



# PANAXIA PHARMACEUTICAL (MALTA) OPERATIONS

Project Description Statement

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## **Disclaimer**

This report is compiled in good faith and is based on the information provided by the Panaxia Pharmaceutical Malta Operations. Also all site plans and images were provided by company representative. The author of this report disassociate himself from any known or concealed information which was not forwarded to their attention during the compilation of the project description statement.

## 1.0 Introduction

This Project Description Statement (PDS) has been prepared and structured in accordance with S.L. 549.46 of 2017 (Environmental Impact Assessment Regulations, 2017).

The main aim of this document is to assess the impacts expected from the proposed development (henceforth referred to as the 'Scheme'), in line with requirements made by the Environment Resources Authority (ERA).

The Scheme is "Panaxia Pharmaceutical Industries Ltd" which shall develop and manufacture medicinal cannabis products in its R&D pilot facility located at Hal Far Industrial Estate (Factory HHF 001A). The facility will manufacture cannabis products solely for medical use and in accordance with GMP guidelines for Panaxia Pharmaceutical Industries Ltd.

The PDS is a detailed report requested by ERA to provide the necessary information for screening in the Environmental Impact Assessment (EIA) process and is aimed to describe the Scheme, the site of the development and its surroundings, and proposed activities. An indication of the main environmental impacts expected is also included in the report. Through the PDS, ERA will be able to establish whether the planning application requires further environmental impact studies.

## 2.0 Background to the scheme

The applicant is Mr Mark Vella (ID card number 69884M), Malta Site Manager and Ing Josef Micallef (ID card number 514474M), Engineering Manager of Panaxia Pharmaceutical Industries Ltd.

Panaxia Pharmaceutical Industries Ltd. is an R&D pilot site cannabis manufacturing company of products for medical use. The facility located at Hal Far Industrial Estate (Factory HHF 001A) will produce all products in accordance with GMP guidelines for Panaxia Pharmaceutical Industries Ltd.

The New production facility will be located in the existing plant building on level 0. The production area ceiling is at 3.00 m height; the rest is used for the technical support space.

## 3.0 Project Description

### 3.1 Site Description

The Scheme site is located within the Hal Far Industrial Area. The industrial building built area is about 1600 m<sup>2</sup>, and it will contain four establishments. The building is gated and surrounded by a high fence.

The Scheme site has an area of approximately of 420 m<sup>2</sup>. It is located in the ground floor of the building. It has a rectangular shape, with two interior walls separating the facility from neighbouring companies, and two exterior walls with several windows. In order to ensure security, some of the windows will be shuttered with steel panels. Other windows will be secured by steel grills. There are two entrances to the factory. The north entrance will have stairs and a ramp, and it will be assigned mainly for material. The west door is designated for personnel.

All motorized and pedestrians' traffic will enter and leave the site through the guarded gates. The surrounding drive way is 8.5 meters wide, which enables parallel parking spaces for cars and trucks. The Scheme site comprises of the administration building as well as the production area (*See Figure 1*).

The Scheme site also includes a number of Development Notification Orders (DNOs) and Planning Applications and that were being built at the time of writing this DPS. The DNO or Planning Application numbers are as follows:

DN 701/19 Internal alterations to the premise HHF001A and addition of a mezzanine floor

DN 499/20 Minor amendments to approved DN701/19



## 3.2 Scheme Site and Immediate Surroundings

A land use survey (See Figure 2) was carried in July 2020 covering approximately 275 m around the Scheme site.

The land uses are as follows:

- Construction activities
- Storage premises
- Manufacturing sites
- Goods and Freight forwarding sites
- Agricultural land
- Neglect sites
- Energy distribution and supply

Some cultivated agricultural land is found along both sides of the Wied Żnuber valley, located to the west of the Scheme site.

The predominant land uses in the surrounding area are mainly manufacturing activities (including pharmaceutical production, printing presses, production of climate control systems) and warehousing facilities.

Also, there are no residential properties within 275m of the Scheme site.

The Scheme site is adjacent to the coastal cliffs that are designated as an Area of Ecological Importance (AEI), Special Area of Conservation of International Importance under GN112/2007 (Rdumijiet ta' Malta – Rdumijiet tan- Nofsinhar), and a Special Protection Area (Rdumijiet ta' Malta – Wied Moqbol sal- Ponta ta' Bengħisa).

