# **PROJECT REPORT**

Of

# **MEDICINAL TABLETS**

# **PURPOSE OF THE DOCUMENT**

This particular pre-feasibility is regarding Medicinal tablets Manufacturing unit.

The objective of the pre-feasibility report is primarily to facilitate potential entrepreneurs in project identification for investment and in order to serve his objective; the document covers various aspects of the project concept development, start-up, marketing, finance and management.

[We can modify the project capacity and project cost as per your requirement. We can also prepare project report on any subject as per your requirement.]



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	PROJECT AT GLANCE								
1	Name of Proprietor/Director		XXXXXXXX						
2	Firm Name		XXXXXXXX						
3	Registered Address		XXXXXXXX						
4	Nature of Activity		XXXXXXXX						
5	<b>Category of Applicant</b>		XXXXXXXX						
6	Location of Unit		XXXXXXXX						
7	Cost of Project		22.47	Rs. In Lakhs					
8	Means of Finance								
i)	Own Contribution		2.25	Rs. In Lakhs					
ii)	Term Loan		15.12	Rs. In Lakhs					
iii)	Working Capital		5.10	Rs. In Lakhs					
9	<b>Debt Service Coverage Ratio</b>		3.00						
10	Break Even Point		41%						
11	Power Requiremnet		30	KW					
12	Employment		14	Persons					
			Pharmaceutica	ls excipients.					
13	Major Raw Materials		pvc.aluminium	foils and					
			cartons.						
14	Details of Cost of Project & Means of F	inance							
	Cost of Project	Amount in Lacs							
	Particulars	Amount							
	Land and building	Owned/Leased							
	Plant & Machinery	15.05							
	Furniture & Fixture	0.75							
	Other Misc Assets	1.00							
	Working Capital Requirement	5.67							
	Total	22.47							
	Means of Finance								
	Particulars	Amount							
	Own Contribution	2.25							
	Term Loan	15.12							
	Working capital Loan	5.10							
	Total	22.47	1						

# MEDICINAL TABLETS MANUFACTURING UNIT

# 1. INTRODUCTION



Oral drug delivery is the most convenient, high patient compliance, cost-effective, and safe route of administration to treat various diseases. They come solid tablets, as capsules, chewable tablets, lozenges to be swallowed whole or sucked on, or as drinkable liquids such as drops, syrups, or solutions. In most cases, the ingredients in oral medication don't enter the bloodstream until they reach the stomach or bowel. A tablet is a pharmaceutical oral dosage form (oral solid dosage, or OSD) or solid unit dosage form. Tablets may be defined as the solid unit dosage form of medicament or medicaments with suitable excipients. It comprises a mixture of active substances and excipients, usually in powder form, pressed or compacted from a powder into a solid dose. Tablets are prepared either by moulding or by compression. The excipients can include diluents, binders or aids) efficient granulating agents, glidants (flow and lubricants to ensure tableting; disintegrants to promote tablet break-up in the digestive tract; sweeteners or flavours

to enhance taste, and pigments to make the tablets visually attractive or aid in visual identification of an unknown tablet. A polymer coating is often applied to make the tablet smoother and easier to swallow, to control the release rate of the active ingredient, to make it more resistant to the environment (extending its shelf life), or to enhance the tablet's appearance. Medicinal tablets were originally made in the shape of a disk of whatever colour their components determined, but are now made in many shapes and colours to help distinguish different medicines. Tablets are often stamped with symbols, letters, and numbers, which enable them to be identified. Sizes of tablets to be swallowed range from a few millimeters to about a centimeter. The compressed tablet is the most popular dosage form in use today. About two-thirds of all prescriptions are dispensed as solid dosage forms, and half of these are compressed tablets. A tablet can be formulated to deliver an accurate dosage to a specific site; it is usually taken orally, but can be administered sublingually, buccally, rectally, or intravaginally. The tablet is just one of the many forms that an oral drug can take suchas syrups, elixirs, suspensions, and emulsions.

# 2 PRODUCT DISCRIPTION

### 2.1 PRODUCT USES

Tablets are chemicals or compounds used to cure, halt, or prevent disease; easesymptoms; or help in the diagnosis of illnesses.

