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I. CLUSTER AT A GLANCE

- The pharmaceutical formulation cluster consists of units manufacturing tablets, capsules, liquid orals, injectibles, and ointments/drops. Though the cluster is small, and not a natural, but very prospering one.
- The Cluster constitutes very small firms with annual turnover of Rs. 10 lakhs to large units with annual turn over of more than hundred crore. There are 43 units (50 including sub-units of Cipla). However large firms dominate the cluster including MNCs. Small firms with annual turn over of less than 5 Crore are about 26% of the total units.
- Turnover of the cluster is about Rs. 1,600 crore, with employment of more than 5,500 persons.
- The growth of the cluster is exponential since late 1990's, more than 50% of the units coming up after 1995. The growth of the cluster is mainly attributed to the fiscal incentives like Income tax holiday for a period of 5 years; Sales tax exemption for 15 years for small firms and 12 years for large firms; Capital Investment Subsidy to the extent of 25% of the fixed assets with a ceiling of Rs. 25 lakhs; developed infrastructure etc. All the firms, which have come up in recent years, are large firms and MNCs.
- The large firms have units in other parts of the country and have corporate offices, centralised marketing, procurement, personnel divisions outside the state mainly Mumbai.
- The units operate on own licence, loan licence and own & loan licence basis. There are group of companies who operate on P2P (Proprietor to proprietor) basis.
- The machinery suppliers and raw material suppliers are located outside the State. Raw materials like basic drug, excipients, empty capsules, preservatives, coating material, glass ampules, bottles, vials etc are procured entirely from outside the State. Packaging units making cartons, corrugated boxes, aluminum foils, printing are existing in the State.
- The Directorate of Food and Drug Administration is the main regulatory body for the pharmaceutical units, located at Panaji-Goa. There is a Govt. College of Pharmacy, which acts as the main source of skilled manpower for the pharma industry.
- There is Goa Pharmaceutical manufacturers' Association (GPMA). The Association is not having secretariat and secretariat staff.
- The quality standards are on par with international quality standards for majority of the firms. About 75% of the units are WHO-GMP compliant. Some units have US-FDA and UK-MCA certifications too. Small and tiny firms numbering about 8-10 are facing the problem of adhering to the revised Schedule-M of the Drugs and Cosmetics Act, 1940.

- There is no public testing laboratory within the State. Large firms have in-house testing facilities and frequency of sending the samples for testing outside the State is less. Small firms also have in-house testing facilities but send the samples for out-side testing to places like Mumbai, Bangalore, in case of testing requiring installation of costly equipments.

II. INTRODUCTION

SSI sector occupies a very dominant place in the Indian Economy. To overcome the two major problems of unemployment and poverty, development of SSI sector has been considered to be essential as it could fulfill the twin objectives of providing large-scale employment in a capital scarce economy. The SSI sector has emerged as a dynamic and vibrant sector. The sector accounts for 40% of the industrial production, 35% of the total exports and employs about 170 lakh people. The sector manufactures a wide range of more than 7,500 products. As per the quick Estimates of Third All India Census of Small Scale Industries, there are over 23 lakhs registered ssi units employing about 34.5 lakh persons. Total investment in the SSI sector is to the tune of Rs.53,35,580.77 lakhs, with the total gross output of 1,14,20,438 lakhs.

The Cluster Development Approach has been quite successful in the national and international arena for the development of small-scale industries. The focussed development of clusters has been strongly recommended by the Abid Hussain Committee as well as by the Dr. SP Gupta Committee for SSIs.

What is a cluster:

In common parlance, cluster of units refers to concentration of firms in a geographical locality, manufacturing similar kind of products. The cluster may be natural or induced. In case of natural clusters, the group of firms making identical products is formed without external inducement, but by natural process. Availability of raw material, traditional and skilled expertise, ethnicity, ready market etc may be the reasons for the formation of natural clusters. Natural clusters are normally confined to a geographical location- eg: hosiery garments in Tirpur, knitted wear in Ludhiana, lock industry in Aligarh, Saree cluster in Chanderi, leather industry in Agra etc.

