PHARMACEUTICAL FORMULATION UNIT (TABALATES AND CAPSULES)

1 INTRODUCTION

The project proposes to establish a small scale unit to manufacture Pharmaceutical Formulations (Tablets, Capsules, etc.).

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 (in value terms),

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. Capsules are mostly antibiotics.

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. The capsules 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 in

capsules 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 DESIRED QUALIFICATION FOR PROMOTER

The promoter should be having formal qualifications in the field of pharmacy (B.Pharm. or M. Pharm). Further he / she should have experience of working in a unit manufacturing such pharmaceutical formulations and recognition as Approved pharmacist from Drug Control Authority.

4 INDUSTRY OUTLOOK / TREND

The Indian Pharmaceutical industry is highly fragmented with about 24,000 players (around 330 in the organised 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’s pharma 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 per cent 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

The Indian Pharmaceutical industry is highly fragmented with about 24,000 players (around 330 in the organised 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’s pharma industry in value terms and 10% in volume terms.

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.

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 per cent 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.

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$ 55 billion by 2020, thereby emerging as the sixth largest pharmaceutical market globally by absolute size, as stated by Mr. Arun Singh, Indian Ambassador to the US. Branded generics dominate the pharmaceuticals market, constituting nearly 80 per cent of the market share (in terms of revenues).

India has also maintained its lead over China in pharmaceutical exports with a year-on-year growth of 11.44 per cent to US$ 12.91 billion in FY 2015-16, according to data from the Ministry of Commerce and Industry. Imports of pharmaceutical products rose marginally by 0.80 per cent year-on-year to US$ 1,641.15 million.

Overall drug approvals given by the US Food and Drug Administration (USFDA) to Indian companies have nearly doubled to 201 in FY 2015-16 from 109 in FY 2014-15. The country accounts for around 30 per cent (by volume) and about 10 per cent (value) in the US$ 70-80 billion US generics market.

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 rate of around 30 per cent a year and reach US$ 100 billion by 2025. Biopharma, 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 or in imparting certain characterizes of the tablets. Some of them are as follows

- **Diluents :** lactose, sodium chloride, starch, powdered sucrose, mannitol, calcium carbonate,
- **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.

All of the above are easily available in India.

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 the industry 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 the type 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
- Compression
- Coating (if required – optional)
- Packaging

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

8 MANPOWER REQUIREMENTS

Sr. No.	Designation	Number	Approx. Salary(Rs. Per month)
1	Manufacturing chemist	1	**15000/-**
2	Production supervisor	2	**20000/-**
3	Manager	1	15000/-
4	Office staff & marketing executive	5	**60000/-**
5	Skilled workers	10	**70000/-**
6	Unskilled workers	7	35000/-
	Subtotal		215000/-
	Perks @ 15 %		32000/-
	Total		2,47,000/-

9 IMPLEMENTATION SCHEDULE

About seven months from the time of sanction of term loan.

Sr. No	Activity	Time
1	Preparation of Project report	**One month**

2	E M Registration & approval from FDCA	One month
3	Financial/Loan from Banker or Financial Institutions	Two months
4	Power connection/Building construction Six months	One month
5	Machinery procurement & Trial run.	Two months
6	Recruitment of Staff & Labour	One month
7	Actual commercial production	One month

10 COST OF PROJECT

The total cost of project is estimated as below:

Sr. No	Component	Particulars	Rs. In lakhs
1	Land	1500 sq. mts	7.00
2	Building	800 sq mts	30.00
3	Plant & Machinery including QC		45.00
4	Other Assets		1..50
5	P & P Expenses		1.00
6	Contingencies		4.50
7	WC Margin		5.00
		Total	**93.00**

11 MEANS OF FINANCE

- Term Loan : Rs.65. 00 lacs
- Promoter own contribution : Rs.18.00 lacs

12 WORKING CAPITAL CALCULATION

Particulars	Duration	Total Estimated cost (Rs. Lacs)
Raw materials/ Packing materials	1 month	**6.00**
Working expenses	1 month	**3.00**
Finished goods	15 days	**2.00**
Receivable	30 days	**4.00**
	Total	**15.00**
	WC Margin	**5.00**