### 2.2 MANUFACTURING PROCESS

The manufacturing process is as follows-

Raw material procurement Making Process Testing

#### **Raw Material Procurement**

The raw materials are checked strictly as per established quality standards and requirements. Individual supplier assessment and supplier rating are done depending upon the rejection levels at the incoming quality control stage. Sorting of raw material will be done as per material type or specifications. The material will be stored in; a dust-free, moisture-free, neat, and clean environment. Quality control of tablet raw materials(APIs and excipients) is one of the main tasks of the quality control unit in any drug manufacturing industry. Raw materials must undergo the necessary tests.

It is often sufficient if identification testing is conducted on the individual packages/containers and content and purity determination in mixed samples. Every manufacturer has the opportunity to carry out further testing if they deem it necessary for guaranteeing a smooth-running production process or a very high-quality product.

Starting materials are released only after their quality is established or judged as satisfactory. Raw materials that fail the quality control test are rejected and returned to the supplier. Any risks that may emanate from starting materials of inappropriate quality must be avoided to preventproduct failure and to ensure a consistent level of quality, as well as safety in consumer and industrial products.

### **Tablets Making Process**

- 1. Dispensing: After receiving raw material it will be procured in the RM store. At dispensing, booth raw material sampling is done. Each ingredient in the tablet formula is weighed and accurately dispensed as per dose. This is one of the critical steps in any type of formulation process and should be done under technical supervision. After sampling it will be sent to under testing. After testing raw materialis stored in an approved area. After dispensing the material is then kept in a pass bag for further processing. After dispensing material is collected through a pass box. Here material will be cross-checked. According to MFR, it is then processed step by step. Shifting, Mixing, Granulation, Drying, Lubrication, etc is then performed step by step. Formulation ingredients must be in finely divided form, otherwise, size reduction should be carried out for better flow property and easy mixing.
- 2. **Powder blending:** Powders are mixed using a suitable blender to obtain a uniform and homogeneous powder mix. The drug substance and excipients are mixed in geometric dilution.
- 3. **Granulation:** Here small powder particles are gathered together into layers, and permanent aggregates to render them into free-flowing states.
- 4. Drying and dry screening: Screened wet granules need to be dried for a particular period in a tray dry or fluid bed dryer at a controlled temperature not exceeding 55°C. Dried granules are screened through the appropriate mesh screen. Here lubrication is done. Lubricated tablet powder is stored separately and sent for sampling.
- 5. **Tablet compression:** Quality passed lubricated granules are used for compression. Before tablet compression line check will be done. The machine is properly cleanedor not is checked. For compression lubricated granules are fed into the hopper, according to MFR parameters tablets are compressed. This step involves the compression of granules into flat or convex, round, oblong, or unique shaped, scored,

or unscored tablets; engraved with an identifying symbol and/ or code number using atablet press. Along with this process, yield is recorded on BMR.

- 6. **Coating:** Tablets and granules are coated if there is a need to mask the unpleasant taste/odor of some drug substance or to increase the aesthetic appeal of uncoated tablets as well as to modify the release or control the release of drug substances from tablets. This is achieved by enclosing or covering the core tablet or granules with coating solutions. Color solution is made first before coating tablets. After coating, the sample is sent to QC for testing.
- 7. **Packing:** First primary packing is done. Blister or Alu alu machine is used for tabletstriping and packing. Hydrogen flushing is done while tablet striping. PVC and aluminum foil is used for tablet packing. After

QC, the tablet is then sent for secondary packing; carton packing. After mass packing, again final QC is done and the tablet is ready to dispatch.



Primary, Secondary, Final packing, Final QC

### Testing

• Quality Control

# 3 PROJECT COMPONENTS

#### 3.1 Land /Civil Work

The land required for this manufacturing unit will be approx. around 2,500-3,000 square feet. Land Purchase and Building Civil Work Cost have not been considered as part of the cost of project. It is expected that the premises will be on rental and approximate rentals assumed of the same will be Rs. 40,000 per month.

Workshop Area- This area includes the setup and foundation space for all equipment's, work floor area, etc. Total workshop area is approx. 1,500 Sqft.

Inventory Area- This area includes the storage space for all the raw materials and finished goods. Total inventory area is approx. 700 Sqft.

Office Area - This space includes staff working region, their accommodation space. Total workshop area is

approx. 200 Sqft. This may be considered above the ground floor.Parking Space, Electric Mounting Space, and Others. This could be approx. 100 Sqft.

Land and building requirement may vary depending on the size of project

# 3.2 Plant & Machinery

**Size reduction equipment:** Size reduction equipment such as hammer mill, vibrationmill, roller mill, pin mill, fluidized energy mill, end-runner mill, edge runner mill, cutter mill, and the ball mill is used for size reduction of raw material if required.



