PHARMACEUTICAL FORMULATION UNIT (TABLETS AND CAPSULES)

Project Report

BUSINESS PLAN

PHARMACEUTICAL FORMULATION UNIT

(TABLETS, CAPSULES, INJECTABLE AND SYRUPS)

Contents

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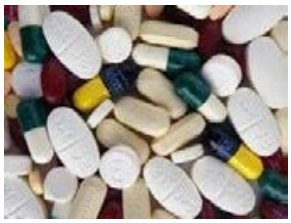
1. INTRODUCTION

M/s Olu Pharmaceuticals (OPC) Pvt. Ltd. a private limited company under the companies Act 2013 was incorporated on 14-12-2023. The registered office of the company is located at R.H. No.11, Mayfair Eleganza – II, NIBM Road, Kondhwa Pune. Maharashtra, India. The Company is promoted by Ms. Stena Shah, Pharmacy Graduate.

M/s Olu Pharmaceuticals (OPC) Pvt. Ltd. will start manufacturing of Tablets, Capsules, Ointment, Liquid Oral, Dry Powder, Herbal and Cosmetic & Foods.

The pharmaceutical industry can be divided into the bulk drug and formulations segments. Bulk drugs are the active pharmaceutical ingredients (APIs) with medicinal properties, which are used to manufacture formulations.

- **Bulk Drugs:** The Indian pharmaceutical industry manufactures about 400 bulk drugs belonging to various therapeutic segments. Formulations still account for a large share of the overall pharmaceutical production.
- **Formulations:** Formulations are the end-products of the medicine manufacturing process, and can take the form of tablets, capsules, Injectable or syrups, and can be administered directly to patients. Tablets are solid forms of the drug which include antibiotics, painkillers and vitamins. Their weight ranges from 25 to 500 mg. Capsules are solid formulations with the powder drug enclosed in a gelatin shell. The shell which disintegrates after swallowing, serves to mask the taste of the active drug.



Tablets

Capsules

2. Product and its application

Tablets may be defined as solid pharmaceutical dosage forms containing drug substances with or without suitable diluents and prepared either by compression or molding methods.

The British Pharmacopoeia States that tablet are solid preparation each containing a single dose of one or more active ingredients is obtained by compressing uniform volume of particles. They have been in widespread use since the latter part of the 19th century and their popularity continues. In the modern days also the tablet are undoubtedly the most popular mode of presentation of solid dosages form intended for oral administration.

Tablets remain popular as a dosage form because of the advantages afforded both to the manufacturer viz simplicity and economy of preparation, stability, and convenience in packaging, shipping, and dispensing and the patient viz. accuracy of dosage, compactness, portability, blandness of taste, and ease of administration.

The tablets vary greatly is shape, size and weight which depends upon the amount of medicaments and the mode of administration. Most commonly, the tablets are disk shaped with convex surface. Although tablets are more frequently discoid in shape, they also may be round, oval, oblong, cylindrical, or triangular.

They may differ greatly in size and weight depending on the amount of drug substance present and the intended method of administration. Tablets are divided into two general classes, whether they are made by compression – compressed tablets or molding- molded tablets or tablet triturates (TT). Compressed tablets are usually prepared by large-scale production methods while molded tablets generally involve small-scale operation

Capsules are solid dosage forms in which the drug substance is enclosed in either a hard or soft, soluble container or shell of a suitable form of gelatin. According to British Pharmacopoeia, the capsules are defined as solid preparation with hard soft shells, of various size, shapes and capacities, containing a single dosage of active ingredient. Thecapsules are intended for oral administration.

The encapsulation of medicinal agents remains a popular method for administering drugs. In prescription practices the use of hard gelatin capsules permits a choice in prescribing a single drug or combination of a drug at the exact dosage level considered best for the individual's patients. This flexibility is an advantage over tablets. Some patient finds it easier to swallow capsules than tablets and prefer this form of dosages. The preference of promoted pharmaceutical companies to market the product incapsules form even though the product has already been produced in tablets forms.