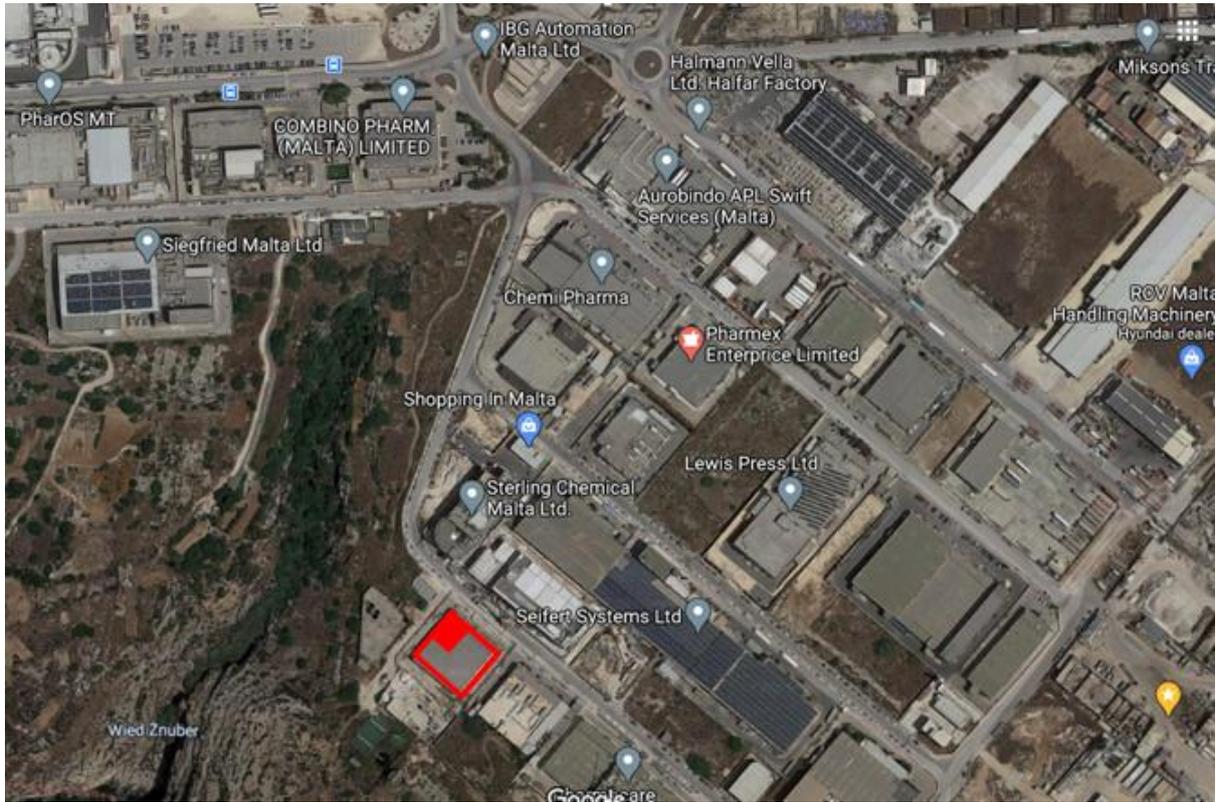


Figure 2: Land Uses and Panaxia Site (in red)

### 3.3 General objectives

Panaxia Pharmaceutical Industries Ltd shall develop and manufacture medicinal cannabis products in its R&D pilot facility. Medicinal cannabis oil is bottled in 15ml and 30ml as finished product. All products will be approved by Malta Medicines Authority (MMA).

The facility will produce all products in accordance with GMP guidelines for Panaxia Pharmaceutical Industries Ltd. The New production facility will be located in the existing plant building on level 0. The production area ceiling is at 3.00 m height; the rest is used for the technical support space.

All the production methods that are expected to be used are mostly manual due to low activity volume. The methods are based on current company methods which are used in the company's production facility in Israel. Current production protocols will be adapted to the new facility's activity and will be re-validated.

### 3.4 Relative activities and process flow

In order to reach the finished good which is Cannabidiol (CBD) oil production the following activity and process flow (See Figure 3) will be utilized.

Activity includes:

- 1) Grinding of the cannabis plant material
- 2) Ethanol extraction
- 3) Filtration, winterization and precipitate separation
- 4) Evaporation
- 5) Decarboxylation
- 6) Liquid formulation - mixing of different extracts to obtain the desirable combination of cannabinoids. Dilution of the extracts with a carrier oil according to the required concentration. Addition of antioxidants and/or preservatives.
- 7) Primary packaging – Bottling and labeling
- 8) Secondary packaging – Leaflet insertion and boxing

The quality control department is fully equipped to perform quantitative HPLC analysis of the major cannabinoids for raw materials, in-process control and finished products. All raw material will also be tested for microbial contamination, toxins- mycotoxins, pesticides residual and heavy metal residual. The QC lab also performs visual inspection of the raw material and final

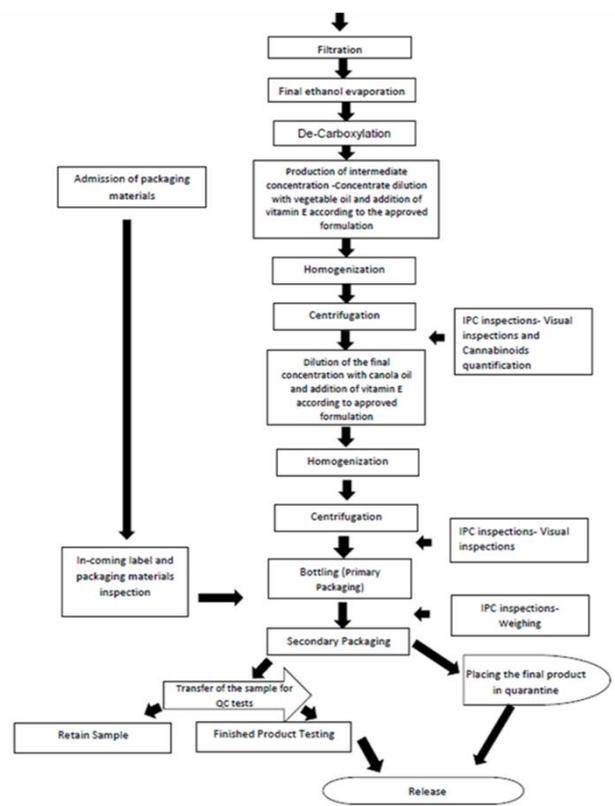
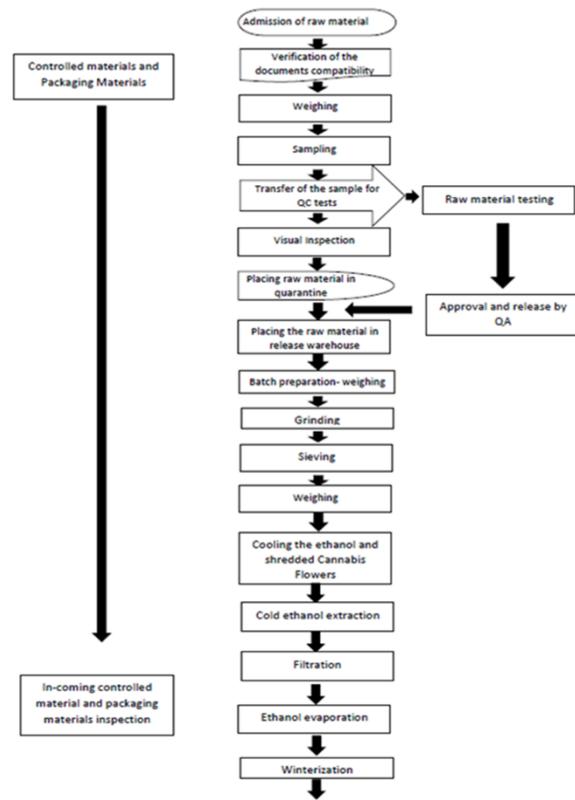


