

IPPC APPLICATION DOCUMENT TO
M.E.P.A.

BLASCHEM (MALTA) LTD.

BLASCHEM (MALTA) LTD.
BA2 Bulebel Industrial Estate
Zejtun ZTN 06
Malta
Tel. +356.21.806.859
Fax. +356.21.806.862

INDEX**1 – Introduction**

- 1.1 – Vision of a group**
- 1.2 – Marketing and Business**
- 1.3 - Evolution of a Group**
- 1.4 - Research & Development**
- 1.5 - Quality**
- 1.6 - Production Facilities**

2 – Description of the Installation

- 2.1 – Plant Overview**
- 2.2 – Plant Location**
- 2.3 – Land Selection**
- 2.4 – Identification of Areas and Building**

3 – Proposed Systems

- 3.1 – Management**

4 – Process Implemented

- 4.1 - Description of the Processes, Operations and Control System**

5 – Details of Production

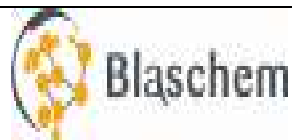
- 5.1 – Products**
- 5.2. – Raw Materials**
 - 5.2.1 – Raw and Auxiliary Materials**
 - 5.2.2 – Release of any Schedule A or Schedule B Substances**
 - 5.2.3 – Release of any List I or List II Substances**
- 5.3 – Waste Management**
 - 5.3.1 – Approach**
 - 5.3.2 – Waste Administration and Storage**
 - 5.3.3 – Solvent Recuperation and Re-utilisation**
 - 5.3.4 – Exportation of Wastes**
 - 5.3.5 – Emissions to the Atmosphere**
 - 5.3.6 – Discharge of Effluent**
 - 5.3.7 – Noise and Vibrations**
 - 5.3.8 – Summary of the Emissions**

- 5.4 – Impact on the Environment**

6 – Emergency Plans for Spillages

- 6.1 – Application**
- 6.2 – Measures Available**
- 6.3 – Forms of Action**
 - 6.3.1 – Acid/Base Spillage**
 - 6.3.2 – Solvent Spillage**
 - 6.3.3 – Solid Product Spillage**
 - 6.3.4 – Observations**
- 6.4 – Designated Personnel**
 - 6.4.1 – Preparation**
 - 6.4.2 – Training**

6.5 – Residual Wastes**6.5.1 – Waste Management****6.5.2 – Washing of Equipment****6.6 – Simulations****6.7 – First Aid****6.8 – Fire Preventive Measures****6.9 – Report of Action Taken****6.10 – Products that React with Water****7 – Improvement of the Installation****7.1 – Modifications to the Plant****7.2 – Target Dates****8 – Energy****8.1 – Use of Electricity****8.2 – Utilities****8.3 – Measures for Improvement of Energy Efficiency****8.4 – Measures for the Prevention of *Legionella* Disease****9 – Proposed Techniques of Improvement****9.1 – Techniques of Emission Prevention****10 – Upon Definitive Cessation****10.1 - Proposed Measures upon Definitive Cessation of Activities to avoid any
Pollution Risk****Attachment I – Plant Location**



1. INTRODUCTION

1.1. VISION OF A GROUP

Blaschem (Malta) Ltd. (from now Blaschem) was founded in January 1997 as a company dedicated to the manufacture of steroidal Active Pharmaceutical Ingredients in bulk and has been working since its establishment until December 2001. Due to various circumstances, the plant remained inoperative through the period until December 2005.

In 2005, a Spanish pharmaceutical company showed interest in acquiring Blaschem. On December 15th, 2005 the transfer of the total shares from Blaschem to Crystal Pharma S.A. was signed. Crystal Pharma is a company that specializes in the development, production and marketing of API (Active Pharmaceutical Ingredients) corticosteroids and progestagens. The company was established in 1996. It is the only company in Spain dedicated to the synthesis of this kind of products, as well as being one of the world leaders in high quality corticosteroids producers for the pharmaceutical industry.

Furthermore, in June 2006, Crystal Pharma S.A., Ragactives S.A. and Blaschem (Malta) Ltd. merged together as one pharmaceutical group called Gadea. The first two companies are located in Spain in the technological park of Boecillo, Valladolid (200 km North of Madrid) whereas Blaschem is situated in the Bulebel Industrial Estate of Zejtun, Malta.

Ragactives was established in 1991 as a Spanish fine chemicals company dedicated to the development, manufacturing and marketing of active pharmaceutical ingredients. Its product list includes various classes, amongst which anti-parkinsonian, ophthalmic and urological drugs.

United as one group, the three pharmaceutical entities share a culture which believes in the excellence of business by continually improving its processes and systems, whilst always ensuring environmental care to be a topmost priority. Substantial investment is produced to achieve such goals, to ensure a sustained development.

Blaschem will use the expertise obtained throughout the years by Crystal Pharma as a role model on which to build its future. The company's philosophy will be based entirely on its mother company, ranging from the products manufactured, the processes utilized, as well as the implementation of environmental protection policies.

1.2. MARKETING AND BUSINESS

The fundamental characteristic of the corticosteroids market is globalization. Gadea Pharmaceutical Group exports more than 90% of the production to countries worldwide, including regulated markets (USA, Canada, West Europe, Japan and Australia) and non-regulated markets (Asia, Africa, Eastern Europe, Central America and South America).

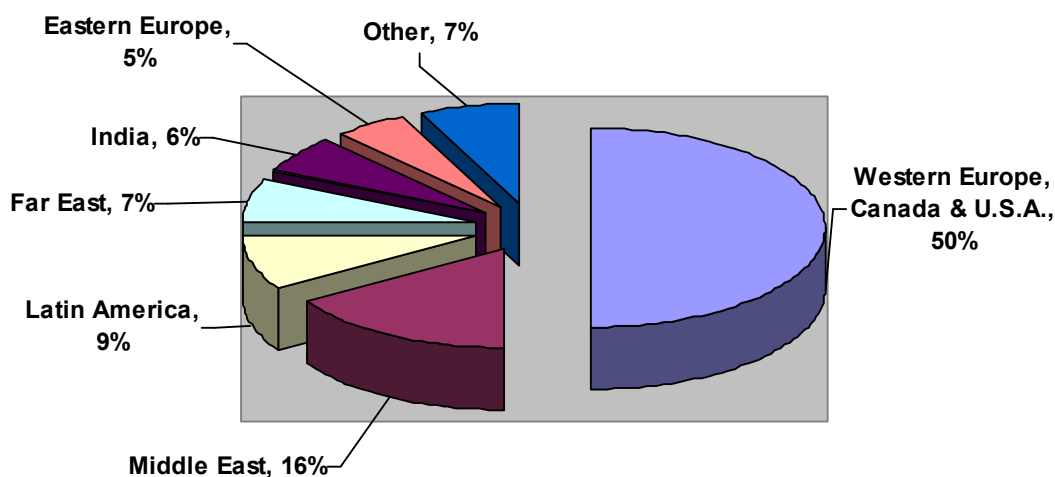


Fig.1: Distribution of Sales

Crystal Pharma, the leading company in Gadea Pharmaceutical Group and model role for emerging Blaschem, aims to supply the market with high quality products manufactured under strict GMP conditions. Quality control and quality assurance are given high priority in order to meet International Pharmacopoeias' specifications, as well as customer requirements.

At its premises located in Spain, Gadea Pharmaceuticals produces:

- (i.) Corticosteroids, which are a class of steroid hormones, are involved in a wide range of physiologic systems. These semi-synthetic drugs are used in a variety of conditions, ranging from brain tumors to skin diseases. This class of drugs, making up 85% of the total sales, is used as anti-inflammatory agents in asthma, allergenic processes and skin diseases.
- (ii.) Progestagens, which are hormones producing similar effects to progesterone. All Progestagens have anti-oestrogenic and anti-gonadotrophic properties. Making up 15% of the total sales of Crystal Pharma, this class of drugs is used in substitutive Hormonal Replacement Therapy (HRT) and for the treatment of certain cancers.

1.3. EVOLUTION OF A GROUP

Gadea Pharmaceutical Group has consolidated its position as one of the leading companies in the manufacturing of steroids all over the world, establishing its presence in various countries all over the world. In 2006 exportation summed up to 95% of the invoices issued by Gadea. The principal characteristic of the products manufactured in Gadea is the complex of the chemical processes implemented in the production. Since the initial stages of the company, the commercial strategy adopted was based on the development of APIs of high quality, which allow us to be competitive in the most exigent markets.

Since the founding of Crystal Pharma and Ragactives in the nineties, there has been a continuous and positive growth in both companies. Furthermore with the expansion to Blaschem and the merging of the three, the group has been further strengthened. The evolution of the company can be resumed in the table below:

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Investment (per 1000 €)		100	500	200	600	550	2250	2850	4000	4750
Costs R&D (per 1000 €)		200	250	350	500	500	600	850	1100	1550
% R&D sales		16.2	6.1	3.2	4.2	3.6	4.7	5.2	4.5	5.7
Sales (million €)	0.1	1.4	4.1	7.1	11.4	14.6	13.3	16.6	19.6	24.2
Kg steroids sales	50	650	2500	4600	5100	7200	6500	8000	11300	14000
Number of products	9	18	25	33	36	41	38	41	45	54
Number of countries	2	25	40	51	50	53	54	64	67	68
Number of DMF prepared	0	1	4	6	8	10	5	9	12	20
Total Staff	10	23	28	35	42	59	68	89	151	167
Staff R&D	2	3	4	7	9	15	16	24	27	32

The manufacturing of more than fifty APIs which have been commercialized, involves the synthesis of more than two hundred different chemical reactions. On average four new products are introduced on the market annually.

1.4. RESEARCH AND DEVELOPMENT

From its creation Gadea has considered Research and Development as a fundamental element for its growth. The company itself was born as an R&D company (Ragactives S.A., former known as Raga Consultores S.A) that implemented its own technology in the production plant. A significant proof of the importance given by the company to this aspect is the ISO certification on R&D management obtained from an accredited Spanish agency. The R&D team is a group of highly qualified people (60% Ph.D., 25% one or more degrees, 15% assistants) with a large experience in both basic research and process development.

Gadea specializes in the development of new processes, which can be designed to ensure the non-infringement of patents, through the application of alternative synthetic routes. The R&D laboratories and facilities, together with the possibilities for process scale-up and plant production, make Gadea the ideal partner for laboratories that specialize in generics. At the same time, Crystal Pharma is able to provide and characterize data and samples of related impurities, stability studies and more, in order to elaborate extensive and complete DMFs (Drug Master Files) for its products.

The objective of the research carried out by the department is to discover the best synthetic route. This definition extends itself to obtaining the most economic, as well as environmentally friendly and less pollutant routes. Awareness of how fragile the environment is to the action of mankind has led Gadea to understand its social responsibility towards a clean and healthy environment. Furthermore, the company has embarked itself more than once in projects involving only the improvement to a more environment-friendly route without any economic benefits being obtained.

In Gadea, the mentality is not only that of complying with the various legal entities protecting the environment, but to also surpass what is expected by the authorities and hence be an example to the other companies on the green aspect.

Whilst keeping in mind that the optimal R&D team is one that collaborates within its specific members as well as with other entities, Gadea R&D focuses deeply on the importance of communication between scientists of the three companies, as well as cooperation with other bodies. Proof of this is the deep collaboration existing between Gadea and the University of Valladolid, where exchanges of information through the projects uptaken, have frequently occurred between the two. As a consequence such an approach should confirm the willingness on behalf of the company to cooperate with the various institutions concerned.