The capsules form of dosage offers the following advantages:-

- Capsules are tasteless, odorless and can be easily administered.
- They are elegant and attractive in appearance.
- The drugs having unpleasant order and taste are enclosed in tasteless shell.
- Can be filled quickly and congenitally, physician can the dosage and combination suiting to individuals patient.
- Capsules are to easy handled and carry.
- The capsules forms are dosage is readability economically

The project envisages the manufacture of drug formulations mainly paracetamol, anta - acid and iron - folic acid in tablet form, vitamin B complex in capsule form and ORS in powder form. Other need based drug formulation could also be manufactured in tablet or Capsule dosage form.

3. Qualification of Promoter

The promoter Ms. Stena Shah is a Pharmacy Graduate (B. Pharm) from Pune University. Further she has strong interest in establishing a unit manufacturing pharmaceutical formulations.

4. Industry Outlook / Trend

The Indian Pharmaceutical industry is highly fragmented with about 24,000 players (around 330 in the organized sector). The top ten companies make up for more than a third of the market. The Indian pharma industry accounts for about 1.4% of the world'spharma industry in value terms and 10% in volume terms.

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, as per a report by Equity Master. India is the largest provider of generic drugs globally with the Indian generics accounting for 20 percent of global exports in terms of volume. Of late, consolidation has become an important characteristic of the Indian pharmaceutical market as the industry is highly fragmented.

5. MARKET POTENTIAL AND MARKETING ISSUES, IF ANY

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Besides the domestic market, Indian pharma companies also have a large chunk of their revenues coming from exports. While some are focusing on the generics market in the US, Europe and semi-regulated markets, others are focusing on custom manufacturing for innovator companies.

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The increased cost competitiveness of Indian producers (for various products), established quality of products, and approval of manufacturing facilities by international regulatory authorities (like the United States Food and Drugs Administration, or USFDA, and the United Kingdom Medicines Control Agency, or UKMCA) have resulted in export orders coming from both developed and developing markets.

India enjoys an important position in the global pharmaceuticals sector. The country also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level. Presently over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immuno Deficiency Syndrome) are supplied by Indian pharmaceutical firms.

The Indian pharma industry, which is expected to grow over 15 per cent per annum between 2015 and 2020, will outperform the global pharma industry, which is set to grow at an annual rate of 5 per cent between the same periods. The market is expected to grow to US$ 155 billion by 2030, thereby emerging as the sixth largest pharmaceutical market globally by absolute size. Branded generics dominate the pharmaceuticals market, constituting nearly 80 per cent of the market share (in terms of revenues).

India is primarily a retail-based branded generic market with 80% dispensed through pharmaceutical outlets. As in most emerging economies, acute therapies dominate and account for close to 70% of the market. Acute Therapies – target short duration diseases – cough & cold, fever, pain – such as anti-infective, analgesics, pain-killers.

Chronic therapies – target lifestyle diseases and/or recurring in nature – such as diabetes, cardiovascular, ophthalmology, and products used to treat central nervous system ailments, are growing faster than acute therapy.

India's biotechnology industry comprising bio-pharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics is expected grow at an average growth rateof around 30 per cent a year and reach US$ 100 billion by 2025. Bio-Pharma, comprising vaccines, therapeutics and diagnostics, is the largest sub-sector contributing nearly 62 per cent of the total revenues at Rs 12,600 crore (US$ 1.88 billion).

6. RAW MATERIAL REQUIREMENTS

The unit would require Paracetamol, Folic Acid, Aluminum Hydroxide, and such other active ingredients.

In addition to basic drug or a combination of drugs commonly known as therapeutic ingredient or active ingredient, the tablet consists of a number of inert ingredients which are called excipients or additives. These additives are added to give the qualities of a good tablet. These additives are formulated in the form of powder or granules before they are made in tablet form. In case of capsules also the active ingredient are invariably formulated with the addition of excipients or additives.

However, their use is move predominant in the production of tablets. These additives are classified in accordance with the function they play in the preparation of tablets orin imparting certain characterizes of the tablets. Some of them are as follows

- **Diluents :** lactose, sodium chloride, starch, powdered sucrose, mannitol, calciumcarbonate,
- **Binders :** starch, acacia, tragacanth, gelatin, glucose, lactose, sucrose, methyl cellulose etc

- **Granulating agents :** maze starch and potato starch
- **Lubricants:** magnesium stearate, calcium stearate, stearic acid and talc.