## **Mixing equipment**

Mixing equipment such as pneumatic mixers (air-mix mixer or air-driven mixer), diffusion/ tumbling mixers (e.g., V-blender, double cone blender, cubic mixer, drum blender), convective mixers (e.g., ribbon blenders, orbiting screw mixers, horizontal high-intensity blenders, planetary blenders, diffusion mixer with intensifier bar/agitator, Forberg blenders, horizontal double arm mixers, vertical high-intensity mixer) is used for mixing raw materials.



### Granulators

Various granulators such as rotating shape granulators, mechanical agitator granulators (e.g., ribbon or paddle blender, sigma blade mixer, planetary mixer, orbiting screw mixers), high-shear granulator, fluidized bed granulator, dry granulator, etc. are used for the granulation process.



## **Dying equipment**

Dryers such as spray dryers, rotary dryers, fluidized bed dryers, etc. are used for drying granules or raw material.



# **Tableting machine**

Single punch tablet press and multi-station/ rotary tablet press (e.g., High-speed rotary tablet machines and multi-layer rotary tablet machines) are used for tablet compression.



# Coating and polishing machines for coated tablets

Standard coating pan, perforated pan, fluidized bed/ Air suspension coating system, etc. This machine is used for the tablet coating process.



### **Packaging machines**

Blister packaging machines, strip packing machines, Alu-Alu/aluminum foilpackaging machines, etc. are used for tablet packing.



## Other:

Coating equipment, weighing balance, quality control equipment, etc. Weighing balance/ balances: bulk weighing balance (weighs in kilogram), electronic weighing balance (weighs in grams and milligrams). Quality control equipment: disintegration equipment, USP Dissolution Tester, Tablet Hardness Tester, Tablet Thickness Tester, Tablet Friability Testers, etc.

S No.	Name of the machineries	Unit Price	Qty	Cost (INR)			
1.	Vibro Shifter	75,000	1	75,000			
2.	Rapid Mixture Granualtor	3,38,000	1	3,38,000			
3.	Tablet Compression Machine	3,50,000	1	3,50,000			
4.	CGMP Model Fluid Bed Dryer	2,50,000	1	2,50,000			
5.	Cone Blender	1,35,000	1	1,35,000			
6.	Coating Pan	1,27,000	1	1,27,000			
7.	Packaging Machine	2,29,500	1	2,29,500			
	TOTAL						

Note: The aforesaid cost of Plant and Machinery is inclusive of GST and other transportation cost.

# 4 LICENSE AND APPROVALS

MSME Udyam online registration. GST Registration BIS Certification Drug licenses (FDA) BIS certification NOC from the Fire and Pollution control board

PROJECTED BALANCE SHEET					(in Lacs)
PARTICULARS	1st vear	2nd year	3rd year	4th vear	5th vear
<u>Liabilities</u>			V		v
Capital					
Opening Balance		4.73	6.31	8.32	10.73
Add:- Own Capital	2.25				
Add:- Retained Profit	5.48	7.58	9.01	10.41	11.85
Less:- Drawings	3.00	6.00	7.00	8.00	9.00
Closing Balance	4 73	6 31	8 32	10.73	13 58
Term Loan	13.44	10.08	6.72	3.36	-
Working Capital Limit	5.10	5.10	5.10	5.10	5.10
Sundry Creditors	4.77	3.76	4.51	4.35	5.55
Provisions & Other Liabilities	1.00	1.50	1.80	2.16	2.59
TOTAL :	29.03	26.75	26.45	25.69	26.81
Assets					
Fixed Assets (Gross)	16.80	16.80	16.80	16.80	16.80
Gross Depriciation	2.48	4.59	6.39	7.93	9.23
Net Fixed Assets	14.31	12.20	10.40	8.87	7.56
Current Assets					
Sundry Debtors	4.08	4.91	5.60	6.35	7.16
Stock in Hand	6.36	7.64	8.71	9.86	11.11
Cash and Bank	0.28	0.25	0.24	0.21	0.48
Loans and advances/other current assets	4.00	1.75	1.50	0.40	0.50
TOTAL :	29.03	26.75	26.45	25.69	26.81