1.5. QUALITY

The department for quality is definitely essential in the pharmaceutical market. Therefore since it is our responsibility and duty to carry out our tasks under strict observance of quality standards, Gadea implements ISO 9002, awarded in 1999 by Lloyds. In addition the Spanish Health Ministry in 1998 certified that the company works in relation with “Good Manufacturing Practices” (GMPs). The latest, most important and decisive certification for the future of the company is the one approved in February 2005, by the FDA (Food and Drug Administration).

In order to fulfill such an important role, the quality department encompasses various tasks, amongst which:

- Certifying the raw materials that arrive to the plant to concord to the specifications required
- Analyse the various intermediates produced
- Analysis of the final products for their purity as well as other characteristics required by the pharmacopoeias
- Assist the R&D department in obtaining products with a high purity profile

As previously mentioned, the company has the ISO certification on R&D management. The company also operates under ISO 9001 and 14000 standards regarding quality and environment respectively.

Such certifications are deemed essential for the Quality Department to carry out its role, which is that of ensuring consistency in our manufacturing processes, in order to guarantee the quality of our products.

1.6. PRODUCTION FACILITIES

The production of Gadea is based on its facilities located at the Technological Park of Boecillo (Valladolid, Spain), that comprises several buildings:

Crystal Pharma:

1. A production plant with a total capacity of 12000 L. The equipment includes 9 multipurpose reactors ranging from 150 to 3500 L, equipped with distillation and reflux condensers, filters (centrifuges and vacuum filters) and other auxiliary equipment. A clean area for finished product is also present. An area of the building is dedicated to the plant services: boiler, brine and air compressors.
2. A new plant with a total capacity of 28000L and also a variety of other equipment. The plant has been officially inaugurated in November 2006, thus increasing the production capacity of Gadea to a total of 54000L.
3. A pilot plant is present in the same building. Its equipment includes reactors, filters and auxiliary material similar to the industrial plant.
4. In addition to this, the following buildings also make up part of the facilities of Gadea:
 - Tank farms for solvents
 - Warehouses for raw materials and reagents
 - Laboratories. The R&D and the QC installations are separated.
 - Maintenance building

Ragactives:

1. A production plant with a capacity of 4000L divided in between 8 reactors. The installation also includes a variety of equipment including distillation and reflux condensers, filters (centrifuges and vacuum filters) and other auxiliary equipment.
2. Together with the plant, other structures are also present, which include the laboratories and the warehouse.

The production plant operates 24 hours a day in 3 shifts, 5 days a week and is managed by qualified staff, which is able to manufacture under cGMP rules. It is important to note the separation of the plants concerning the classes of drugs produced in each one. The new production plant deals specifically with the synthesis of corticosteroids, these being the mainstay production of the company. Whereas the older plant deals specifically with the Progestagens, since its smaller capacity can deal quite well with the lesser quantities of this class.



The Sterile Plant present in Boecillo

As a consequence to the commitment of Gadea within the R&D aspect, the company has recently opened a sterile crystallization plant, becoming one of the only 3 facilities in the world using this concept. This allows the company to produce sterile product hence making the company one of the most technologically avant-garde in the world.

Furthermore, Gadea is in the process of completing a new project for the production of highly potent drugs, which requires advanced technology, such as isolators, where the greatest precaution relies in preventing the employee from exposing himself to the product.

Besides the above-mentioned project, Gadea is also developing a new project for the manufacturing of the final product related to the API produced.

In order to bring up so much technology together and maintaining it one must understand that holding tight such structures are the pillars of quality, technological development and internalization which have sustained the fast, but robust ascend of the company.

2. DESCRIPTION OF THE INSTALLATION

2.1. PLANT OVERVIEW

Blaschem will continue on the same footsteps in which it had started when it was created. These activities are concomitant to the activities of Crystal Pharma, meaning the manufacturing of API's of steroidal origin following cGMP standards.

According to the schedule 1 of the LN 165/2002 of IPPC the proposed activity is classified in the point 4.5 as: "installations using a chemical or biological process for the production of basic pharmaceutical products".

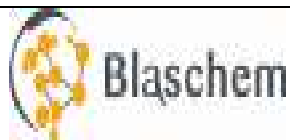
Blaschem manufacturing plant is located into the site BA2 of Bulebel Industrial Estate (Zejtun). The building is property of Malta Industrial Parks and Crystal Pharma has a rent contract until 2029. The factory is an existing installation and an application is being forwarded in accordance to the timetable to be recognized as compliant with the IPPC Regulations.

By the present document Blaschem is submitting the IPPC Application as new, in order to allow us to manufacture in the existing production plant of Blaschem. In order to update the information, we present the consolidated document, which replaces the one sent to MEPA in December 2005. Crystal Pharma S.A. will maintain the name of Blaschem for the moment.

2.2 PLANT LOCATION

Blaschem facilities are located in the outskirts of Bulebel Industrial Estate, Zejtun. Bulebel is an industrial area belonging to Zejtun, found in between Zabbar and Fgura. The production plant has been operating since 1997. The industrial estate was established in 1964. The plant is presently administered by MIP Ltd. (Malta Industrial Parks), which has rented it by contract to Gadea until 2029. The installation is located in the area of the Local Council of Zejtun. (Please view attachment 1)

The site in itself has a very long history. During the colonial times of the British, the land formed part of a British fort used by the colonists as barracks for its army. Later, upon receiving Independence in 1964, the Maltese government located the site for industrial development. Thus, the primary structure standing still today was erected, with the intention of setting up an iron foundry. However, this project never reached its end and the site was then leased to an Italian investor, who devoted his business to the production of iron nails. Such activity kept going on for some years until the site was again abandoned in the late eighties. The place was then used irregularly by various entities as stores and warehouses until on the 4th of July 1997 the company of Blaschem Ltd. was founded. The plant was entirely dedicated to the manufacturing of the API corticosteroids. The activity continued until 2003, when divergences in opinion occurred between the shareholders and the company's operations halted.



In December 2005, Crystal Pharma S.A., which later merged with Ragactives as Gadea, acquired the entire company of Blaschem Ltd.

On the right-hand side of the plant there is situated a scrap yard of iron wreckages. Leading through a passage on the right side of the factory is a site specialized in the production of fiberglass boats. On the left there is a closed area surrounded with walls without any activity. Blaschem (Malta) Ltd. has a written permission from the neighbors opposite the plant and a Police permit to conduct its activities, and there has never been any claim about loud noise.

The area is adequately serviced with all the basic utilities including a sewer system, electricity and water supply systems and a telephone system. All these services are located underground. The road surface is asphalted, however it presents itself with various cracks.

2.3. LAND SELECTION

The location was chosen due to the activity present previously, which adapted perfectly with the current production of Gadea pharmaceutical group, allowing the company to start production immediately. The site selected was the only available with such infrastructure to accommodate the project, as well as permitting the possible future expansion of the company.

The process for choosing the site was undertaken by Malta Enterprise and Malta Industrial Parks (MIP). The process was initiated by Malta Enterprise, which approved the new project by its Board of Directors based on an in-depth evaluation of economic and social criteria. The proposal was then forwarded to MIP for the allocation of an appropriate site.

An assessment of the suitability of all available sites in the various industrial zones was undertaken. Another possibility offered to Gadea was that of opening a new plant in Hal Far industrial Estate. However, due to the much higher costs to be incurred and the availability of starting production immediately, the site in Bulebel was considered more opportune. The proposition of joining the already existing Pharma-park in Hal Far has not been totally scraped and might be considered in the distant future.

2.4. IDENTIFICATION OF AREAS AND BUILDING

The location is rectangular in size with a length of 58m and a breadth of 44m, thus giving a total area of 2552m². The building is located at the posterior part of the site. From an aerial view it can be seen to have the shape of an F. The edifice is divided mainly into 3 areas with each one dedicated to a particular part of the manufacturing process:

In the largest part of the constructed area, at the back of the site is the production area. The five reactors are placed on a platform. The individual capacities vary from 120 L to 2000 L. Three of the reactors are made of stainless steel, whilst the other two are glass-lined. Whilst half of the production area is committed to the manufacturing, the other half is devoted to warehousing. At right angles to the plant, lays access to two constructed segments. At one side is the drying area, where the oven and lyophiliser are present.

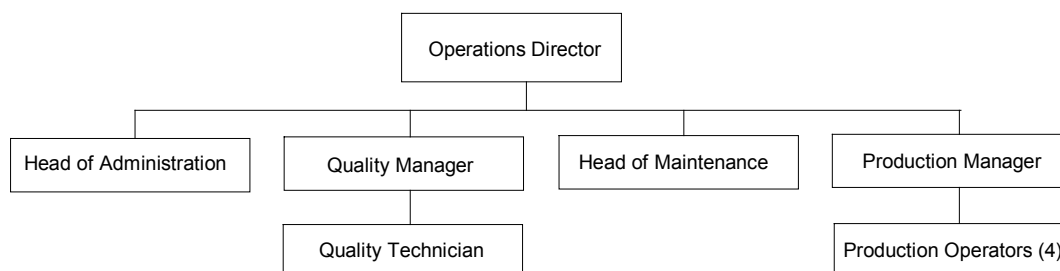
In separate rooms accessed from outside are also the boiler room, together with the general electric panel, whilst in another room is a substation of Enemalta. In a compartment of its own there is also present the Reverse Osmosis plant.

In the second access from the plant there are the analytical laboratories, together with the offices. Further down, there is also the canteen present, which is the only area allowed for smoking.

3. PROPOSED SYSTEMS

3.1. MANAGEMENT

The departments making up Blaschem will be Production, Quality, Maintenance, Research & Development and Administration. Heads of the departments will report directly to the Operations Director, who will report to the headquarters in Spain.



The number of employees in Blaschem at the moment is 9. By the end of 2007 this would have increased to 11. The staff to be taken up includes an Administrator and a Chemist. An important characteristic of Gadea is continual education of its employees. To achieve such a goal employees are sent for training periods at the mother company where they will be able to learn the mode of operating by observing it directly. Such training varies from simple laboratory procedures, to plant production operations up until emergency situation handling. Besides the Maltese employees, constant assistance from Spain will be given through various Spanish staff relocated in Malta. Their role varies in different departments, in order to ensure a healthy growth of the company in all the sectors. The Operations Director is also Spanish, since a certain amount of experience is required to lead the company.

Concerning issues for Health, Safety & Environment, the person in charge is Mr. Ilde Fonso Vaquero (ilde.vaquero@gadea.com). Mr. Vaquero is the Head of Department in Spain and communicates directly with the Operations Director for any matters concerning Malta.