Figure 3: Process Flow

product, Loss on Drying tests, foreign matter and additional tests. The HPLC analysis tests are validated according to the ICH, and the tests are performed according to the regulations and in-house specification/s.

### 3.4 Description of room activities

Floor layout indicating production activity (See Figure 4), raw material and waste flow, personnel flow, room classification and pressure regime between adjoining areas (See Figure 5). Also Table 1 provides an overview of any technical details for each room.

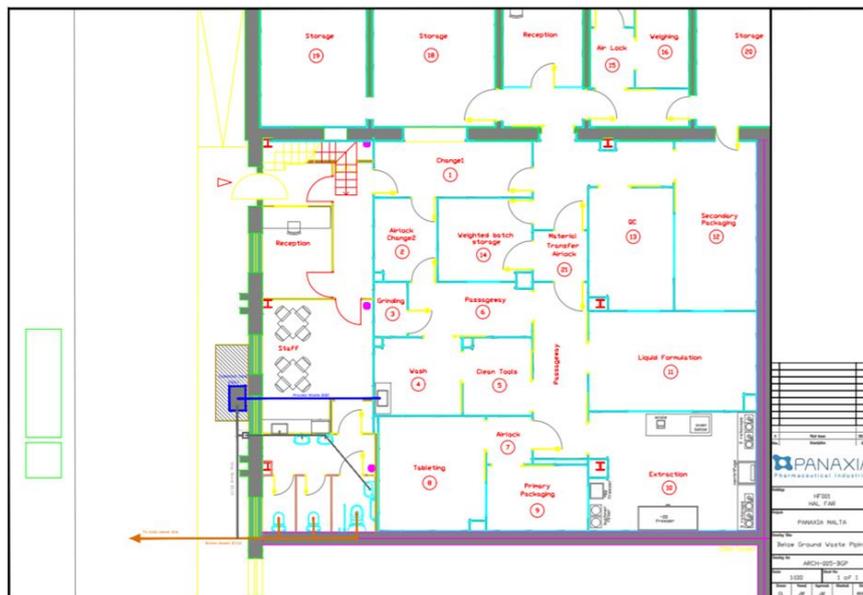


Figure 4: Facilities

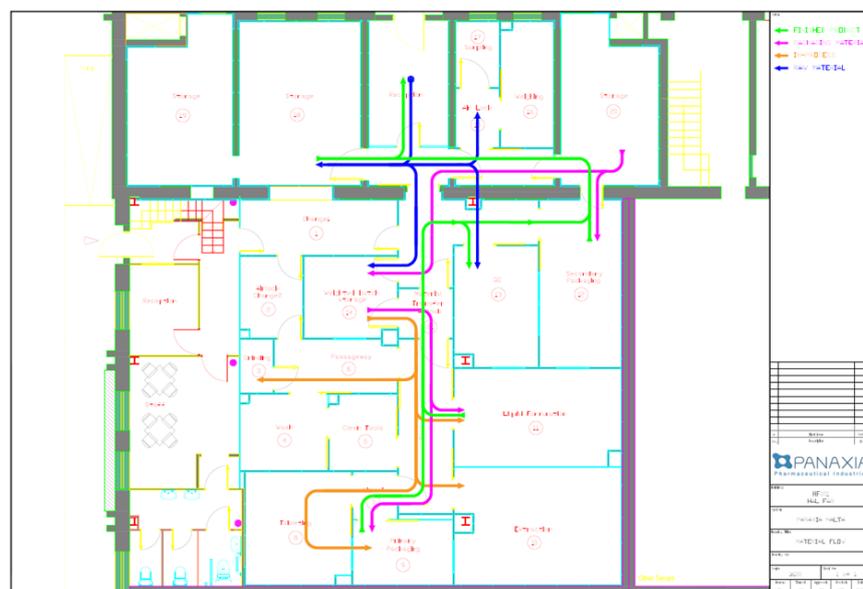


Figure 5: Flow of material and personnel movement

Room No.	Room Description	Estimated Area (m <sup>2</sup> )	Estimated Height (m)	Door Type	Walls Type	Ceiling Type	Floor Drainage	Lights (Not ATEX)
1	Change 1 - Lobby	13.6	2.8	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED
2	Change 2 - Airlock	7.8	2.8	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED
3	Grinding: grinding of the dried medical cannabis inflorescences.	2.9	2.8	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED
4	Wash: washing of manufacturing instruments.	9.8	2.8	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
5	Clean equipment	7.3	2.8	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
6	Clean passageway	22.3	2.8	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
7	Air lock - Tableting	2.6	2.8	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED
8	Production Room	17.2	2.8	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
9	Production Packaging	9.8	2.8	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
10	Production - Extraction	28.6	2.8	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
11	Production - Liquid Formulation	23.8	2.8	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
12	Secondary Packaging	19.1	2.8	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
13	QC laboratory	12.8	2.8	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
14	Weighted Batches Storage	10.5	2.8	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED
15	Airlock - Sampling / Weighing	3.3	3.0	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
16	Weighing	9.2	3.0	Sliding	Sandwich panels	Walkable ceiling	NO	Flat LED
17	Sampling	4.1	3.0	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED
18	Storage - Vault	27.3	3.0	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED
19	Storage - Vault	22	3.0	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED
20	Storage - Consumables	20.7	3.0	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED
21	Airlock - Material Transfer	6.9	2.8	Hinged	Sandwich panels	Walkable ceiling	NO	Flat LED