The project would also require packaging materials and consumables. These include empty hard gelatin capsules, boxes, bottles, caps, etc.

7. MANUFACTURING PROCESS

The Drugs and Pharmaceutical Industry in general is highly regulated in India. Regulatory authorities at the Central level and the State level monitor the same.

At the Central level, the **Central Drugs Standard Control Organisation (CDSCO**), Ministry of Health & Family Welfare, Government of India is the apex organisation. At the state level the **Food and Drugs Control Authority (FDCA**) is the regulatory authority.

Drugs & Cosmetics Act and Schedule M

These authority monitor and control the production of Drugs and Pharmaceutical products under the provisions of **the Drugs and Cosmetics (amendment) Act, 2005 & 2008** and guidelines (July 2015).

The revised **Schedule M** under this Act is the main basis which specifies the detailed norms for location; building premises plant lay out, building, plant & machinery, manufacture, sterilization, packaging, quality control and such other key components.

Good Manufacturing Practices (GMP)

The Drugs and Pharmaceutical Industry in general is highly regulated in India. Regulatory authorities at the Central level and the State level monitor the same.

The revised **Schedule M** under this Act is the main basis which specifies the Further the pharma units in general and such sterile products manufacturing units in particular would also have to comply with following:

- Good Manufacturing Practices (GMP),
- Current Good Manufacturing Practices(cGMP) and
- WHO-GMP

Good manufacturing practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

WHO-GMP certification is essentially for the plant set up, manufacturing facilities and related aspects. However **Certificate of Pharmaceutical Products (CoPP**) is also required for each of the products to exporting the same. This is given only after six months (stability period) of getting WHO-GMP Certificate.

Current GMP (cGMP) is essentially an updation of the systems and facilities as per the requirement of regulated pharma market at the international level

The above are in the form of guidelines and not part of any Act (except basic GMP). However they are essential to follow and implement to fulfill the requirement of theindustry and the international market.

Further highly systematic documentation and record keeping is a must as per the requirement of concerned authorities.

It is to be noted that the Department of Health and Family Welfare proposes to introduce the **Drug and Cosmetics (Amendment) Bill, 2015**. This is in process. As and when this is passed and put into effect by way of an Act, all the Drugs and Pharmaceutical units (existing and new) would have to follow the norms under the amended act.

Technology

Different technologies and processes are used at various stages for the

Manufacture of tablets and capsules are depending on the type of drug formulation.

Similarly, different types of packaging techniques are employed keeping in view thetype of drug formulation and target market.

The key steps of manufacturing for tablets and capsules are given below

Manufacturing process for tablets

Compression molding is the most widely used technology for the manufacture of tablets. The project also envisages the use of compression molding technique. The manufacture of compressed tablets involves the following four process operations.

- **Formulation & Granulation:** The raw material (various ingredients), viz the powder is sieved through a "sifter" so as to have the powder of equal mesh sizes after which, it is finely grind(through a Multi Mill) and mixed homogenously in a Mass- Mixer. This mass is then kept for drying (in a fluid bed dryer) for varying time and temperatures depending upon the quality of the product. The dried powder is ready to be converted in tablet form in the compression department.

- **Compression:** The dried powder from the granulation department is fed through a hopper to a Rotary Tableting machine where it is compressed into tablets, which can be of different sizes depending upon the requirements. The process is carried out under controlled temperature, which is done by Air-conditioning.

- **Coating (if required – optional):** This is an optional process depending on the customer's requirement. At the same time it is also essential in order to maintain highest quality standards. In this process, the compressed tablets are coated (in a Tableting machine) with the help of a compressor. The tablets may

be coated by sugar, material cellulose or any other material. Again the work area shall be Air-conditioned.