PROJECTED CASH FLOW STATEMEN	<u>IT</u>				(in Lacs)
PARTICULARS	1st year	2nd year	3rd year	4th year	5th year
SOURCES OF FUND					
Own Margin	2.25				
Net Profit	5.76	8.16	10.19	12.19	14.25
Depriciation & Exp. W/off	2.48	2.11	1.80	1.53	1.31
Increase in Cash Credit	5.10	-	-	-	-
Increase In Term Loan	15.12	-	-	-	-
Increase in Creditors	4.77	- 1.01	0.75	- 0.16	1.20
Increase in Provisions & Other liabilities	1.00	0.50	0.30	0.36	0.43
TOTAL :	36.47	9.76	13.04	13.91	17.19
APPLICATION OF FUND					
Increase in Fixed Assets	16.80				
Increase in Stock	6.36	1.28	1.07	1.16	1.25
Increase in Debtors	4.08	0.83	0.69	0.75	0.81
Increase in loans and advances	4.00	- 2.25	- 0.25	- 1.10	0.10
Repayment of Term Loan	1.68	3.36	3.36	3.36	3.36
Drawings	3.00	6.00	7.00	8.00	9.00
Taxation	0.28	0.57	1.18	1.78	2.40
TOTAL:	36.19	9.79	13.05	13.95	16.92
Opening Cash & Bank Balance	-	0.28	0.25	0.24	0.21
Add : Surplus	0.28	-0.03	-0.01	-0.03	0.27
Closing Cash & Bank Balance	0.28	0.25	0.24	0.21	0.48

# PROJECTED PROFITABILITY STATEMENT

PARTICULARS	1st year	2nd year	3rd year	4th year	5th year
Capacity Utilisation %	53%	58%	63%	68%	73%
SALES					
MEDICINAL TABLETS	122.35	147.35	168.11	190.58	214.88
Total	122.35	147.35	168.11	190.58	214.88
COST OF SALES					
Raw material cost	71.55	80.65	90.23	100.31	110.92
Electricity Expenses	3.82	4.18	4.54	4.90	5.26
Depreciation	2.48	2.11	1.80	1.53	1.31
Wages & labour	15.84	18.69	22.06	26.03	30.71
Repair & maintenance	1.22	1.84	2.52	3.34	3.76
Consumables	3.67	4.42	5.04	5.72	6.45
Packaging cost	2.45	3.32	4.20	5.24	6.45
Cost of Production	101.03	115.21	130.39	147.06	164.84
Add: Opening Stock	-	6.12	7.37	8.41	9.53
Less: Closing Stock	6.12	7.37	8.41	9.53	10.74
Cost of Sales	94.91	113.96	129.35	145.94	163.63
GROSS PROFIT	27.44	33.39	38.76	44.65	51.25
Salary to Staff	11.16	13.17	15.54	18.34	21.64
Interest on Term Loan	1.49	1.31	0.94	0.57	0.20
Interest on working Capital	0.56	0.56	0.56	0.56	0.56
Rent	4.50	5.04	5.64	6.32	7.08
Selling & Administration Expenses	3.98	5.16	5.88	6.67	7.52
TOTAL	21.68	25.24	28.57	32.46	37.00
NET PROFIT	5.76	8.16	10.19	12.19	14.25
Taxation	0.28	0.57	1.18	1.78	2.40
PROFIT (After Tax)	5.48	7.58	9.01	10.41	11.85

# CALCULATION OF D.S.C.R

PARTICULARS	1st year	2nd year	3rd year	4th year	5th year
CASHACCRUALS	7.96	9.70	10.81	11.94	13.16
Interest on Term Loan	1.49	1.31	0.94	0.57	0.20
Total	9.45	11.01	11.75	12.51	13.36
<b>REPAYMENT</b>					
Instalment of Term Loan	1.68	3.36	3.36	3.36	3.36
Interest on Term Loan	1.49	1.31	0.94	0.57	0.20
Total	3.17	4.67	4.30	3.93	3.56
DEBT SERVICE COVERAGE RATIO	2.98	2.36	2.73	3.18	3.75
AVERAGE D.S.C.R.					3.00