Table 1: Technical details of the areas

### 3.5 List of Ozone depleting substance equipment on site

Unique identity number	Use of equipment	Type of substance	Charge (Kg)	Local Service	Type of Equipment	Control Inspection
1	Air conditioner	R-410A	11.5	Production Area	Fixed System	Yearly
2	Air conditioner	R-410A	11.5	Production Area	Fixed System	Yearly
3	Air Conditioner	R-410A	11.5	Warehouse	Fixed System	Yearly
4	Air Conditioner	R-410A	0.52	IT server	Fixed system	Yearly

Table 2: List of Ozone depleting substances

### 3.6 List of Chemicals used on site

Location Code	Chemical	CAS Number	Risk Phrases	Maximum amount stored at any one time	Annual Consumption	Mitigation and monitoring procedures
16	Ethanol GMP Grade (raw material)	64-17-5	H225 H319	200L	2500L	To be stored in assigned storage area with secondary containment
20	Tocopherol (raw material)	10191-41-0	H317	5L	15L	To be stored in assigned storage area with secondary containment
18/19	Cannabis (raw material)	67-64-1	-	200kg	200kg	To be stored in assigned storage area with secondary containment
20	Acetone HPLC Grade	75-05-8	H225 H319 H336	2.5L	5L	Chemical cabinet
20	Acetonitrile HPLC Grade	302-17-0	H225 H332 H312 H302 H319	2.5L	150L	Chemical cabinet
20	Chloral hydrate v.p.	75-09-02	H301 H315 H319	500g	1000g	Chemical cabinet

20	Dichloromet hane HPLC Grade	67-68-5	H351	1L	2L	Chemical cabinet
20	Dimethyl sulfoxide HPLC Grade	1314-56-3		1L	8L	Chemical cabinet
20	di-Phosphorus pentoxide a.r.	64-17-5	H314	1Kg	2kg	Chemical cabinet
20	Ethanol 96% a.r.	141-18-6	H225	2.5L	5L	Chemical cabinet
20	Ethyl acetate LC-MS Grade	64-18-6	H225 H319 H336	1L	2L	Chemical cabinet
20	Formic acid 10% in water, for Cleaning Purposes LCMS	56-81-5	H314	1L	2L	Chemical cabinet
20	Glycerol anhydrous for Molecular Biology	110-54-3	-	500mL	100mL	Chemical cabinet
20	Hexane (n) 99+ %, HPLC Grade	67-64-1	H225 H361F H304 H373 H315 H336 H411	1L	2L	Chemical cabinet
20 / 13	Hydralyt <sup>®</sup> Water Standard sol. (10x10mL)	0	H225 H361 H304 H373 H315 H336	10mL	20mL	Chemical cabinet / QC LAB
20	Iodine Pellets a.r.	7553-56-2	H312 H332 H315 H319 H335 H372 H400	100g	200g	Chemical cabinet
20 / 13	Methanol HPLC Grade	67-56-1	H225 H331 H311 H301 H370	2.5L	150L	Chemical cabinet / QC LAB
20 / 13	Methanol, anhydrous a.r. 99.8+%	67-56-1	H225 H331 H311 H301	1L	2L	Chemical cabinet / QC LAB

			H370			
20	Phenolphthal ein indicator	77-09-8	H350 H341 H361F	100g	200g	Chemical cabinet
20	Phosphorus pentoxide, 98%, extra pure	1314-56-3	H34	1Kg	2kg	Chemical cabinet
20	Piperazine.6a q v.p	142-63-2	H361fd H334 H317 H314	100g	200g	Chemical cabinet
20	Potassium iodide a.r.	7681-11-0	H372	1Kg	2kg	Chemical cabinet
20	Potassium Permanganat e a.r.	7722-64-7	H272 H302 H400 H410	1Kg	2kg	Chemical cabinet
20	Propanol-2 (Isopropanol) HPLC Grade	67-63-0	H225 H319 H336	2.5L	5L	Chemical cabinet
20	Pyridine hydrobromid e perbromide, tech 90%	39416-48-3	H302 H314	500g	1000g	Chemical cabinet
20	Silica Gel	7631-86-9		1Kg	2kg	Chemical cabinet
20	Sodium Chloride a.r.	7647-14-5		1Kg	2kg	Chemical cabinet
20	Sodium Hydroxide pellets a.r.	1310-73-2	H290 H314	1Kg	2kg	Chemical cabinet
20	Sodium nitroferricya nide dihydrate, 99+%	13755-38-9	H301	25g	50g	Chemical cabinet
20	Sodium pentacyanoni trosoferrate(I II)2.aq a.r.	13755-38-9	H301	25g	50g	Chemical cabinet
20	Sulfuric Acid 0.1mol/L	7664-93-9	H290 H315 H319	1L	2L	Chemical cabinet
20	Sulfuric Acid 1mol/L	7664-93-9	H290 H314	1L	2L	Chemical cabinet
20	Sulfuric Acid 95-97% a.r.	7664-93-9	H290 H314	2.5L	2L	Chemical cabinet
20	Water, HPLC Grade	7732-18-5		2.5L	150L	Chemical cabinet

Table 3: List of Chemicals

### 3.7 Emissions to Atmosphere

The below table highlights the point source emissions to atmosphere from process or any related activities (See Figure 6).