- **Packaging** Ready tablets are packed through "Blister Pack Machine". The general pack size is of ten tablets

Manufacturing process for Capsules

The most commonly used dosages in capsules form hard gelatin capsules. In the manufacturer of hard gelatin capsules following process operations are used:

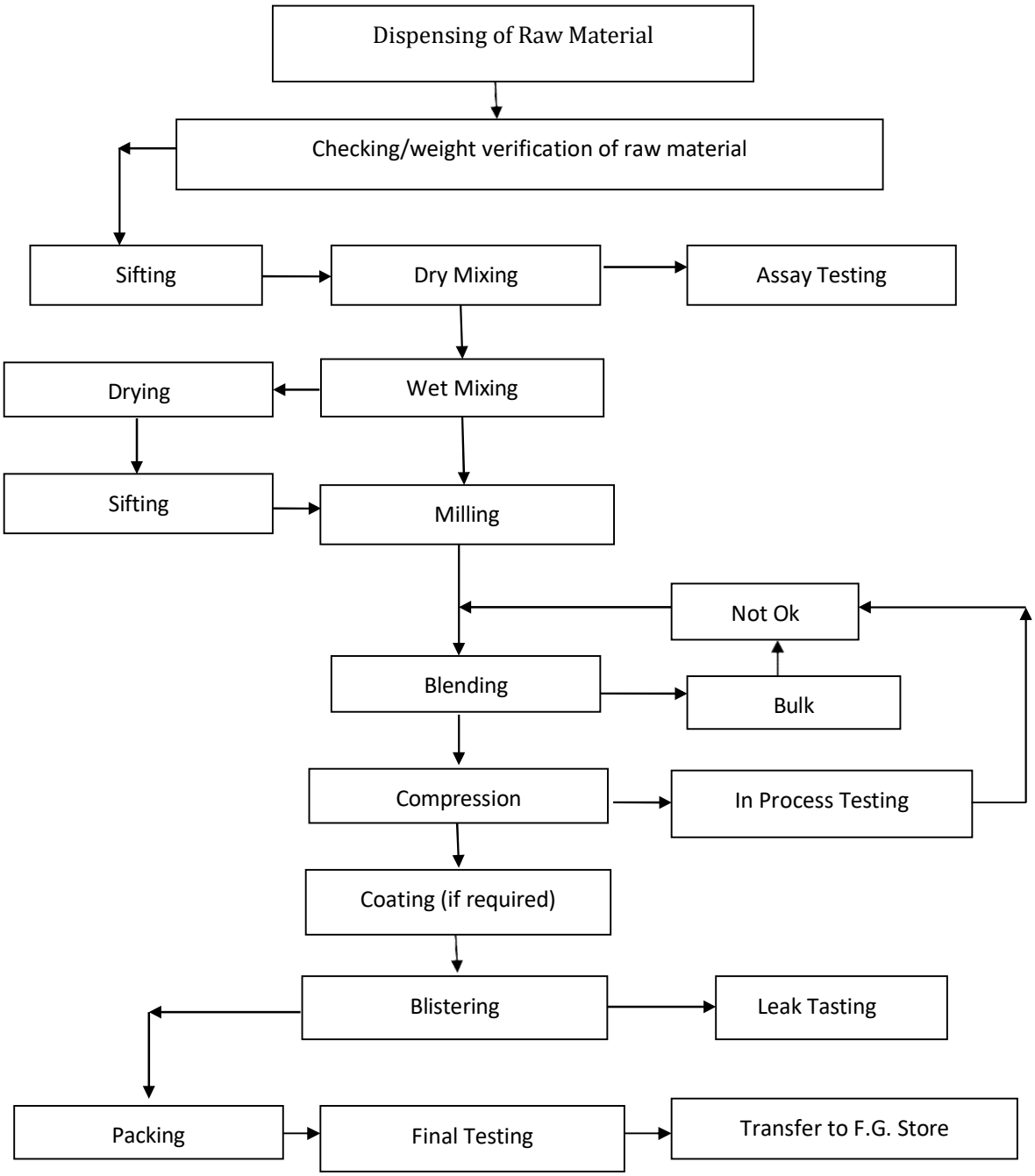
- Mixing / blending and granulation
- Capsules filling
- Capsules packing