Whilst acknowledging the importance of having the plant accredited, the main concern of the company is to establish a feasible schedule in which certification would be acquired. To ensure the correct management of the plant, three Management Systems, together with the schedule for obtaining such accreditation, will be implemented:

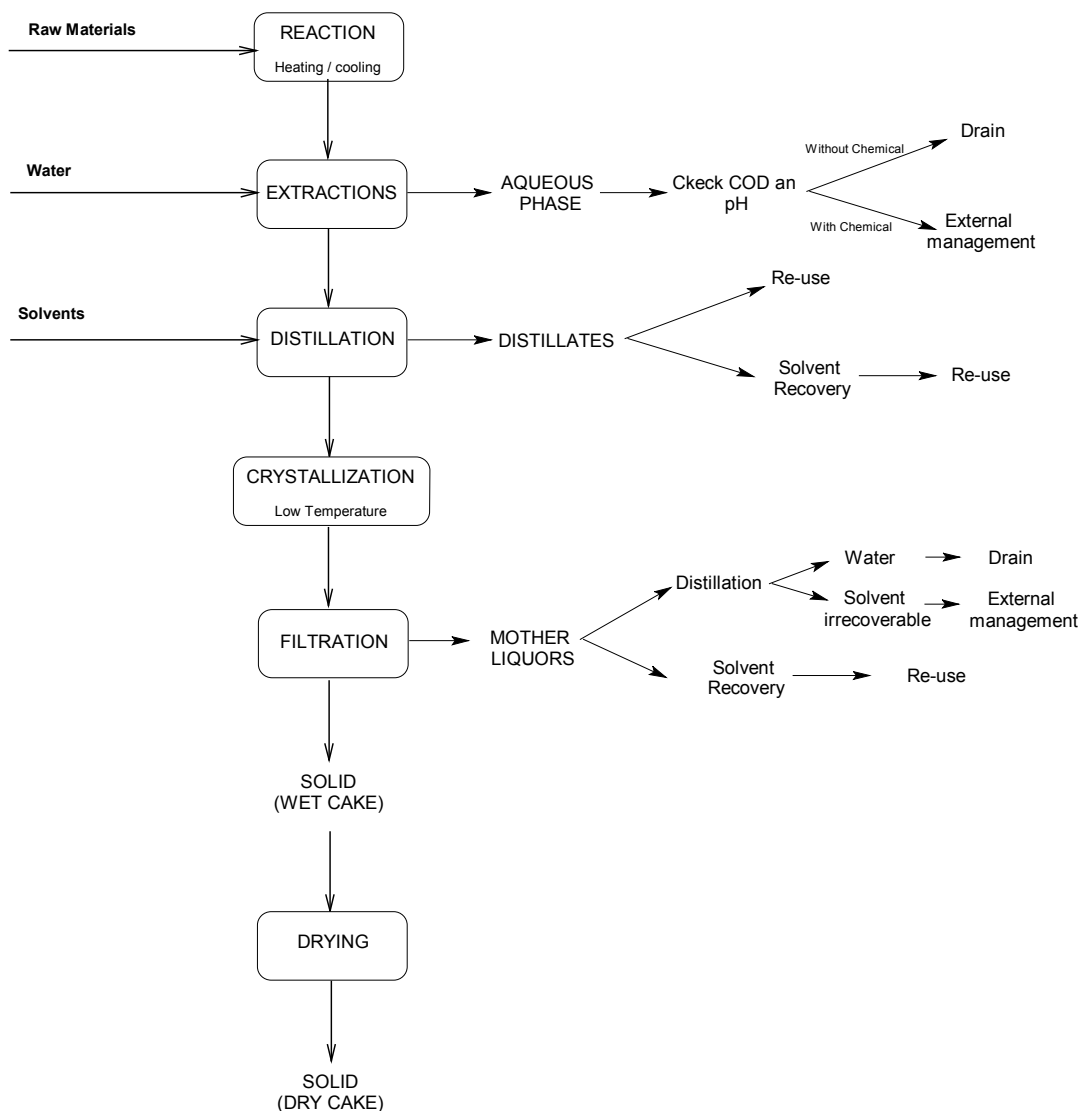
- Production and Quality: Good Manufacture Practices (December 2008)
- General: ISO 9002 (August 2009)
- Environment: ISO 14000 (August 2010)

Such procedures will be implemented, using the general policies from the mother company. This will be until certifications by the authorities are obtained. Environmental aspects will have a priority concern in the policies implemented.

4. PROCESS IMPLEMENTED

4.1. DESCRIPTION OF THE PROCESSES, OPERATIONS AND CONTROL SYSTEM

Manufacture of the products is done in batch processes. The batch size may be from 5 to 50 Kg. A general description of the chemical process is described in the following flow chart. Depending on every particular process some operations are not performed.



The solid obtained in the end is the intermediate to be further processed or the final product to be exported.

5. DETAILS OF PRODUCTION

5.1. PRODUCTS

Gadea produces, amongst others, corticosteroidal API's in bulk. The list of products includes up to 40 different final API's. The equipment used is multipurpose and multi-product, meaning that different unitary operations can be performed in any equipment and each batch can be of a different product. These can be divided into two families according to its properties and chemical structure:

- Progestagens – derivatives of the progesterone hormone
- Corticosteroids. This is the largest group and can be divided into several subfamilies:
 - Betamethasone derivatives.
 - Prednisolone derivatives.
 - Hydrocortisone derivatives.
 - Dexamethasone derivatives.
 - Other corticosteroids.

The products to be manufactured by Blaschem, along the next years include a selection of the various corticosteroids. No progestagens have been forecasted for the production in Malta. A detailed list of the production foreseen for the coming years is attached:

LIST OF PRODUCTS
Beclomethasone Dipropionate
Betamethasone Acetate
Betamethasone Dipropionate
Betamethasone Valerate
Clobetasol Propionate
Dexamethasone base
Dexamethasone Sodium Phosphate
Prednisolone Acetate
Hydrocortisone Acetate
Mometasone furoate
Prednisolone Sodium Phosphate

It is important to note that production trends can vary considerably between the years and throughout the year itself. Hence this influences also the kind and quantity of raw materials required as well as the wastes generated. Production depends entirely on the “demand and supply” rule, which is administered directly from Spain.

The production forecast is the following:

PRODUCT (Kg)	2007	2008	2009	2010
Beclomethasone Dipropionate	96,5	101,3	106,4	111,7
Betamethasone Acetate	4,9	5,2	5,4	5,7
Betamethasone Dipropionate	178,7	187,6	197,0	206,8
Betamethasone Valerate	507,4	532,7	559,4	587,3
Budesonide	34,7	36,4	38,2	40,1
Clobetasol Propionate	188,5	197,9	207,8	218,2
Dexamethasone base	70,2	73,7	77,4	81,3
Dexametasone Sodium Phosphate	109,4	114,9	120,7	126,7
Mometasone furoate	53,5	56,2	59,0	62,0
Prednisolone Sodium Phosphate	273,0	286,7	301,0	316,0
TOTAL FINAL PRODUCT	1516,8	1592,6	1672,3	1755,9

The planned annual production for years 2007-2010 is shown in the table above. Estimation for year 2008-2010 was taken assuming a 5% growth per year. The amounts are expressed in Kg.

5.2. RAW MATERIALS

5.2.1. RAW AND AUXILIARY MATERIALS

The table below shows the amount of raw materials needed for the next five years (expressed in kg/year). As the steroids market is very variable only rough calculations can be done for long-term estimations. Data for 2007 are obtained according to the sales forecast provided by the Sales Department of Crystal Pharma. Data have been calculated assuming the production forecast.

Raw materials	2006	2007	2008	2009	2010
Water	69000	71700	75300	78500	80000
Organic Solvents	47214	56657	58961	61910	65003
Inorganic Solvents	560	671	678	712	749
Solids	5060	6070	6353	6669	7006

Raw materials are divided into groups according to the procedures adopted by the mother company in Spain:

- Non-Halogenated Organic Solvents (NHOS).
- Halogenated Organic Solvents (HOS).
- Acids and alkalis (AcAl).
- Toxic reagents (Tox).
- Inert solids (Inert).

Furthermore, in the table below is the annual consumption for auxiliary materials:

Auxiliary materials	2006	2007	2008	2009	2010
Nitrogen Gas / m ³	1377	1520	1585	1610	1675
Diesel Fuel / L	10000	12000	12000	13000	14000

5.2.2. RELEASE OF ANY SCHEDULE A OR SCHEDULE B SUBSTANCES

The installation does not release any Schedule A or Schedule B substances into the sewers. The process only involves the use of one Schedule A substance (Methylene Chloride), which whenever used, is disposed of directly as Halogenated Organic Waste in metal drums to be exported as Hazardous Waste to be treated abroad. Wastes, which would contain organohalogen compounds, are always identified in the Standard Operating Procedures used in the processes, so that operators can identify easily which wastes have to be directed for export.

5.2.3. RELEASE OF ANY LIST I AND LIST II SUBSTANCES

The only substance present in List I and II to be used in the plant is the organohalogen compound, methylene chloride. Whenever this is used, it is disposed of directly as Halogenated Organic Waste in metal drums to be exported as Hazardous Waste to be treated abroad. Organohalogen wastes are always identified in the Standard Operating Procedures used in the processes, so that operators can identify easily which wastes have to be directed for export.

5.3. WASTE MANAGEMENT

5.3.1. APPROACH

Gadea makes use of the waste management system ISO14000, which is pending of being certified. In the company a person is in charge for all that concerns the management of environmental matters, as well as the management of the health and safety at work.

Blaschem, taking advantage of this organisation built up during years of experience, will designate the responsibility for the environmental concern referred to before to the same responsible person in Spain, who will conduct the mentioned management through the director of operations assigned in Malta.

Blaschem, once that it is settled will have as an aim not only to implement quality management systems, but also an environmental management system. As a reference on which to build this system, the one implemented in Gadea will be used, once this will be certified.

As a priority, Blaschem considers to start with the implementation of a quality management system. In order to achieve such standards, a series of improvements in the installation are planned, which will permit the company to obtain standard of quality sought for. Furthermore in these improvements, it has been taken into consideration all the necessary measures to protect the environment, as well as to comply with the legislation that already exists with regards to these matters.

5.3.2. WASTE ADMINISTRATION AND STORAGE

The management of the different types of wastes produced in Blaschem presents itself as a serious problem, not only in cost, but also concerning in logistics, since there isn't an easy and rapid way of managing such wastes. Currently, on the island there doesn't exist an authorised entity for dealing with the wastes, therefore creating a very difficult situation and leaving only the possibility of exporting such wastes. Recently it has been mentioned that an incinerator should be opening in Marsa, which should be able to deal with hazardous wastes. However, this option is still pending of approval from MEPA.

The approach adopted by Blaschem will be to substantially reduce the amount of wastes generated from the processes. These recovered solvents from these minimisation measures will be supposedly re-used and the external management will be only for the irrecoverable wastes.

The company's guideline is crystal clear, where all the possible solvents will have to be recovered, to be reutilised inside the production processes and to treat the rest as wastes, which do not imply any value or use to the company.

In general, there are various mechanisms of minimisation that can be exploited:

1. Those wastes that contain a mixture of water and a solvent with a boiling point inferior to that of water.
 - The wastes can be tackled by distilling the solvent, which would be used as a re-utilisable solvent. At a higher temperature water would then be distilled and discharged into the drains. The remaining liquids in the reactor will be treated externally.
2. Those wastes that contain a mixture of water and a solvent with a boiling point superior to that of water.
 - The wastes would be distilled and the water recovered would be discharged into the drain, whilst the remaining wastes would be treated through the external dealer.
3. Management of the wastes that consist of a mixture of two solvents with separate boiling points at a difference of more than 10°C.
 - The management of these wastes entails the distillation of the various solvents present in the mixture.
4. Management of the wastes, which contain distilled solvents obtained from anyone of the processes.
 - In such a situation the wastes can be reused as cleaning solvents without any requirements of previous treatments.
5. Management of the wastes that contain a mixture of more than two solvents with separate boiling points at a difference of more than 10°C, and therefore which can be separated by means of distillation.
 - In this case the management of the wastes is very much determined by the type of solvent present, since a common treatment is used for all of them.
6. Waste management that comes from the extractions of aqueous phases.
 - The wastes originating from the aqueous phases of extractions will be analysed for their COD (Chemical Oxygen Demand) and pH to be eliminated afterwards. If any of these wastes will give an inadequate COD or pH, this will be treated externally as hazardous waste.