Emission Location Code	Source of emission	Content of emission	Treatment/abatement	Stack height (m)
EM1	QC Fume hood	Chemical Vapours	None	5
EM2	Grinding Extract	Dried cannabis	Synthetic media filters	5
EM3	Washroom Extract	Water vapour	None	5
EM4	Bathroom Extract	Odours	None	5
EM5	Recirculated Exhaust	Heat emissions	Synthetic media filters	5
EM6	Sampling	Chemical vapours	None	3

Table 4: List of Emission Points

#### 3.7.1 Boilers / Generators on site:

No Boilers on site. A generator is in place. This generator will be used for emergency situation only i.e. power failure.

The following are the technical specification of generator  
Diesel engine emissions EU Stage II/U.S. EPA Tier 2

- 1) Net power (Kw):  $130 \leq P \leq 560$
- 2) CO (g/kWh): 3.5
- 3) HC (g/kWh): 1
- 4) NOx (g/kWh): 6.0



EM6 – Sampling/Weighing Room Extract (located in internal shaft inside building)

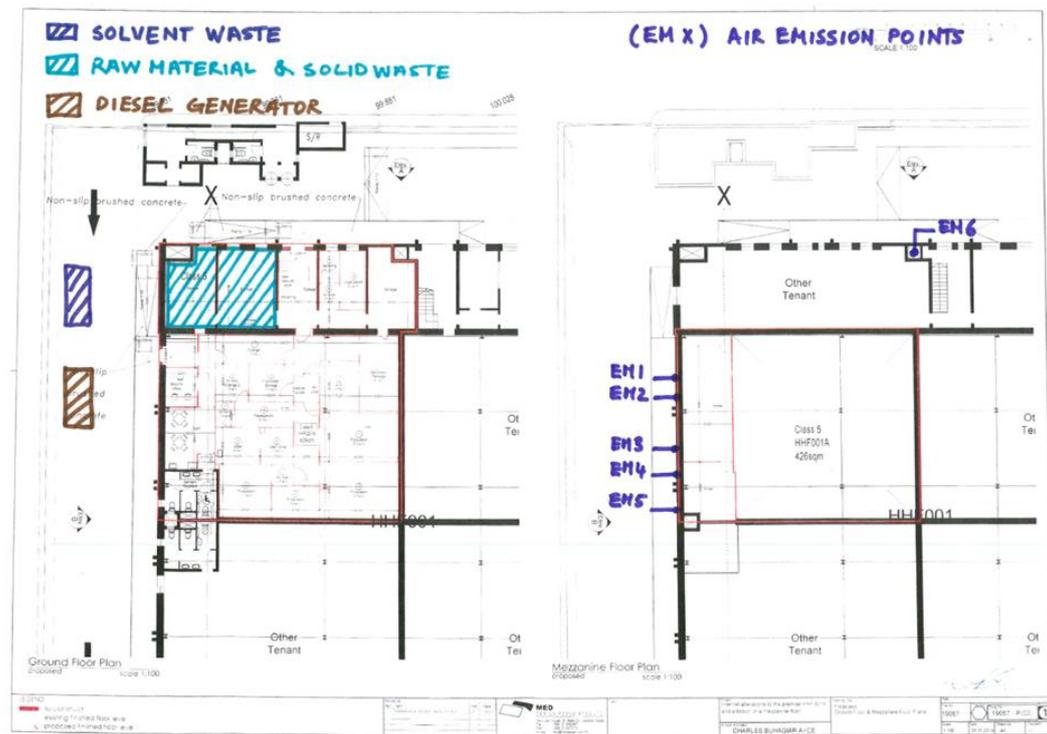


Figure 6: Photo showing the Emission points

### 3.8 Waste Management

This section details the information regarding the waste being generated or processed on site (See Figure 7).

Location code	Type of waste	EWC CODE	Maximum site Capacity	Method of processing and/or disposal	Method of storage and containment
WM1	Aqueous washing liquids and mother liquours	07 05 01*	468ltr	Sent for disposal by waste contractor	Collected in jerry cans and stored in outdoor storage deposits with containment
WM2	Organic haloganted solvents, washing liquids and mother liquours	07 05 03*	5ltr	Sent for disposal by waste contractor	Collected in jerry cans and stored in outdoor storage deposits with containment
WM3	Cannabis (hazardous)	07 05 13*	78kg	Sent for disposal by waste contractor	Collected in jerry cans and stored in outdoor storage deposits with containment
WM4	Lab Chemicals	16 05 06*	10ltr	Sent for disposal by waste contractor	Collected in jerry cans and stored in outdoor storage deposits with containment
WM5	Paper and cardboard packaging	15 01 01	30kg	Sent for disposal by waste contractor	Stored in skip bin.
WM6	Plastic packaging	15 01 02	20kg	Sent for disposal by waste contractor	Stored in skip bin.
WM7	Wood packaging	15 01 03	50kg	Sent for disposal by waste contractor	Stored in skip bin.
WM8	Absorbents, filter materials, wiping cloths, and protective clothing	15 02 02*	20kg	Sent for disposal by waste contractor	Sealed in plastic bags and stored in skip bin.
WM9	Mixed municipal waste	20 03 01	30kg	Sent for disposal by waste contractor	Collected in garbage bags and stored in skip bin.