REPAYMENT SCHEDULE OF TERM LOAN								
						Interest	11.00%	
							Closing	
Year	· Particulars	Amount	Addition	Total	Interest	Repayment	Balance	
1st	Opening Balance	-						
	1st month		15.12	15.12	-		15.12	
	2nd month	15.12	-	15.12	0.14	-	15.12	
	3rd month	15.12	-	15.12	0.14	-	15.12	
	4th month	15.12	-	15.12	0.14	-	15.12	
	5th month	15.12	-	15.12	0.14	-	15.12	
	6th month	15.12	-	15.12	0.14	-	15.12	
	7th month	15.12	-	15.12	0.14	0.28	14.84	
	8th month	14.84	-	14.84	0.14	0.28	14.56	
	9th month	14.56	-	14.56	0.13	0.28	14.28	
	10th month	14.28	-	14.28	0.13	0.28	14.00	
	11th month	14.00	-	14.00	0.13	0.28	13.72	
	12th month	13.72	-	13.72	0.13	0.28	13.44	
					1.49	1.68		
2nd	Opening Balance							
	1st month	13.44	-	13.44	0.12	0.28	13.16	
	2nd month	13.16	-	13.16	0.12	0.28	12.88	
	3rd month	12.88	-	12.88	0.12	0.28	12.60	
	4th month	12.60	-	12.60	0.12	0.28	12.32	
	5th month	12.32	-	12.32	0.11	0.28	12.04	
	6th month	12.04	-	12.04	0.11	0.28	11.76	
	7th month	11.76	-	11.76	0.11	0.28	11.48	
	8th month	11.48	-	11.48	0.11	0.28	11.20	
	9th month	11.20	-	11.20	0.10	0.28	10.92	
	10th month	10.92	-	10.92	0.10	0.28	10.64	
	11th month	10.64	-	10.64	0.10	0.28	10.36	
	12th month	10.36	-	10.36	0.09	0.28	10.08	
				1	1.31	3.36		
3rd	Opening Balance							
	1st month	10.08	-	10.08	0.09	0.28	9.80	
	2nd month	9.80	-	9.80	0.09	0.28	9.52	
	3rd month	9.52	-	9.52	0.09	0.28	9.24	
	4th month	9.24	-	9.24	0.08	0.28	8.96	
	5th month	8.96	-	8.96	0.08	0.28	8.68	
	6th month	8.68	-	8.68	0.08	0.28	8.40	
	7th month	8.40	-	8.40	0.08	0.28	8.12	
	8th month	8.12	-	8.12	0.07	0.28	7.84	
	9th month	7.84	-	7.84	0.07	0.28	7.56	
	10th month	7.56	-	7.56	0.07	0.28	7.28	
	11th month	7.28	-	7.28	0.07	0.28	7.00	

	124 4	7.00		7.00	0.06	0.20	( 70
	12th month	7.00	-	7.00	0.06	0.28	6.72
/th	Opening Balance				0.94	3.30	
4111	1 st month	672		6 72	0.06	0.28	6 11
	and month	6.14	-	6.14	0.00	0.28	6.16
	2nd month	0.44	-	0.44	0.00	0.20	0.10 5 00
		0.10	-	0.10 5.00	0.00	0.28	5.00
	4th month	5.88	-	5.88	0.05	0.28	5.00
	5th month	5.60	-	5.60	0.05	0.28	5.32
	6th month	5.32	-	5.32	0.05	0.28	5.04
	7th month	5.04	-	5.04	0.05	0.28	4.76
	8th month	4.76	-	4.76	0.04	0.28	4.48
	9th month	4.48	-	4.48	0.04	0.28	4.20
	10th month	4.20	-	4.20	0.04	0.28	3.92
	11th month	3.92	-	3.92	0.04	0.28	3.64
	12th month	3.64	-	3.64	0.03	0.28	3.36
					0.57	3.36	
5th	Opening Balance						
	1st month	3.36	-	3.36	0.03	0.28	3.08
	2nd month	3.08	-	3.08	0.03	0.28	2.80
	3rd month	2.80	-	2.80	0.03	0.28	2.52
	4th month	2.52	-	2.52	0.02	0.28	2.24
	5th month	2.24	-	2.24	0.02	0.28	1.96
	6th month	1.96	-	1.96	0.02	0.28	1.68
	7th month	1.68	-	1.68	0.02	0.28	1.40
	8th month	1.40	-	1.40	0.01	0.28	1.12
	9th month	1.12	-	1.12	0.01	0.28	0.84
	10th month	0.84	-	0.84	0.01	0.28	0.56
	11th month	0.56	-	0.56	0.01	0.28	0.28
	12th month	0.28	-	0.28	0.00	0.28	_
					0.20	3.36	
	DOOR TO DOOR	60	MONTHS				
МО	RATORIUM PERIOD	6	MONTHS				
RE	PAYMENT PERIOD	54	MONTHS				



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