- Manufacturing process for Liquid

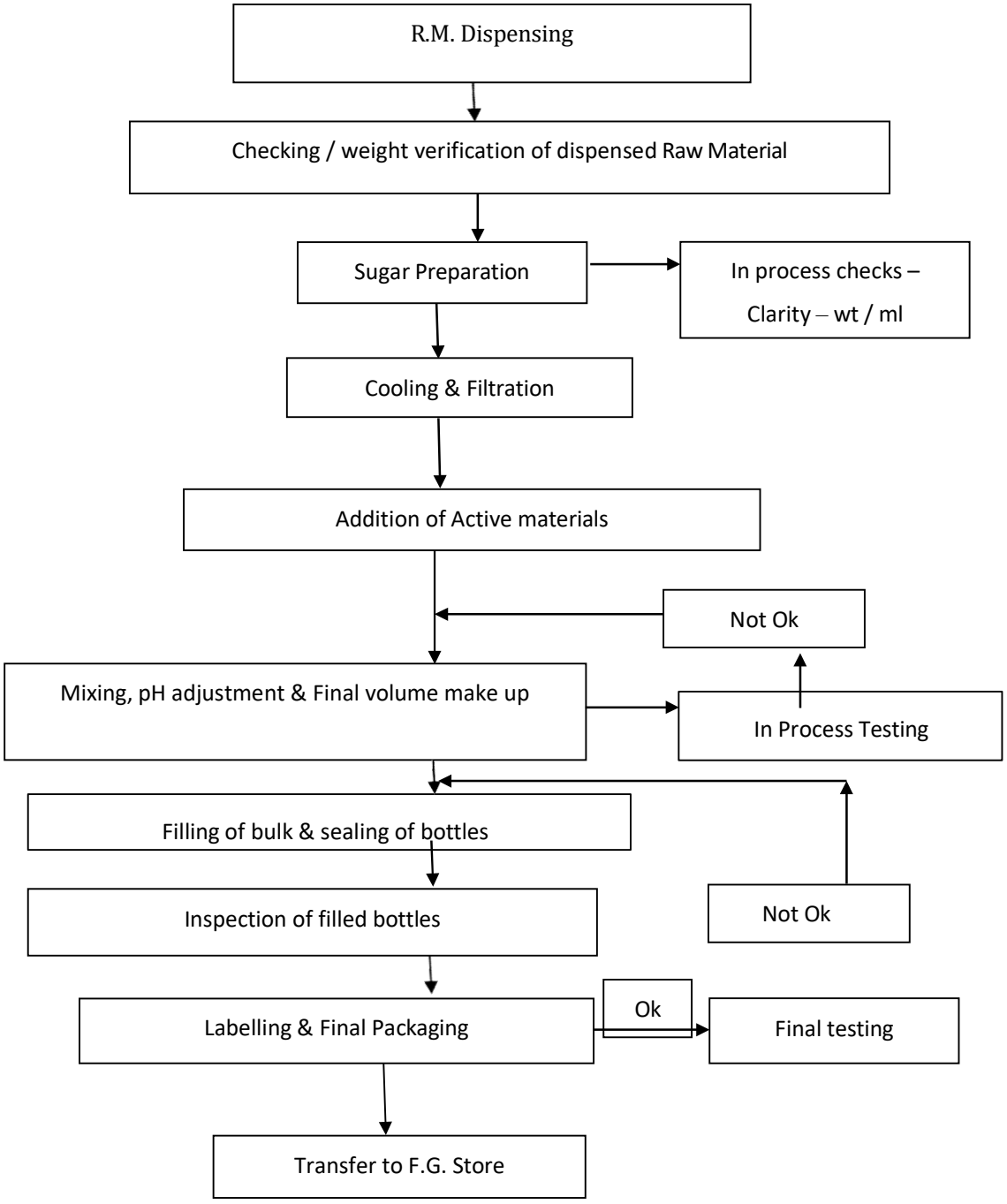
In preparing Liquid, utmost care is taken in purifying the water. The waters purified with the help of de-mineralizer plant. Only then it is used for manufacturing purposes. From the de-mineralizer the water is collected in a stainless steel tank. The necessary ingredients are added into it and mixed with the help of an electric stirrer. If suspensions are to be manufactured, then it is churned with the help of homogenizer. Further, they are also churned by a Colloid Mill, which mixes the fine particles of water insoluble compound into an emulsion. After sometime, the stirred/churned liquid is passed through a volumetric filling machine in to bottles / jar as required. The Bottle is then sealed with the help of a sealing machine. It is then visually checked under light for any foreign particles in the syrup. After labeling the bottle is ready for dispatching. The bottles used in filling the liquids are thoroughly washed with the help of Bottle Washing machine and then dried in Bottle Dryer for sterilization. This is a very important process for the product to be of best quality.