The wastes generated will be stored inside the warehouse for the solvents, situated on purposely-made shelves and labelled accordingly to the current legislation. The wastes will be classified according to the danger they present (flammable, toxic and corrosive). Refer to the details of the storing of the solvents in the chapter of the new improvements. Currently, the wastes present included a number of drums, which were stored outside. However, a warehouse is being constructed at this time, in order to store the wastes away from the elements of the weather.

5.3.3. SOLVENT RECUPERATION & REUTILISATION

One very important policy implemented in the company is that to generate as few wastes as possible. Implemented since the beginning of 2007, the procedures mentioned above in section B.5.3.2. are being used in order to recover the solvents. These solvents are generally used again for washing the reactors from the inside. Such a task requires a solvent of low purity, when considering the amount of water present with the solvent.

In addition to this, there is also the possibility of reutilising the solvents recovered in the same processes. However, such a delicate decision requires various laboratory analysis and experiments to verify that such a step would produce a product with the expected purity. Obviously not all wastes can be considered for such recovery. It will be the role of the R&D department to determine which types of wastes can be re-processed to recover pure solvents and which can be used only for cleaning.

Considering both recoveries of solvents for processes and for cleaning, it can be deduced that a system of recycling solvents is built up. This aids substantially the company not only in reducing its environmental impact, but also in reducing the costs incurred in purchasing the solvents. In theory, this can sum up to an infinite use of the solvents in question. However, although solvents are recovered from every batch produced, still one has to keep in mind that 100% recycling of solvents is difficult to obtain and a certain amount of solvents would still need to be purchased regularly. With the actual system of recuperation and reutilisation of the solvents, the quantities of the generated wastes are the following:

	2007 (Kg)	2008 (Kg)	2009 (Kg)	2010 (Kg)
Total consumption raw materials	63398	65992	69291	72758
Consumption of water estimated	69000	72000	76000	80000
Total	132398	137992	145291	152758
Non halogenated organic solvent	-11122	-11548	-12125	-12731
Halogenated Organic solvent	-2540	-2667	-2801	-2941
Waste Process Water	-15550	-16227	-17118	-18015
Water non contaminated	-62202	-64907	-68471	-72058
Solvent to re-use	-40984	-42643	-44776	-47013
Total	132398	137992	145291	152758

The uncontaminated residual water will be stored in a 15,000L cistern, where the pH and COD will be tested daily before being forwarded to the drains. Such water would definitely have trace compounds. Therefore it is definitely not possible to use the water for any purpose.

5.3.4. EXPORTATION OF WASTES

Keeping in mind the waste management mentioned in the upper sections, a number of residues considered as hazardous would still be created. Such wastes cannot be dealt with locally on the island, since at the moment no such facility exists. Hence, the necessary steps have been taken to contract a foreign waste services company, called Indureco S.L., which can deal with such wastes. The company is located at Poligono Industrial, Parcela 174, 34200 Venta de Baños Palencia, Spain. On behalf of Indureco S.L., the contact person is Ms. Ana Bernal (ana.bernal@indureco.com). A contract has been issued with this Spanish company, situated in central Spain, which has a vast network of establishments all throughout the Spanish peninsula.

To ensure the provision of the necessary logistics of such hazardous waste from the island right up to the doorstep of the waste service facility, the drums will be loaded into a container and taken down to port by ADT-authorised MJK Transport, located at 50, Watermill Street Kalkara. Handling the sea transport and the delivery on Spanish roads is Central Marine Ltd. situated at 38, Xatt l-Ghassara ta' l-Gheneb, Marsa.

Currently, Blaschem has applied for a permit for transboundary movement of hazardous substances through MEPA, which will allow the company to export the wastes abroad, where these can be dealt with accordingly. Until then all the wastes intended for export are stored at Blaschem in Zejtun, on the outside, to avoid any dangerous accumulation of vapours on the inside of the plant.

NHOW: 25% of the total consumption of non-halogenated organic solvents will require to be dealt with externally by the Spanish waste services.

HOW: 25% of the total consumption of methylene chloride (the only halogenated organic solvent to be utilised) will require to be dealt with externally by the Spanish waste services.

AW: 20% of the total quantity of the rest of raw materials will require to be managed externally by the Spanish waste services, including the water.

All the wastes, which require to be exported, are inserted into a specific system of analysis. Such a system consists in specifying what the wastes are made up, as well as quantifying the amount of wastes. These are then stored in 200L drums and stored away, whilst waiting to be exported. For every different batch of waste generated an analysis by gas chromatography is carried out, so as to determine using reference retention times the components in the waste and their relative quantities. Once all the necessary permits will be obtained, a full load container will be exported out of the island to the authorised Spanish waste dealer. At the moment all the wastes are being warehoused, until the bureaucratic procedures are terminated.

5.3.5. EMISSIONS TO THE ATMOSPHERE

The installation focuses on two main points of such emissions:

1. Vent scrubber: All the reactors are connected to the scrubber to prevent the uncondensed vapours or any process gases are emitted in the atmosphere without being processed.

Release Point	Height from the ground / m	Diameter / mm
Vent scrubber	5.5	250

The scrubber permits through the absorption with water or the neutralisation with an alkaline or acid solution to retain the vapours, which did not condense, or the gases from the processes formed during the production. To avoid the entrance into the scrubber of vapours that did not condense, the reactors include condensers, in which cool fluid circulates at a temperature inferior to -10°C.

An accredited laboratory (AIS Environmental) has been contracted to measure the emitted gases or vapours emitted through the scrubber, to confirm that the values comply with the limit values established by the current legislation.

The monitoring consists in the measurement of the volatile organic compounds and the hydrogen chloride fumes during normal conditions of work of the plant.

Once these values will be confirmed, a monitoring of the focus point will be established. Such legal notice is found in the Spanish legislation and was incorporated into the IPPC application since at the time of compiling the first IPPC application this law was deemed as fit for the regulation of atmospheric gases. No relevant Maltese law was encountered. Therefore the Spanish equivalent was used, keeping in mind that both countries were based on EU standards. A copy of this legislation is found at the end of this document as Attachment 12. The results obtained will be published in Annex I.

2. Boiler chimney: The boiler produces the necessary vapour to produce the heating of the different equipment required for the process. This is obtained using a thermal input of 0.697 Mega Watts.

Release Point	Height from the ground / m	Diameter (mm)
Boiler	10	370

The boiler functions uses diesel to heat up the oil, which in turn heats up the water. Apart from the diesel, the boiler also requires electricity to run the pumps (oil pump and water pump) as well as the motor, which burns the diesel to heat up the oil. It is possible to obtain an estimation of the contaminants emitted in the atmosphere by taking into account the emission factors of the fuel consumed.

Fuel "C" Data

Density	0.8583 Tm/m ³
Conversion in units of energy	1 Tm = 43.3 Gj/Tm
Factor of emission "CO"	10g/Gj
Factor of emission "CO ₂ "	73.4 Kg/Gj
Factor of emission "NO _x "	80 g/Gj
Factor of emission "SO ₂ "	92.31 g/Gk

The reference data has been obtained from the "Document of sectional orientation for the measurement, calculation and estimation of the emissions of the EPER substances. Section of galvanisation."

During the year 2006, Blaschem had a consumption of 8000L of diesel fuel "C". According to this consumption, the emissions produced where the following:

$E_i = 8m^3 \times 0.8583 (Tm/m^3) \times 43.3 (Gj/Tm) \times F_i$	
Emission "CO"	2.97 Kg/2006
Emission "CO ₂ "	21822.93 Kg/2006
Emission "NO _x "	23.78 Kg/2006
Emission "SO ₂ "	27.44 Kg/2006

A suitably accredited laboratory (AIS Environmental) is measuring the emissions during the first semester of 2007. The results obtained will be published in Annex I. Once the above values would be confirmed, a monitoring of the focus point will be established.

5.3.6. DISCHARGE OF EFFLUENT

Non-contaminated water will be managed through the drains, forming part of the mains. In order to be able to pour effluent in the drains, Blaschem have applied for a sewer discharge permit from Water Services Corporation. The application has already been handed in. However, the various analyses still have to be carried out by an accredited laboratory (MNL and Institute of Water Technology).

The corresponding permit has been requested to the Water Services Corporation, explicitly showing in the mentioned permit that the physico-chemical analysis of the samples obtained from the drains through which it will be eliminated, has been done. Wastewater will be deposited in a cistern of 15,000L of capacity, where periodically in function to the occupancy of the pit (25%, 50%, 75% and before discharge), the corresponding analysis of COD (Discharge limit to be yet determined by WSC) and pH (Discharge range between 6 and 10) will be made always previous to discharge. Due to the limitations of the site, currently no rainwater is being collected. Therefore no dilutions are to be carried out in the cistern, prior to discharge in the sewers.