13 LIST OF MACHINERY REQUIRED AND THEIR MANUFACTURERS

Sr. no.	Machine	Number	Approx. Cost
1	Mechanical sifter, 30” diameter	1	Rs. 1,00,000/-
2	Powder and mass mixer	1	Rs. 3,00,000/-
3	Multi mill	1	Rs. 90,000/-
4	Granulator	1	Rs. 60,000/-
5	Double cone blender	2	Rs. 5,00,000/-
6	Tray drier with 48 trays	2	Rs. 3,60,000/-
7	Peristatic pumps	1	Rs. 50,000/-
8	Rotary tablet machine	2	Rs. 24,00,000/-
9	Semi automatic Capsule filling & Sealing Machine	1	Rs. 75,000/-
10	Automatic capsule loader machine	1	Rs. 1,30,000/-
11	De dusting unit	1	Rs. 55,000/-
12	Coating machine with SS coating pan 30 “ diameter (Optional)	1	Rs. 2,90,000/-
13	Strip packing machine	2	Rs. 4,00,000/-
14	Quality Assurance & Quality Control equipments	**-**	**Rs. 3.00 lacs**
15	SS Storage Tanks		Rs. 2,50,000/-
	Total		**Rs. 45.00 lacs**

Indicative Sources:

- Cadmach machineries, Ahmedabad
- Pharmatech Enginers, Indore
- Ambica Machineries, Vatva, Ahmedabad
- ARV Engineering, Thane

Note: All machinery to be of WHO GMP standards

14 PROFITABILITY CALCULATIONS

- **Annual production capacity Recommended**

  - Pharmaceutical tablets – 1200 lacs
  - Pharmaceutical capsules – 100 lacs

- Total Sales turnover: 150.00 lacs
- Cost of production & other expenses: 125.00 lacs
- Profit : Rs. 25.00 lacs

Profitability projections – Rs. Lacs (Indicative only)

Particulars	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5

Capacity utilisation (%)	**60**	**75**	**80**	**80**	**80**
Production (Lac numbers)					
Tablets	720.00	900.00	960.00	960.00	960.00
Capsules	60.00	75.00	80.00	80.00	80.00
Sales	90.00	112.50	120.00	120.00	120.00
Expenses	75.00	94.00	100.00	100.00	100.00
Gross profit	15.00	18.50	20.00	20.00	20.00
Profit to Sales (%)	16.60	16.40	16.80	16.80	16.80

Note: The profitability basis and projections are indicative and on approximate basis only.

Key Assumptions and The basis of profitability calculation:

As mentioned above, The Unit will have capacity of 1200 lakh tablets and 100 lakh capsules per annum. The capacity build up is taken considering the sales related from OEM/ Retail network that is built up by the entrepreneur based on his prior experience in the industry.

This project has to have diverse group of **Pharmaceutical formulations.** The sales prices of these products vary. Accordingly an average sales price of Rs. 8/- to Rs. 10/- per unit has been assumed. The cost of production, inclusive of major cost heads such as raw materials, labour & power has been considered based on prevailing industry standards and assumed @ 80 %.

On indicative basis, power Costs are considered at Rs 7/- per Kwh and fuel cost is considered at Rs. 50/- to 60/- per liter. The depreciation of plant is taken at 10-12 % and Interest costs are taken at 12 % - 14% depending on type of industry. All these are wherever applicable.

It may be kindly noted that basis / assumptions for such kind and size of the projects in a profile can be on indicative basis only. At the same time it does provide a reasonably accurate scenario.

15 BREAKEVEN ANALYSIS

FC X 100 : 15.00 X 100 = 1500

FC + Profit: 15.00 + 16.00 = 31

BEP = 48.30%

16 STATUTORY/ GOVERNMENT APPROVALS

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

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.

17 BACKWARD AND FORWARD INTEGRATION

As backward integration, Entrepreneur may think of going for the production of bulk drugs / APIs

18TRAINING 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 EDP centers.

Udyamimitra portal (link : www.udyamimitra.in) can also be accessed for handholding services viz. application filling / project report preparation, EDP, financial Training, Skill Development, mentoring etc.

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.

Disclaimer:

Only few machine manufacturers are mentioned in the profile, although many machine manufacturers are available in the market. The addresses given for machinery manufacturers have been taken from reliable sources, to the best of knowledge and contacts. However, no responsibility is admitted, in case any inadvertent error or

incorrectness is noticed therein. Further the same have been given by way of information only and do not carry any recommendation.

Source:- Udyami Mitra/Sidbi