

MULTI PRODUCT BULK DRUG (API) PROJECT

At present the global Pharma market is estimated at US\$ 500 billion. The market is expected to continue to grow at the rate of 5 to 6% per year. During the last decade India has built up strong position as a bulk drug (Active Pharmaceutical Ingredients – API) supplier to the international market and expects to further consolidate the position. For this reasons many new entrepreneurs are considering entering this industry.

New aspirants will have to consider following aspects at the time of making the investment decision

WTO regime that came into effect from 2005 provides for product Patent protection.

Environmental protection rules are stringent now

CGMP (current good manufacturing practices) requirements are to be met.

In effect there are entry barriers for small units. However a well planned medium size unit is still an attractive investment proposition

Proposal:

A grass root project in a declared chemical zone, having environmental clearances is a profitable proposition. The plant should be constructed to meet environmental and GMP requirements

Product mix

A number of APIs have come off patent are about to come off patent during 2007. (List at Annexure). The new project can be planned with one or two of these products along with one two older products.

Suggested product mix

Drug	Brand name	Used for treatment of	Suggested manufacturing capacity
Lansprazole / Rabeprazole	Prevacid / aciphex	Acidity / heart burn	30 TPA
Ceterizine / Fexofenadine	Zyrtec / Allegra	allergies	30 TPA
Zolopidem	Ambien	Insomnia	15 TPA
Fluticasone	Advair	Asthma	15 TPA
Torosemide / Hydrochlorothiazide		Diuretic	30 TPA
Sparfloxacin		Infections	60 TPA
Diclofenac / Aceclofenac		Arthritis	300 TPA

Market

Top selling therapeutic groups in developed countries and in India are shown below. It would be advisable to select two products aimed at export market (developed countries) and two products for Indian market.

Developed countries

Cardiovascular
Anti-ulcerants
Anti-depressants
Anti-infective

India

Anti-infective
Anti-rheumatic
vitamins
Anti-ulcerants

It should be understood that the market will remain highly competitive. Marketing tie-ups and contract manufacturing up to 50 % capacity can reduce the risk.

Manufacturing process

The manufacturing process of bulk drugs consists of chemical synthesis extending to seven eight stages of processing involving different type of chemical reactions.

Technology

Technology for manufacturing of the product listed under product mix are available from private consultants. Some times the technology is available on lab scale. In such cases the process has to be scaled up. Choosing one or two proven technologies and one or two technologies under development will be cost effective.

Plant and Machinery

Plant and Machinery for bulk drug project consists of Glass lined, stainless steel reactors, heat exchangers, centrifuges, filters, dryers and tanks. The utility systems consist of boiler, chilling plants, and water purification systems. All the equipment is indigenously available.

Raw materials

Raw materials consist of various chemicals and solvents. Some of the raw materials have to be imported.

Utilities

Utilities required are, steam, Power and water.

Project cost:

Over all capacity of 300 Tons per annum is recommended (one lac liter reactor volume) spread among four products. The project cost would be Rs. 15 to 20 crores.

Turnover and profitability:

Turnover of Rs. 50 to 60 crores per annum can be obtained by judiciously choosing medium and high value products.

Suggested location:

Pharma city near Vizag

Entrepreneur profile:

Bulk drug manufacturing line is more suited to Technocrats, who can plan for development of new technologies. Alternately the entrepreneur should be able to develop a very good technical team.

Apitco's consultancy:

1. Product mix selection based on market survey and technology availability.
2. Technology tie-up
3. Project planning.

List of top selling drugs going off patent is given below.

	DRUG	Treats	Company	Sales (billion)
1	LIPITOR	High cholesterol	Pfizer	\$8.4
2	ZOCOR	High cholesterol	Merck	\$4.4
3	NEXIUM	Heartburn	AstraZeneca	\$4.4
4	PREVACID	Heartburn	Abbott & Takeda	\$3.8
5	ADVAIR DISKUS	Asthma	GlaxoSmithKline	\$3.6
6	PLAVIX	Heart disease	Bristol-Myers Squibb & Sanofi-Aventis	\$3.5
7	ZOLOFT	Depression	Pfizer	\$3.1
8	EPOGEN	Anemia	Amgen	\$3.0
9	PROCRIT	Anemia	Johnson & Johnson	\$3.0
10	ARANESP	Anemia	Amgen	\$2.8
11	ENBREL	Rheumatoid arthritis	Amgen & Wyeth	\$2.7
12	NORVASC	High blood pressure	Pfizer	\$2.6
13	SEROQUEL	Schizophrenia	AstraZeneca	\$2.6
14	EFFEXOR XR	Depression	Wyeth	\$2.6
15	ZYPREXA	Schizophrenia	Eli Lilly	\$2.5
16	SINGULAIR	Asthma & Allergies	Merck	\$2.5
17	PROTONIX	Heartburn	Wyeth	\$2.4
18	RISPERDAL	Schizophrenia	Johnson & Johnson	\$2.3
19	NEULASTA	Chemotherapy side effects	Amgen	\$2.2
20	REMICADE	Rheumatoid arthritis	Johnson & Johnson	