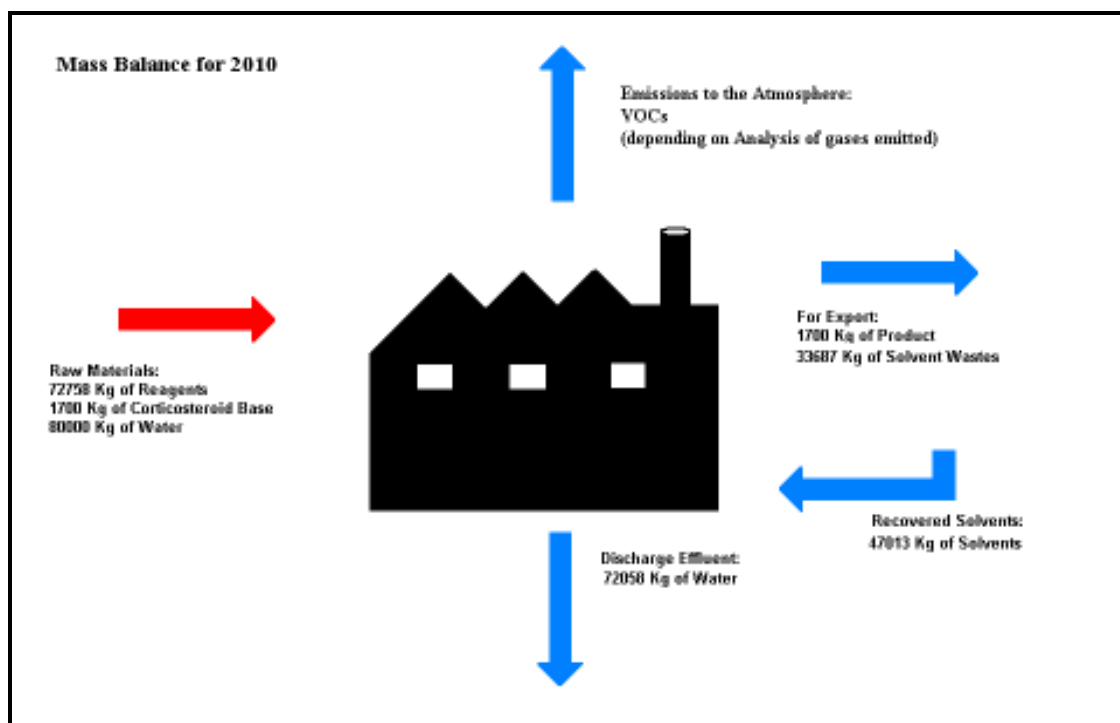
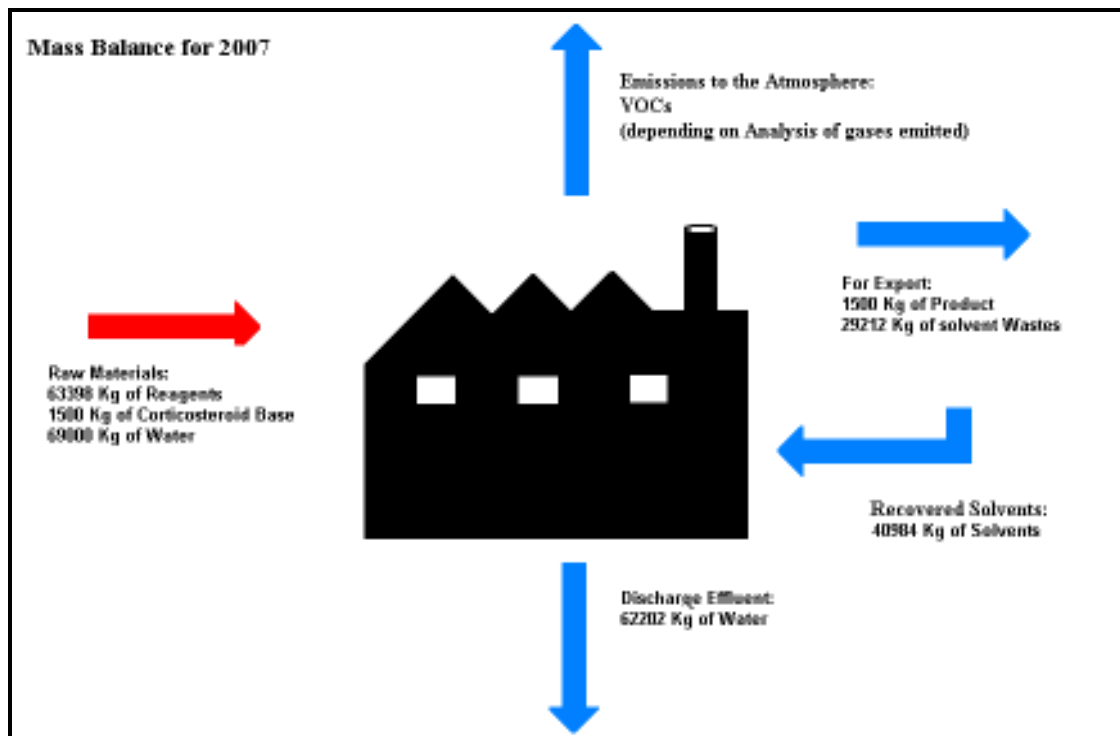
It ought to be mentioned that the analysis of the wastewater carried out was for the specifications that are effected by the production in Blaschem. The legislation specifies various other characteristics, which haven't been tested for. However, these were not taken into consideration since they are not applicable to our kind of production. The type of analysis left out was that concerning the heavy metals, since no such substances are used at this facility.

5.3.7. NOISE AND VIBRATIONS

Under normal operation conditions, noise and vibrations in the plant are associated mainly to the generation of utilities used in the process, notably the steam, compressed air, chilled water, water of refrigeration and vacuum.

As a general rule the supplier specification of equipment (boiler, compressors, pumps) guarantees a low level of noise. In order to certify that Blaschem does not surpass the limits stated, an Audiologist (Ms.Nadine Calleja B.Sc., M.Sc.) has been contracted to provide an environmental noise assessment of the premises. The results of the study will be presented in Annex I.

5.3.8. SUMMARY OF THE EMISSIONS



In the diagrams above a summary of all the emissions into the environment are given for the year 2007 and 2010. The emissions include both liquids and gases emitted, however no solids are included in the diagram since the plant will not produce any significant amount of solid wastes (Less than 10 Kg/year). For the years 2008 and 2009 the values will be an intermediate between the two years depicted. An important issue to be raised is the re-utilisation of the solvents. Its effect will be that of reducing substantially the solvent wastes, as well as a reduction in the solvents consumed as raw materials.

5.4. IMPACT ON THE ENVIRONMENT

The wastes generated are from plant operations including reactions, filtrations, distillations and extractions will be treated adequately and won't be discharged in the environment. All the liquids would either be treated for recovery internally or exported and treated accordingly. The solid residues generated in the filtration processes will also be treated by the Spanish waste services although such waste is produced once or twice annually. Solid wastes account for less than 10 Kg per year. Therefore such trivial quantities are dealt with once a significant volume of solid waste has accumulated.

Other residues are typically urban residues such as paper, toners, plastic and glass. As a fundamental part of the policy of Gadea is the environmental care, a new system is being sought in order to separate the wastes produced. The system has not as yet been finalised. However, the idea is to separate the wastes at source into various containers, including wood, plastic, paper and metal. An authorised waste management company would then collect these. Once the final agreement would be reached, a copy will be forwarded to MEPA.

Waste minimization is an important aspect for our company and in this context it is fundamental to ensure that the processes are optimized and the smallest quantities of raw materials, water and energy are used and the smallest quantities of waste are generated.

Taking into account the solvents that will be recovered by distillations, up to a total global savings of 20% on the used solvents could be easily reached.

Since all the waste is going to be treated according to current regulations, no significant impact on the environment is expected. Nevertheless, appropriated procedures will be established to avoid the accidental pollution caused by spillages during the internal managing of waste.

6. EMERGENCY PLANS

6.1. APPLICATION

The actions mentioned are to be taken in the event of a chemical emergency. These actions are to be undertaken by the personnel of BLASCHEM in the case of:

- Acid spill
- Solvent spill
- Solid product spill

These norms have been designed in the event of spills of medium proportions (eg.: drum or container leak).

6.2. MEASURES AVAILABLE

In order to contain the possible spills the following Personal Protective Equipment is used:

- Tychem® C suit
- Full-face mask with mixed protection filters (Types A, B, E, K and P)
- Motorised helmet for aeration with mixed filters
- Neoprene gloves

As footwear the standard boots used by the personnel in the plant will be used. The plant personnel responsible for collecting the spill avail of part of the protection equipment required. The rest of the protection equipment to be utilised is found in the production warehouse. The materials required to handle the spill include:

- Absorbent paper
- Humid Sand
- Dry Filter Aid

6.3. FORMS OF ACTION

The actions to be taken will be decided separately depending on the material leaking or spilled. The present norms of action are designed to act over spills of small or medium magnitude (up to 1000 litres), corresponding to the largest container present in BLASCHEM.

6.3.1. ACID OR BASE SPILLAGE

The nature of the waste will be confirmed through the verification of the label on the container. Once the verification will be done the operator will wear the Tychem® (yellow) as well as the mask complete with mixed filters. Instead of the full mask the motorised helmet could be used, assuring that the mixed filters are available. The operator will benefit of neoprene gloves during the intervention.

The waste will be gathered once the sand or filter aid will be applied on top of the spill. Filter aid will be used if the product might react with water. Afterwards the product will be collected as solid waste and stored in double polyethylene bags tightly sealed. The waste will be labelled (origin, date and signature) and will be deposited in the zone designated for wastes. It will then be treated as hazardous waste to be exported.

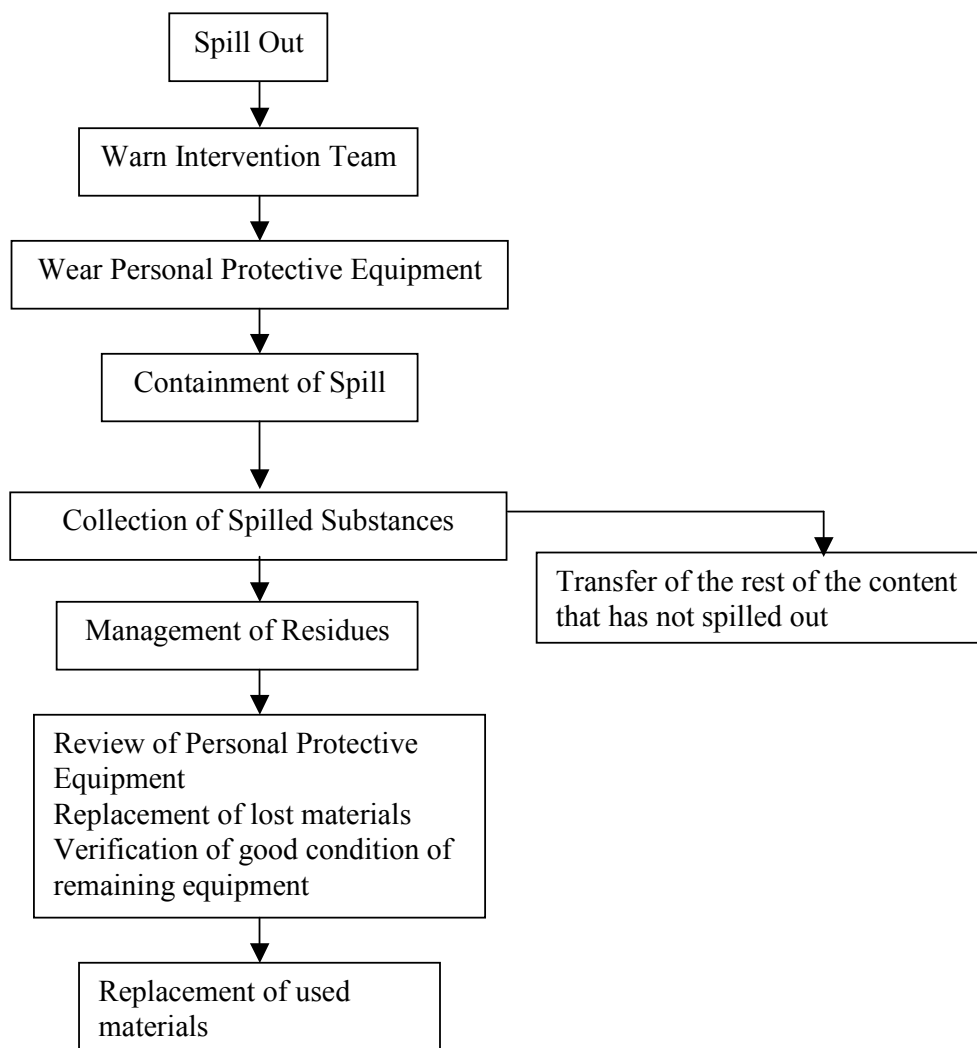
The use of the sand (or the filter aid) is to be used as quickly as possible to avoid that the spill reaches any culverts and gets to some course through which water passes. As a first priority access to the spill will be prohibited to the drains that collect rainwater and afterwards the access will be barred to the drains, which conduct to the wastewater reservoir.

Once the product will be gathered the zone will be intensely washed with water.