8. Flow Chart of Manufacturing Process

Tablet / Capsule Manufacturing



Liquid Manufacturing



9. LIST OF MACHINERY REQUIRED AND THEIR MANUFACTURERS

Sr. No.	Machine	Number
A	**Production Section**	
1	Starch Paste kettle	1
2	Mechanical sifter, 30" diameter	1
3	Powder and mass mixer	1
4	Multi mill	1
5	Granulator	1
6	Double cone blender	2
7	Tray drier with 48 trays	2
8	Peristaltic pumps	1
9	Rotary tablet machine	2
11	Automatic capsule loader machine	1
12	Capsule Polishing & Inspection Machine	1
13	Coating machine with SS coating pan30 " diameter	1
14	Capsule filling and Sealing Machine	1
15	De dusting unit	1
16	Double track blister machine	1
17	Strip packing machine	1
18	Quality Assurance & Quality Control equipments	-
19	SS Storage Tanks	
	Total	
B	**Utility Section**	
1	Boiler	1
2	D. G. Set, UPS, Rooftop Solar Power System	1
3	Double R.O.	1
4	Air Compressor	1
5	Loop System	1
	Total	

Note: All machineries are of WHO GMP standards

10. POWER REQUIREMENT

Total Power requirement is 500 KVA

1. Main Power requirement will be met from Maharashtra Electricity Board,
2. Additional Power Backup of DG set of 250 KVA
3. Solar Rooftop System of 100 kW with Battery Backup

11. WATER REQUIREMENT AND SUPPLY SYSTEM

Water requirement in industrial process shall be 40 KLD which will be met from bore wells. Water required for domestic consumption shall be around 10 KLD, most of this shall be met from recycling of treated effluent.

Water Requirement (Quantity)

Use Of Water	Quantity of Water Required	Waste Water Generation	Treatment Method	Reuse Of Water
Process	40 KLD	35 KLD	ETP	Gardening & Flushing
Domestic	10 KLD	8 KLD	Septic Tank And Soak Pit.	-------

12. Sewage System

Soak pit and septic tank arrangement shall be provided or the waste generated from toilets and domestic use.

13. Industrial Waste Management & Solid Waste Management

Effluent Treatment Plant is proposed for industrial waste. Capacity of ETP shall be 30 KLD

Solid waste generated from sludge drying beds of ETP shall be disposed to TSDF as per the norms of State Pollution Control Board. Used oil shall be disposed to

authorized recycler. Expired drugs shall be disposed as per HWM rule regulation.

14. STATUTORY/ GOVERNMENT APPROVALS

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MSME & GST registration, IEC Code for Export of end products and local authority

clearance may be required for Shops and Establishment, for Fire and Safety requirement and registration for ESI, PF and Labour laws may be required if applicable.And promoter has to take approval from Pollution Control Board.

15. BACKWARD AND FORWARD INTEGRATION

Entrepreneur may think of going for the production of bulkdrugs / APIs

16. TRAINING CENTERS/COURSES

For pharmaceutical industry training and short term courses may be availed from the Institutions such as NIPER, B V Patel PERD Centre and Pharmacy collages.. Also EDPcenters.

Entrepreneurship development programs help to run businesses successfully and are available from Institutes like Entrepreneurship Development Institute of India (EDII) and its affiliates all over India.

17. Key Management Organization Structure