Table 5: List of type of waste on site

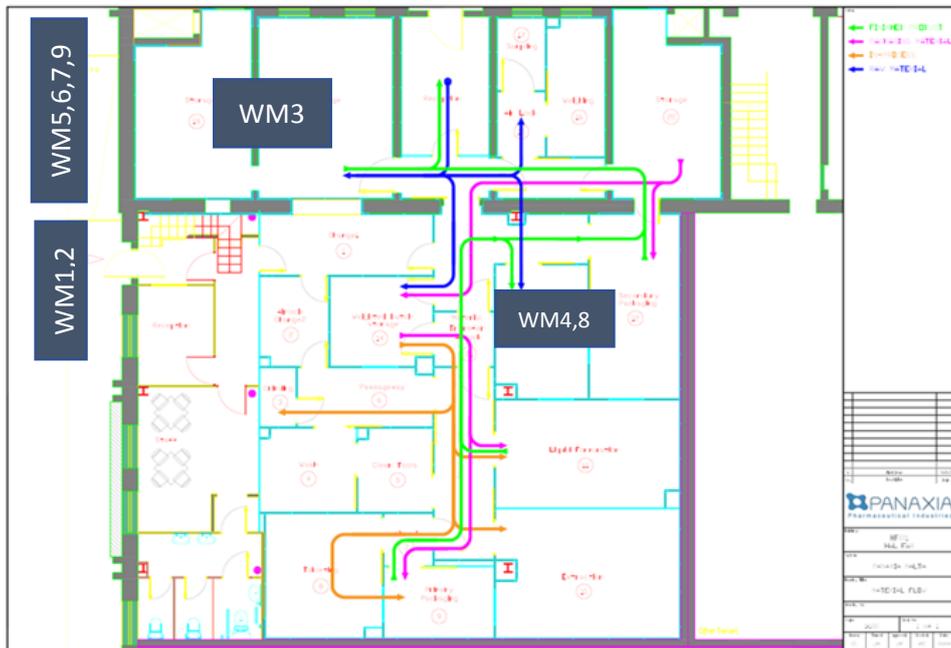


Figure 7: Location of waste categories

## 4.0 Environmental impacts and mitigation

This section carries out a preliminary analysis of the environmental impacts that can be attributed to the implementation of the project. This qualitative assessment takes into account both the construction phase of the work and the operational of the production site.

- a) The construction phase: it includes the preparation of the site in terms of construction, possible demolition, and installation of utilities and transportation of materials for the construction phase.
- b) The operational phase includes the operational of the production activities, raw materials handling, storage and waste management.

### 4.1 Environmental aspects

The most concerned environmental aspects include:

1. Noise
2. Air Quality
3. Land Uses
4. Land Pollution
5. Water Bodies
6. Visual

#### 4.1.1 Noise

The following criteria were used in order to determine the **severity** and **significance** of this scheme in relation to noise.

Level	Criteria
High	Exceeds current noise limits and can be perceived within 500m from source.
Moderate	Exceeds current noise limits and can be perceived within 200m from source.
Low	Noise generated does not exceed noise limits but can be heard within 100m radius from source.
insignificant	Noise generated does not exceed noise limit and is not perceived from anywhere in the vicinity.

*Table 6: Assessment Criteria - Severity*

Level	Criteria
High	Noise generated will be so high that it will stop operations close by.
Moderate	Noise generated, can somehow cause any physiological disorders to the scheme employees.
Low	The noise generated is below the noise limit and is considered harmless.
Insignificant	The noise generated is temporary and for a very short period of time.

*Table 7: Assessment Criteria - Significance*

#### 4.1.1.1 Construction Noise

During **construction phase**, noise and vibration emissions will be generated, however it should be noted that the construction site area is in an industrial area and it is temporary.

#### 4.1.1.2 Operational Noise

##### **Summary of impacts – Noise**

**Specific process:** Noise that is generated by plant utilities or generators during operations of the scheme.

**Project phase:** Operational

**Receptors:** Employees and neighbours of the scheme

**Effects and scale of impact (Direct/Indirect/Cumulative):** Cumulative

**Beneficial / Adverse:** Adverse

**Severity:** Medium

**Short/medium/long term:** Medium term

**Temporary / Permanent:** Temporary

**Probability – Significance – Mitigation – Residual impacts – Other Requirements**

**Probability of impact:** Inevitable

**Significance overall impact:** Insignificance

**Proposed mitigation measures:**

- Choice of machines should be in line with the noise machinery directive 2006/42/EC
- In the event that limits are not achieved as tabled in the directive 2006/42/EC alternative solutions need to be explored
- Install extra silencers to the engines and
- Limit the certain usage of equipment during a period of the day.

## 4.1.2 Air Quality

The following criteria were used in order to determine the **severity** and **significance** of this scheme in relation to air quality.

Categories	Criteria
High	If the air monitoring results that exceeded the air quality limits and if air quality will lead to the complete shutdown of the operations.
Moderate	If the air monitoring shows that the pollutants concentration is below the limit
Low	If the entry limits prescribed by the current legislation are far more than 50% of the value.
Insignificant	If the air monitoring results in relatively low levels in the air

*Table 8: Assessment criteria for Air quality significance and severity*

### 4.1.2.1 Construction Air Quality

During the **construction phase**, atmospheric emissions will be emanated primarily related to the combustible engines processes.

Also when one is moving around the “inert materials” can also result in the diffusion of dust and particulate in the atmosphere.