Until all the process of collection and elimination will not be terminated, the operators will work with all the necessary personal protection equipment.

Once the collection and elimination will be finalised, the operators will remove all the personal protection equipment and proceed to the elimination of these disposable materials (Tychem® suits, gloves, filters of respiratory equipment).

If the spill would have reached the wastewater reservoir, before discarding in the public drains the values of the wastewater will be verified and if necessary these will be managed as hazardous waste.

OPERATIONAL SCHEME:

6.3.2. SOLVENT SPILLAGE

The personal protective equipment to be worn will include:

- Tychem® C suit
- Full-face mask with mixed protection filters (Types A, B, E, K and P)
- Motorised helmet for aeration with mixed filters
- Neoprene gloves

When a spillage of a solvent occurs, in general due to its high flammability, the first action to be taken is to avoid the generation of any sparks or source of ignition. Any activities that can generate sparks or can be sources of ignition in the vicinity will have to be halt. The means of transport present in the zone will have to be held to a standstill. These include private vehicles, suppliers' vehicles and fork-lifters). If the accident involves a fork-lifter the first action to be taken is to withhold the vehicle and annul the electronic system. This will require switching it off and removing the key from the ignition.

It will be totally prohibited to use metal parts, tools or equipment in the vicinity. Before handling the spill, the portable fire extinguishers will be made available close by. One of the members of the intervention team will be in charge of the extinguishers all throughout the operation, while the other will proceed to collect the spill.

The first step will be to confine the spill using the sand and or filter aid, hence avoiding that the leak ends up in the drains. Amongst other priorities, care will be taken to avoid penetration of the spill into the water drains, which collect rainwater. Once the spill is restrained, sand will be distributed over the solvent in order to absorb it. Once the sand has absorbed the solvent, the operators will proceed to sweep it up, whilst avoiding abrupt movements that can generate sparks. The residues will be stored in double polyethylene bags.

The waste will be labelled (origin, date and signature) and will be deposited in the zone designated for wastes. It will then be treated as hazardous waste to be exported.

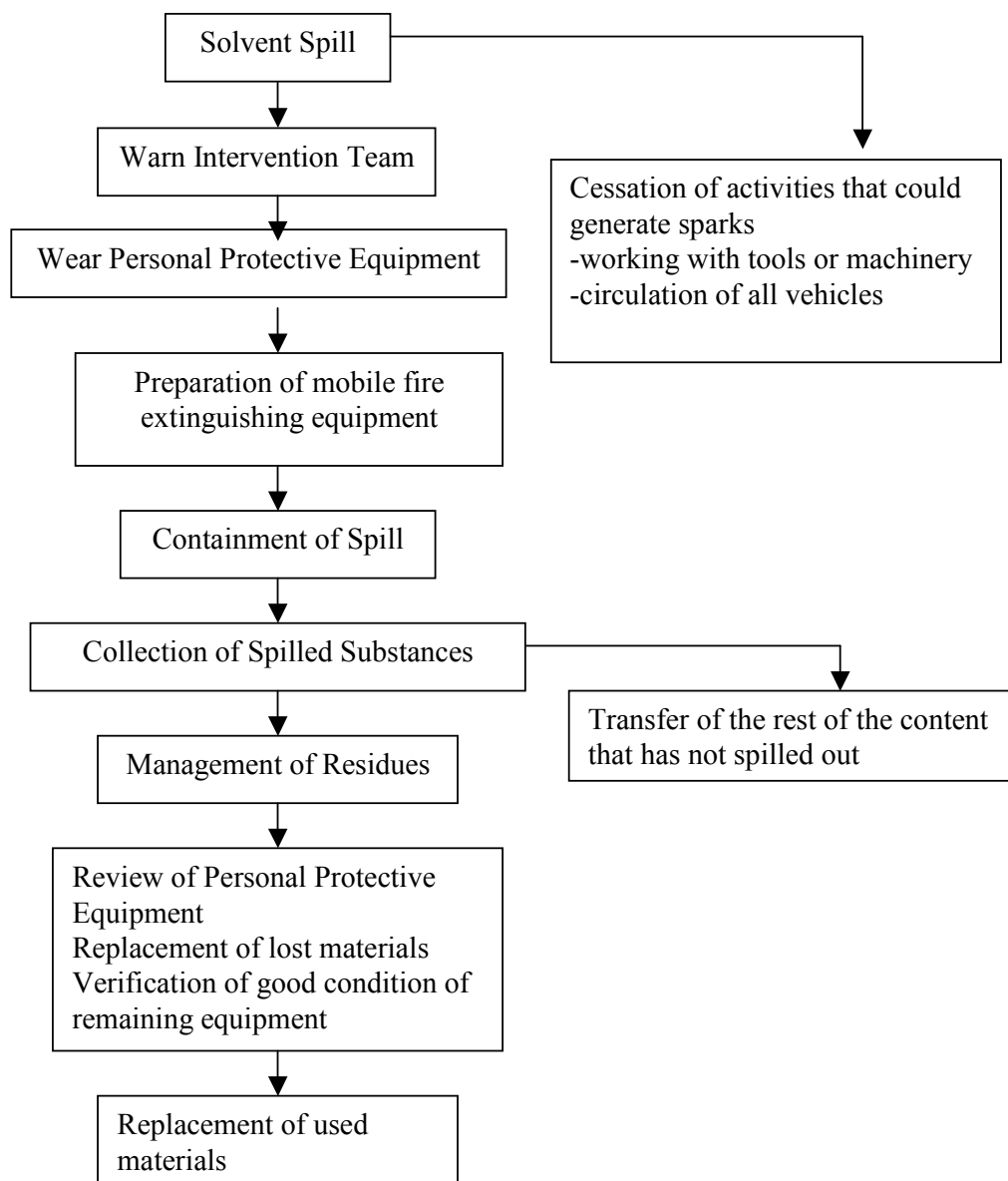
The operators will work with all the necessary personal protection equipment and one of the members will remain constantly with the portable fire extinguishers until all the collection and elimination procedures would be completed.

Once the product will be gathered the zone will be intensely washed with water. The wash water utilised will then be collected again using filter aid and sand. This will be managed directly as solid waste for export. The area would then be cleaned one final time with water. This water will then be thrown away directly to the public drainage.

On discharging the wastes to the drains, the siphons would be opened up in order to allow the vapours to ventilate outside, and avoid any accumulation of vapours inside the sewage system.

Once the collection and elimination will be finalised, the operators will remove all the personal protection equipment and proceed to the elimination of these disposable materials (Tychem® suits, gloves, filters of respiratory equipment).

If the spill would reach the wastewater reservoir, lab analysis for pH and COD would be carried out. Should these parameters comply with the specified values of a pH 6-10 and a COD below 3000 mg/L, the operators would go proceed in discharging the wastes into the main sewers. Otherwise, the wastes will be pumped into metal drums and sent for treatment abroad. Should he wastes contain methylene chloride, which is the only halogenated compound present in our raw materials, it will be managed directly for export as hazardous waste.

OPERATIONAL SCHEME:

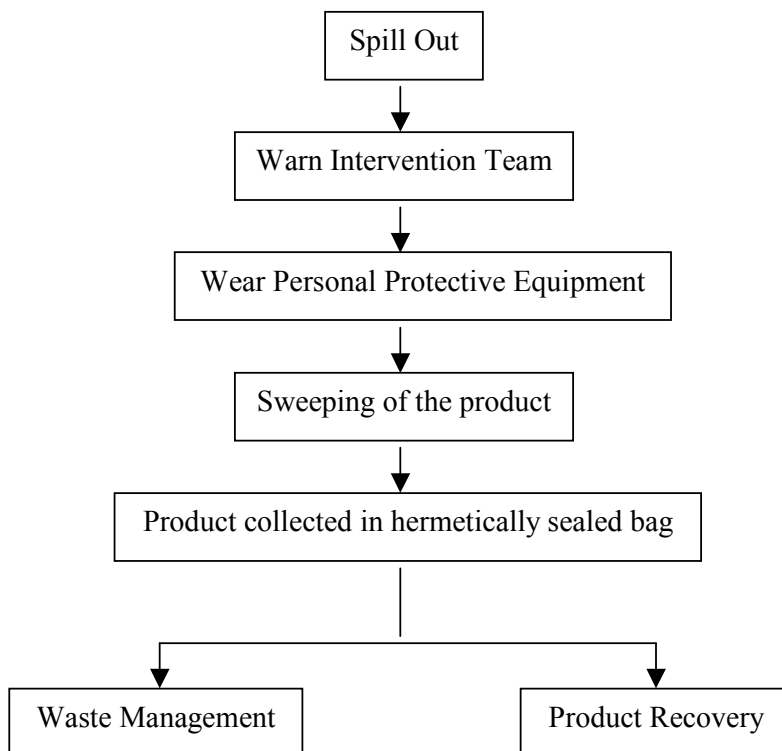
6.3.3. SPILLAGE OF SOLID MATERIAL

For the collection of a spillage of solid material, the following personal protection equipment is necessary:

- Tyvek® suit white (Tychem® C suit yellow if the solid material is reactive)
- Full-face mask with mixed protection filters (Types A, B, E, K and P)
- Motorised helmet for aeration with mixed filters
- Neoprene or latex gloves

To gather the product, the operators will sweep the product, ensuring to raise the least possible amount of powder into the air. Once collected, the product will be deposited in double polyethylene bags, which will be closed tightly. The product collected will be managed as solid waste, with the exception of cases when recovery of the product will be necessary.

OPERATIONAL SCHEME:



6.3.4. OBSERVATIONS

The observations that follow are valid for any type of spillage of those mentioned previously.

If the spillage occurs in a container or drum located on a shelf, the steps will be taken to contain the spillage and draw together the spilt material as indicated. The use of the fork-lifter will be avoided. Afterwards the remaining contents will be transferred in a more adequate container, labelling correctly according to the existent procedures. The damaged container will be identified and removed to avoid that it is used any further.

The transfer of the material will be carried out in a well-ventilated area. If a fork-lifter will be required, an explosion-proof fork-lifter will be used.

If during any step, the spillage where to reach any water culverts or electric circuits, the maintenance personnel will be warned in order to verify any damages present inside.

Should a spillage occur in the inside of the plant, the mode of operating will be done the same as if the spillage occurred outside, with the exception of prohibiting personnel to circulate inside the plant until all the spillage has been collected and cleaned. Afterwards, great care will be taken in ensuring that the zone is aerated adequately.

Once the spillage is collected, it will be labelled as “Solid Residue of XXXXX”, indicating origin, date and signature. The residue will be placed inside the area designated for wastes.

6.4. DESIGNATED PERSONNEL

To be able to perform the required tasks of collection of a spillage, the production staff has to be trained. This personnel has to be trained sufficiently in order to be able to cope with such an intervention.

6.4.1. PREPARATION

The designated personnel have to have practical knowledge of the spilled material (most remarkable characteristics and properties) and have readily available the Material Safety Data Sheets of the products to be able to consult them before intervening. Besides they will be expected to have practical knowledge of:

- Use of the portable fire extinguishers present and their characteristics
- Use and characteristics of the personal protection equipment
- Waste management of the residues generated

The personnel who will perform these operations will be production operators and/or technical services personnel.

The personnel performing as the intervention team should not suffer from any physical and/or psychological problems that can pose a risk in the case of an intervention.

