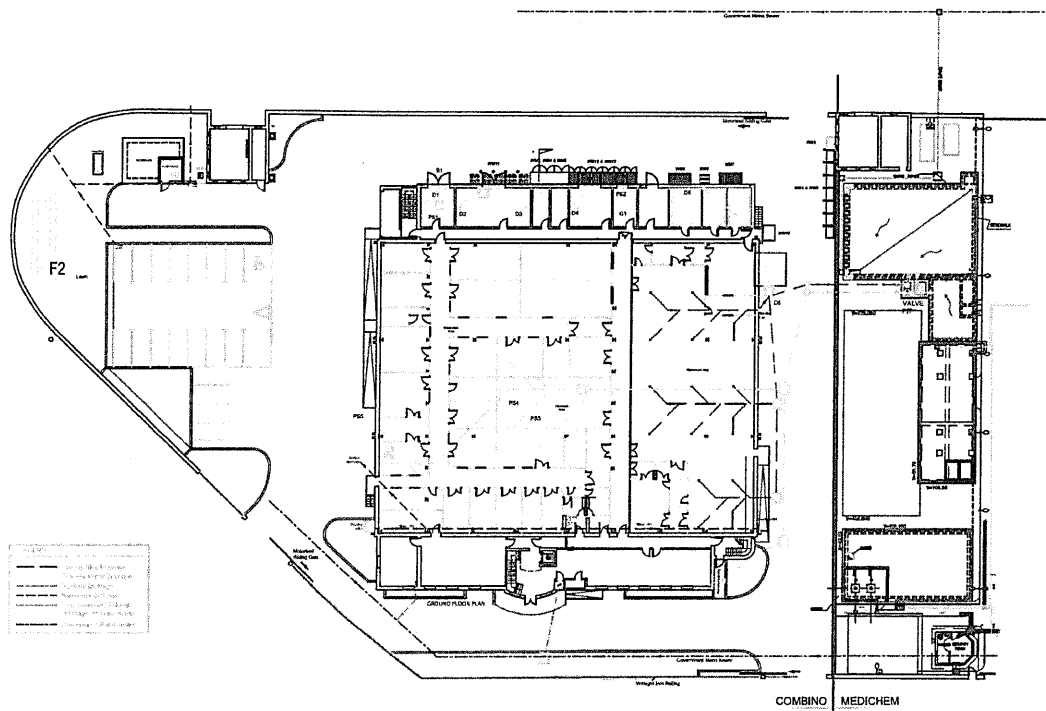


Fig. S2.1: Site of installation, showing extent of area authorised for activity (outlined in bold blue).

Schedule 3
Site Layout Plan



Schedule 4

Submission of certificates/monitoring

Kindly provide status update for the requirements tabled below. Where relevant supporting documentation is to be attached-

Monitoring results as per section 2.2 and 2.3 on an annual basis	<input type="checkbox"/>
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Applicant's declaration		
<i>I declare that, to the best of my knowledge, all the above information is correct and substantiated.</i>		
.....	
Name	ID Card Number	on behalf of / in my own
name		
<i>(in block letters)</i>		<i>(in block letters)</i>
.....		
Signature		Date

END OF PERMIT