#### 4.1.2.2 Operational Air Quality

##### **Summary of impacts – Air Quality (scenario 1)**

**Specific process:** Possible air pollutants released into the atmosphere by fixed emission points.

**Project phase:** Operational

**Receptors:** Employees and neighbours of the scheme

**Effects and scale of impact (Direct/Indirect/Cumulative):** Direct

**Beneficial / Adverse:** Adverse

**Severity:** Depends on type of substance and quantities emitted

**Short/medium/long term:** Short term

**Temporary / Permanent:** Temporary

**Probability – Significance – Mitigation – Residual impacts – Other Requirements**

**Probability of impact:** Remote

**Significance overall impact:** Insignificance

**Proposed mitigation measures:**

- Two point sources equipped with filtration:
  - EM2 Grinding - Synthetic media filters are installed on the Low-Level Extract (LLE) in the grinding room to prevent any grinded material from travelling into the duct and out into external environment.
  - EM5 Recirculated Exhaust - Synthetic media filters are installed internally to the external grill to prevent any solid particulate from travelling out into external environment.
- The other remaining point sources are not equipped with filtration or abatement because volumes used are very small in nature.

**Summary of impacts – Air Quality (scenario 2)**

**Specific process:** Accidental release/leakage of chemicals (including wastes) during storage or transport within the production site.

**Project phase:** Operational

**Receptors:** Hal Far Area

**Effects and scale of impact (Direct/Indirect/Cumulative):** Direct

**Beneficial / Adverse:** Potentially Adverse

**Severity:** It depends on the source of the release and the quantity.

**Short/medium/long term:** Short term

**Temporary / Permanent:** Temporary

**Probability – Significance – Mitigation – Residual impacts – Other Requirements**

**Probability of impact:** Remote

**Significance overall impact:** Insignificance

**Proposed mitigation measures:**

- Training of the operators
- Declarations of compliance by suppliers of raw materials and packaging
- Periodic maintenance of the equipment

## **Summary of impacts – Air Quality (scenario 3)**

**Specific process:** Release/accidental leakage of chemical from transportation outside of the production site

**Project phase:** Operational

**Receptors:** Hal Far Area

**Effects and scale of impact (Direct/Indirect/Cumulative):** Indirect

**Beneficial / Adverse:** Potentially Adverse

**Severity:** It depends on the cause of the Accidental release and the types of the spilled substances. The main raw material is ethanol.

**Short/medium/long term:** Short term

**Temporary / Permanent:** Temporary

**Probability – Significance – Mitigation – Residual impacts – Other Requirements**

**Probability of impact:** Remote

**Significance overall impact:** Insignificance - It depends on the source of the release and the quantity.

**Proposed mitigation measures:**

- Outdoor storage deposits ECO 704 (See Figure 8 & 9). The units come ready with a spill containment basin and will house 20Lt jerry cans. The maximum storage capacity of each is 800Lt.
- 2 units will be used to store ethanol for production use while the 3rd unit will be used to store solvent waste. The units will be protected from direct sunlight by way of a fully enclosed/lockable shed and barriers for vehicular movement protection.
- Jerry cans will be transported using a manual pallet truck and a spill kit will be located in close proximity of the storage deposits for emergency case



### 4.1.3 Land Uses

The following table highlights the criteria used to establish the levels of significance of the likely impacts (if any) of the proposed on land uses.

<b>Categories</b>	<b>Criteria</b>
High	A substantial change in its original use and if the ground is highly permeable.
Moderate	A moderate change in its the original use, infrastructural network/s of the site earmarked for the development in question and If the ground has no high permeability.
Low	A small change in its original use, infrastructural network/s and if the ground is not permeable.
Insignificant	The change would be so minor that it would lead to insignificant.

*Table 9: T Assessment criteria – significance with respect to the HHF 001A site.*

#### 4.1.3.1 Operational & Construction Land Uses

**Summary of impacts** – Land pollution (scenario 1)

**Specific process:** Accidental spill of chemicals

**Project phase:** Operations and constructions

**Receptors:** Hal Far Area

**Effects and scale of impact (Direct/Indirect/Cumulative):** Direct

**Beneficial / Adverse:** Potentially Adverse

**Severity:** Low to medium

**Short/medium/long term:** Depending on the nature of the spilled substance, there are substances that can stay in the soil for long-term.

**Temporary / Permanent:** Temporary

**Probability – Significance – Mitigation – Residual impacts – Other Requirements**

**Probability of impact:** Remote

**Significance overall impact:** Insignificant

**Proposed mitigation measures:**

- Storage in areas and on impermeable containment basins of raw materials and waste;
- Set up of anti-spill kits for prompt intervention;
- Control check of the containment basin
- Procedures, instructions and training for operators;

**Summary of impacts – Land pollution (scenario 2)**

**Specific process:** Changes to the existing land use arrangements and land take-up within and surround of the HHF 001A

**Project phase:** Construction

**Receptors:** Hal Far Area

**Effects and scale of impact (Direct/Indirect/Cumulative):** Direct

**Beneficial / Adverse:** Potentially Adverse

**Severity:** Depends on type of disturbance and quantities involved.

**Short/medium/long term:** Should an impact occur it would be short term. However no impact of significance is expected to occur.

**Temporary / Permanent:** Should an impact occur it would be temporary. However no impact of significance is expected to occur

**Probability – Significance – Mitigation – Residual impacts – Other Requirements**

**Probability of impact:** Remote

**Significance overall impact:** Insignificant

**Proposed mitigation measures:**

The adoption of appropriate mitigation measures during construction works:

- Wet ground flooring
- Limitation of the equipment with higher noise in the morning with the exception of the lunch break
- Choice of less noisy equipment
- Limitation of vehicle access on site

#### 4.1.4 Water bodies

The following table highlights the criteria used to establish the levels of significance and severity of any impacts (if any) on aquatic environments in the Hal Far area which may result from this development.

Categories	Criteria
High	The impact caused would be so irreversible and that would occur over more than 50% of area of influence.
Moderate	The impact would be reversible and that would occur less than 50% of area of influence.
Low	The impact would be reversible and that would occur less than 10% of area of influence.
Insignificant	Any impact that is low as to be ignored in the assessments.