6.4.2. TRAINING

The designated personnel will have to participate in simulations that will be carried out periodically with the aim of getting the staff to know the practical way of acting in front of different dangerous situations related to the spillage of chemical products used in the production.

6.5. RESIDUAL WASTES**6.5.1. WASTE MANAGEMENT**

The solid wastes that will be produced will be stored in tightly sealed, double polyethylene bags. These bags will be adequately labelled (origin, date and signature) and will be located in the zone designated for wastes.

6.5.2. WASHING OF EQUIPMENT

The equipment used will be washed after the entire residue generated is collected and before removing the personal protective equipment. The equipment would then be available to be stored away.

6.6. SIMULATIONS

Simulations will be carried out periodically as a means to ensure that the designated personnel is prepared to handle the situation they may encounter and verify the suitability of the proposed measures.

The frequency of the simulations will be determined according to the Emergency Plan for the collection of spillages of the mother company in Spain. Anyhow, initially the frequency of the simulations carried out will be higher than normal until the personnel will be adequately prepared.

In each simulation, various risk situations will be taken up relative to different spillages. These situations will be planned to obtain in the least possible time the personnel full trained for any type of situation they may encounter.

6.7. FIRST AID

In the different medicine kits situated all over the facility, there will be available the necessary material required to take action, should there be a predictable accident during the collection of the spillage, such as burns on contact with the material. The contents of the medicine kits will be periodically checked to assure that all the necessary items are present.

6.8. FIRE PREVENTIVE MEASURES

Presently Blaschem makes use of a fire alarm system with sensors distributed all over the plant, laboratories and offices. The alarms are heat-sensitive since smoke sensors would prove themselves futile. On the other hand, a fire-fighting system has yet to be installed on the facility. Such a measure is described in detail in the modifications (Section 7) to be carried out in the plant. Furthermore the operators have been booked for a course in fire-fighting measures with a local company in order to get them trained to fight fires of small and medium size. Employees will be taught on how to use extinguishers, fire blankets and how to respond in the case of fire. Currently the operators have already undergone training in first aid.

6.9. REPORT OF ACTION TAKEN

After an intervention on a spillage a report of investigation of the accident has to be carried out, with the purpose of establishing the cause of the event and the possible suggestions that can help in improving the present procedures.

The report will have to be completed by the person in charge of the plant at the moment of the accident and will be revised by the Production Manager and the person responsible for Health & Safety.

The report will contain at least the following points:

- Date and time of start and finish
- Personnel implicated
- Type of incident
- Observations from incident
- Proposed improvements

As a model, the following report will be used:

REPORT OF THE ACTION TAKEN ON A SPILLAGE					
DATE		START		END	
TYPE OF INCIDENT					
PERSONNEL IMPLICATED					
OBSERVATIONS FROM INCIDENT					
PROPOSED IMPROVEMENTS					
RESPONSIBLE PERSON AT TIME OF INCIDENT		PRODUCTION MANAGER		HEALTH & SAFETY MANAGER	

6.10. PRODUCTS THAT REACT WITH WATER

- ACETIC ANHYDRIDE (M016)
- PYROPHOSPHORYL TETRACHLORIDE (M048)
- FUROYL CHLORIDE (M097)
- PHOSPHOROUS OXYCHLORIDE (M180)



7. IMPROVEMENT OF THE INSTALLATION

7.1. MODIFICATIONS TO THE PLANT

When Blaschem was bought from its previous owner, it was clear that the plant itself did not comply with the requirements of GMP. Therefore, plans were made in order to modify the current edifices. In these changes the significance lies in giving a new image of the company. Such improvements would give the best possible working environment for Blaschem.

Warehouse:

A totally segregated area will be erected, devoted entirely for storage of the solid and liquid raw materials and also for the wastes. This zone will be taken from the production area since the latter is too large. Thus a more effective utilisation of the space provided will be made. The new zone for warehousing will be divided into two perfectly segregated areas.

(Please refer to the plan for details.)

In the zone dedicated to the solids, all the solid raw materials will be stored, including the steroids used as starting materials and the intermediate products.

In the zone assigned for the solvents, there will be stored all the solvents required for the process and all the residues. In this same warehouse there will also be constructed an internal partitioning to divide the liquids, according to the characteristics of the substances with reference to the danger they represent. This refers to inflammable, toxic and corrosive.

In both zones the drains are connected to a storage tank situated beneath the ground, which would prevent any leaks outside the premises. Any outflow of solvent that might occur in the warehouses would collect in this tank.

Once raw materials arrive at the plant, these will present two kinds of labels. The first one refers to the labels provided by the supplier. The second kind refers to the labelling utilised internally in the company, to guarantee at all moments, all the necessary information to work with the raw material. In addition the second labelling system provides essential information concerning the quality of the material, whether it is approved, rejected or still in quarantine.

The wastes produced will be stored in 200L metallic drums. These drums would be the same ones, in which the raw materials would have arrived. Hence such a system allows us to reduce to almost zero the packaging waste. Obviously, only the drums adequate for reutilisation will be used to store the waste.

Clean room:

One of the significant improvements of the plant will be the construction of a clean room, where all the operations will be done with the solid product. This is a specially designated area to avoid contamination of the product from the surrounding environment, as well as to protect the employee while carrying out the required procedures with these products. This area will be separate from the other rooms, since the air will be filtered, and the entrance and exit of air will be regulated through HEPA filters (Efficiency: 99.995%). In addition, with the aim of being able to work in different rooms with different products, all the area will be maintained below atmospheric pressure, in order to avoid that product crosses over from one room to another.



Inside this area, there will be situated two vacuum ovens, a lyophiliser and a micronisation mill. With this equipment it will be possible to carry out the drying and milling operations of both the intermediate and final products.

Laboratories:

The present laboratories do not comply with standards by far. Hence, a total remodelling of the laboratories is required, in order to equip them with the necessary equipment. Thus such laboratories will provide sufficient functionality and security. There are two laboratories to be planned. One will be totally dedicated to the area of research and development, whereas the second one will encompass the quality control department. In the vicinity of the laboratories, lie also the offices as well as the canteen, which will be remodelled too, in order to give a completely new image to the company.

Fire Protective Measures:

Blaschem will have a totally new fire preventive system installed, which will allow the company to increase the safety in case of fire in most of the areas of the installation.

The new system will rely on a storage deposit of water which will be found beneath the ground, and which will allow us to have a water reservoir to supply the different extinguishers, thus permitting to put out a fire in any area of the installation.

Furthermore the system will include also a fire detection system and alarm, which will permit to act rapidly on any incident.

(Please refer to detailed plans of actual and modified plant attached, as well as the Fire Protective System to be installed.)

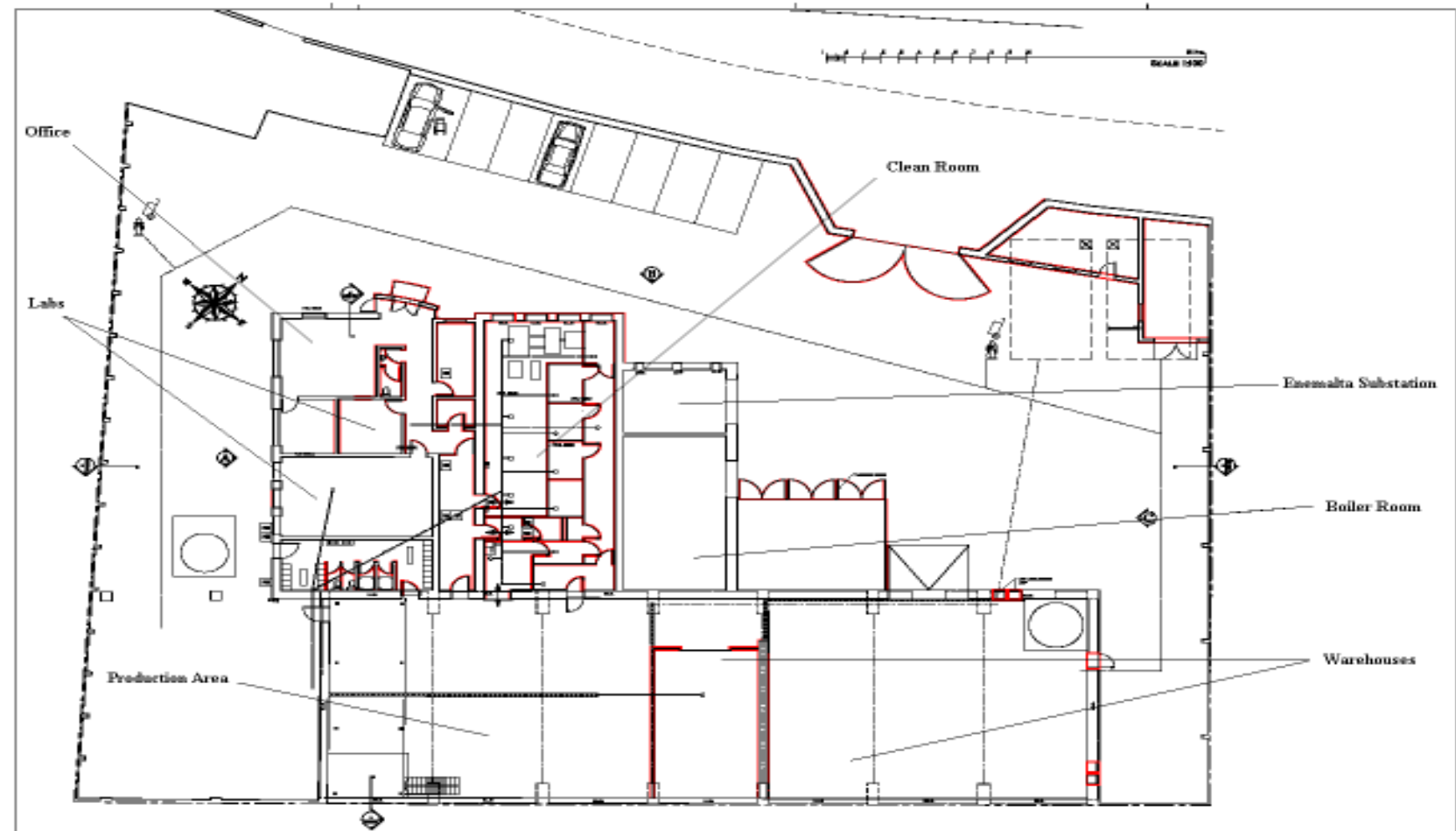
Chemical or Oil Spillage Measures:

The two major areas with the highest risk of spillage are the plant and the warehouse. In order to front this issue, a series of drains will be constructed in the warehouse to collect any leaks or spillages, which will then convert to a subterranean deposit. Spillages or leakages in the plant will have to be tackled "in situ". A detailed plan of such measures is found in Section 6.

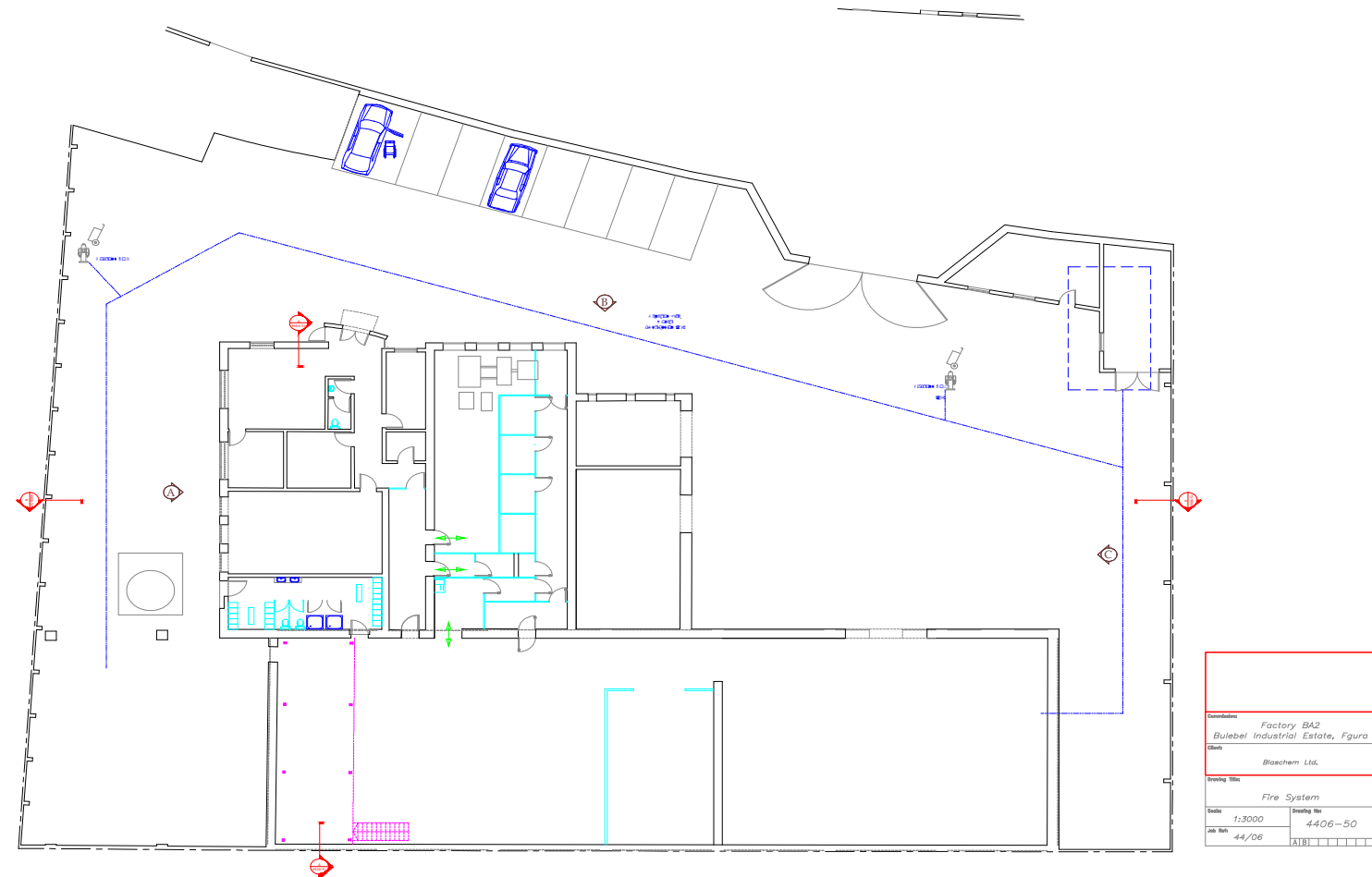
Production Preview:

Owing to the modifications carried out in the plant, the production amounts will not change and the same levels of production held currently will be maintained.

Modified Plant of Blaschem:



Fire Preventive System:





Blaschem

**BLASCHEM (MALTA) LTD.
IPPC APPLICATION DOCUMENT**

Page 43 of 43
Date: 28/09/2007

7.2. TARGET DATES

The modifications to be brought about depend on various factors. The main factor that is holding back the development of these plans is the permit (PA 07583/06) to be issued by MEPA. Considering that this permit will be obtained by July 2007, in August these modifications will start taking place for around three to four months, until which the plant will be ready to be fully functional.

8. ENERGY

8.1. USE OF ELECTRICITY

Energy supply

Electricity is used at Blaschem to supply all the equipment: boiler, pumps, brine production, reactor stirrers, lyophilizer, centrifuges, analytical instruments, computers, general lighting, laboratory equipment and scrubber.

The power installed in the plant is 150 kW. In case of failure of electrical supply a diesel generator of 80 kW enters in function.

Annual consumption

Based on the data of year 2006 the annual consumption we estimate that will be 115331 kWh.

8.2. UTILITIES

The utilities required will consume the following elements:

- Electric power
- Fuel oil
- Municipal water supply
- Atmospheric air

The consumption of energy that we estimate for the next five years are the following:

	2006	2007	2008	2009	2010
Energy (Kw)	115331	175680	184464	193687	203371
Consumption of water estimated (Tm)	910	960	1001	1005	1008
Fuel oil (L)	10000	12400	13560	14380	14900
Nitrogen (m ³)	2250	2750	3200	3449	3567

With these elements the following utilities will be generated:

Steam

Steam will be generated through a steam boiler using fuel oil and distributed through the facility. The condensates will return to a condensate tank, which will return it in the boiler. The boiler will be fed with boiler quality feed water. Boiler purges are sent to plant drain.

Cooling water

The cooling water utility is a closed loop of water re-circulated from a basin. Water is pumped to consumers and returned to cooling towers for heat removal through water evaporation.

Cooling water is consumed mainly in cooling of refrigeration groups, generation of the medium glycol for reactors and condensing in distillation column.

Cooling water is distributed to consumers and returns pressurized to the cooling towers.

Maintenance programs and water treatment will be implemented to avoid *Legionella* disease.

Cooling ethylene glycol

For cooling the reactors, injection of ethylene glycol/water at different temperatures allows continuous operation in order to allow reactors to operate in the lowest range -7°C :

The mixture of glycol and water at -20°C is used for low temperature cooling. In order to compensate pressure, return of all three circuits are connected to a pressurized expansion vessel, thus there are no pressure surges when a change in fluid temperature is performed.

All three circuits have a bypass with a control valve that guarantees constant pressure at the inlet line, thus ensuring reliability of the service and best operation of pumps.

The ethylene-glycol and water mixture circulates in a pressurised closed loop. Glycol is pumped to consumers and returned to a 2m^3 tank. Up to 42000 Kcal/h may be removed this way at a service temperature of -10°C . Refrigeration group is cooled with cooling water.

Nitrogen

Nitrogen gas is used for blanketing of process equipment and pressurizing during processes involving flammable liquids. The nitrogen will be supplied from cylinders of gas containing nitrogen.

In 2007 a vertical tank will be installed of 5 m^3 , situated in a specific area, to store liquid nitrogen ($>99.99\%$ purity). This will allow us to generate nitrogen through evaporation and use it for reactors, centrifuges and filters.

At the moment nitrogen is bought in racks containing 12 cylinders. However, this system is quite inconvenient and the nitrogen storage tank would facilitate the process much more. Apart from installing the tank, there should also be installed a network of tubing in order to connect the nitrogen supply to all the reactors.

Compressed air

Air is used for pneumatic elements (except valves and pneumatic instruments).

Process vacuum

Process vacuum is a required condition during specific processes. Such procedures would require to be carried out under vacuum in order ensure that no oxygen is present, hence reducing the risk of explosion when using dangerous chemicals. Vacuum is also used in order to achieve distillation/reflux in the reactors. Loading vacuum is used for blanketing and vacuum loading.

Specifications are up to 3 mbar when operating for a long time.

Currently all the extracted vapours from the reactors through the use of the vacuum pumps ends up in condensers. Once these are full they are emptied in 1000L tanks together with solvents of the same type and used for cleaning.

8.3. MEASURES FOR IMPROVEMENT OF ENERGY EFFICIENCY

Gadea Pharmaceutical Group holds a reputation for its continuous development. Such a name can be built up only by the involvement in various projects being carried out, whilst others which are kept pending for the future. It is the intent of the company that once it has fully developed its basic structure it can then dedicate its resources to improve its structures, amongst which those for energy efficiency. Various plans have been put forward, some of which are still found as ideas. Therefore not clear-cut commitment can be put to these propositions. However, at the top of the list the following improvements were planned:

- (i) Owing to the large surface area of the plant, as well as the possibility of applying solar energy, the use of solar panels has been considered. Such a project would require the involvement of the Engineering Department from Spain. This plan is still under development on their behalf.
- (ii) Although the collection of rainwater has been suggested in the latest IPPC application presented, a decision was reached that for now such a project would be kept aside. Undergoing such a kind of task would require various added water analysis to be able to incorporate it into our system. Such work would better be taken up once a solid foundation in the analytical section would be setup.
- (iii) All the brine produced from the reverse osmosis is directly discharged into the sewers. This will finally sum up to a concentration of salts similar to that which enters from the municipal water supply, since almost the de-ionised water obtained, ends up together with the brine residue. This leads to an annual consumption of 69,000L.
- (iv) The water source in the plant comes directly from the Reverse Osmosis plant installed directly on site. The RO plant is fed directly by the municipal water supply, which processes the water and produced demineralised water for the plant and the saline residue that is directed to the wastewater sump.

8.4. MEASURES FOR PREVENTION OF *Legionella* DISEASE

The *Legionella* bacterium is known to cause Legionnaire's Disease. *Legionella* transmission occurs via the inhalation of mist droplets containing the bacteria. A common source of this type of disease is cooling towers that tap into the public water supply. Due to the presence of a cooling tower on the premises, adequate prevention is being implemented. Currently, the most suitable measures of prevention are being worked out together with Mr. Charles Bonnici of the Environmental Health Unit. Once the measures are put into practice, a full update will be presented to MEPA.

9. PROPOSED TECHNIQUES FOR IMPROVEMENT

9.1. TECHNIQUES OF EMISSION PREVENTION

Reactor vent condensers

A safety condenser will be installed in reactors, in addition to the main condensers, to reduce the flow of vapours to the scrubber. In case of stainless steel reactors a cooling glycol loop is proposed.

10. UPON DEFINITIVE CESSATION**10. 1. PROPOSED MEASURES UPON DEFINITIVE CESSATION OF ACTIVITIES
TO AVOID ANY POLLUTION RISK**

Blaschem has studied a plan to prevent the pollution from the plant, and all the necessary techniques to be implemented to reduce until minimum the environment impact in case of cessation of the activity. Blaschem could return the equipment and installation into the same conditions as were received, and would develop a complete plan of cessation.



Blaschem

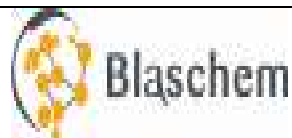
**BLASCHEM (MALTA) LTD.
IPPC APPLICATION DOCUMENT**

Page 50 of 50
Date: 28/09/2007

ATTACHMENT I

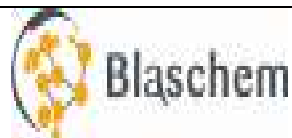
Plant Location

(See Map)



BLASCHEM (MALTA) LTD.
IPPC APPLICATION DOCUMENT

Page 51 of 51
Date: 28/09/2007



BLASCHEM (MALTA) LTD.
IPPC APPLICATION DOCUMENT

Page 52 of 52
Date: 28/09/2007

IPPC Application Document team

Mr. Gerardo Gutiérrez, General Manager
Mr. Jose Maria Martinez, B.Sc., Technical Director of Operations
Mr. Claude Vella Bonanno, B.Pharm., Production Manager