*Table 11: Assessment criteria – significance*

Categories	Criteria
High	A moderate to high probability of it occurring over the whole area of influence.
Moderate	A moderate probability occurring over the whole area of influence.
Low	Any impact which may be mitigated and is low level of occurrence of pollution on a localized geographical extent.
Insignificant	When no known impact are predicted.

*Table 12: Assessment criteria – severity*

##### 4.1.4.1 Construction Water bodies

During the construction phase the possible causes of pollution which were directly induced by this phase were due to:

- spills of oils / petrol /diesel along the movement of the construction vehicles.

The principal receptor would be the Wied Żnuber water course, and eventually the sea. This possibility is very unlikely to occur because the quantities of oils/petrol/diesel involved should this happens is minimal.

**Summary of impacts – Water Bodies /Aquatic Environment (scenario 1)**

**Specific process:** Leaks or spillages of hazardous liquids which may end up in Wied Zhuber

**Project phase:** Construction

**Receptors:** Aquatic Environment

**Effects and scale of impact (Direct/Indirect/Cumulative):** Direct

**Beneficial / Adverse:** Potentially Adverse

**Severity:** Moderate to Low (dependent on the quantities involved)

**Short/medium/long term:** Short to medium.

**Temporary / Permanent:** Temporary

**Probability – Significance – Mitigation – Residual impacts – Other Requirements**

**Probability of impact:** Remote

**Significance overall impact:** Insignificant

**Proposed mitigation measures:**

- Any hazardous liquids ( applies also for waste) will be placed on a secondary containment
- Waste will be placed in a designated area which is waterproof area.

#### 4.1.4.2 Operation Water bodies

**Summary of impacts – Water Bodies /Aquatic Environment (scenario 1)**

**Specific process:** Operation of the grinding extract, QC fume hood, washroom/Bathroom and sampling emission points

**Project phase:** Operation

**Receptors:** Aquatic Environments

**Effects and scale of impact (Direct/Indirect/Cumulative):** Direct

**Beneficial / Adverse:** Adverse

**Severity:** Moderate to Low (dependent on the quantities involved)

**Short/medium/long term:** Medium – dependent on the volume of emission and on wind direction.

**Temporary / Permanent:** Temporary

**Probability – Significance – Mitigation – Residual impacts – Other Requirements**

**Probability of impact:** If the mitigation measures are adhered to it will be unlikely.

**Significance overall impact:** Low to Medium

**Proposed mitigation measures:**

- Emission point sources equipped with filtration:
- EM2 Grinding - Synthetic media filters are installed on the Low-Level Extract (LLE) in the grinding room to prevent any grinded material from travelling into the duct and out into external environment.
- EM5 Recirculated Exhaust - Synthetic media filters are installed internally to the external grill to prevent any solid particulate from travelling out into external environment.
- The other remaining point sources are not equipped with filtration or abatement because volumes used are very small in nature.

**Summary of impacts – Water Bodies /Aquatic Environment (scenario 2)**

**Specific process:** Accumulation and disposal of hazardous waste generated by operations

**Project phase:** Operation

**Receptors:** Aquatic Environments

**Effects and scale of impact (Direct/Indirect/Cumulative):** Direct

**Beneficial / Adverse:** Adverse

**Severity:** Low

**Short/medium/long term:** Short

**Temporary / Permanent:** Temporary

**Probability – Significance – Mitigation – Residual impacts – Other Requirements**

**Probability of impact:** Remote

**Significance overall impact:** Low

**Proposed mitigation measures:**

- Spill kit containers located in strategic locations
- Any liquid hazardous is stored on secondary containment.
- Personnel will be trained in spill responders.
- No hazardous waste will be stored outside.

#### 4.1.5 Visual

The following tables highlights the criteria used to establish the levels of significance and severity of any impacts on visual environment (if any) in the Hal Far area which may result from this development.

Categories	Criteria
High	Uprooting of trees or any other natural habitat
Moderate	If the project provides a height higher than the original or any adjacent buildings.
Low	If the project changed slightly from its original state.
Insignificant	If the project did not change any height or any dimensions from its original state.

*Table 13: Assessment criteria – significance*

Categories	Criteria
High	If the visual damage is seen from a radius more than 150m from the site
Moderate	If the visual damage is seen from a radius more than 100m from the site
Low	If the visual damage is seen from a radius more than 50m from the site
Insignificant	If the visual damage can be seen by the neighbouring lands

*Table 14: Assessment criteria – severity*

During the **construction phase**, there will be some type of impact since there will be temporary presence of heavy machinery and building materials. This mean that attention will be given to consumables or machinery to be located in areas with less visual accessibility.

#### 4.1.6 Other impacts

- There are no predictable impacts on the area since all areas can be reached from existing roads, so there is no need to change road traffic.
- There are no impacts on cultural heritage either in the construction phase or in the operational phase.
- There are no significant impacts on climate factors caused by the construction phase.

### 5.0 Residual impact

The following are the residual impacts that should be expected to prevail following the implementation of the mitigation measures discussed in the previous section:

#### 5.1 Impact on land use

The proposed development would result in the upkeep of an abandoned site in Hal Far Industrial Zone. In other words, the level of significance of the residual impact of the proposed development is on the low side.

#### 5.2 Water bodies

The residual impacts resulting from the construction and operations of the development is expected to range from none (specifically where impacts are temporary) to ones of low significance, mainly in cases where contaminated waters from the plant, manage to make it to the Wied Żnuber watercourse.

#### 5.3 Cultural heritage (terrestrial)

Cultural heritage features in the area are not expected to be affected by the development

#### 5.5 Air Quality

The filtering and monitoring systems in charge of the control of the atmospheric emissions are considered sufficient to prevent the introduction into the environment of chemical pollutants.