Induced clusters are those which have come up as a result of policy measures taken by the concerned agencies/govt. The Govt. may decide to locate a particular group of industries at a specific locality. For example, creation of software park for the software industries, creation of agro-processing zones for setting up of agro based units etc.

However, a cluster is not just an agglomeration of firms. It is a cluster of firms faced with common opportunities and threats. We find a number of linkages also in a cluster. These linkages are at the backward level- with machinery suppliers, raw material suppliers and at the forward level with the selling agents, exporters, customers etc. There will be linkages with technical institutions, financial institutions, regulatory bodies and other support institutions. Thus, a cluster is not just a group of industry as we find in an industrial estate.

The Cluster Development Programme (CDP) envisages strengthening the inherent advantages of the cluster as a whole. Here, the approach is towards a group and not individualistic.

The advantages of CDP for cluster units are:

- Helps to overcome disadvantages of economies of scale and weak capital base
- Increased responsiveness to market challenges
- Easy and faster diffusion of information
- Speedy dissemination of best practices in organisational capabilities, skills and technological innovation
- Distribution of fixed costs of intervention among large number of beneficiaries
- A wider appropriation of benefits
- Enhanced bargaining power for commercial gains and favourable policy environment

Agencies like SBI, SIDBI, NABARD, Textile Committee, NSIC, UNIDO have initiated programmes for development of SSI through Cluster Development Programme (CDP). The office of the DC (SSI) has also initiated interventions directly and in collaboration with UNIDO, in 45 clusters in recent years. The approach to develop SSI through CDP has been found successful in the select clusters.

Now, the time appears to be ripe to explore ways and means to replicate the results in other clusters as well. Therefore, it has been decided to take up a larger number of clusters for development. To begin with, under the Cluster Development Programme of the Ministry of SSI, 21 clusters have been selected across the country and the Pharmaceutical Cluster of Goa is one among them.

The CDP starts with the Diagnostic study. The diagnostic study attempts to analyse the following:

- To analyse the current position of the cluster, i.e, nature of its working, turn over, employment, its constituents, marketing etc.
- To know the nature and strength of business linkages- both vertical and horizontal at the backward and forward levels
- To know the nature of linkages with technical, financial institutions, regulatory bodies and other support institutions and associations.
- To identify the areas of intervention for sustainable growth of the cluster
- To prepare an action plan acceptable to all cluster actors, if there is scope for intervention

The pharmaceutical industry is the part of mother Health Care Industry. There has been positive growth in the pharmaceutical industry in Goa, during recent years. Although there are units other than pharmaceutical formulations, which require to be registered under the Drug & Cosmetics Act, for the purpose of CDP, formulating units have been taken for the study. One or two units each in basic drugs, laboratory reagents, anti disinfectants, contraceptives, diagnostic equipments etc do

exist, but cannot form a sizeable number relevant for the CDP. Hence, pharmaceutical formulation units have been taken for study for this diagnostic study.

In order to understand the status and functional dynamics of the cluster, basic information about no. of units, own licences, loan licences etc were collected from the Directorate of Food and Drug Administration, Govt. of Goa and the firm level information was collected through schedules of enquiry. Discussions were held with the entrepreneurs, Govt. officials, industry associations, raw material suppliers, knowledgeable persons etc. Following table gives an idea about the units/institutions visited/surveyed for the diagnostic study.

Category	Persons/organisations interviewed
Small firms	9
Medium firms	6
Large firms	4
Regulatory bodies	2
Technical Institutions	1
Financial Institutions	3
Raw material suppliers	4

Relevant data was also collected from the Internet, news items, magazines etc. A special mention has to be made here about the Diagnostic Report of the Ahmedabad Pharma Cluster, made by the UNIDO, which helped in understanding the basic concepts of pharmaceutical industries and their functioning, relevant rules and regulations governing the pharmaceutical industry. The report also guided in designing the schedule of enquiry for collecting information from the individual units.

III. INTERNATIONAL SCENARIO

2002 World pharma sales growth:

The World pharmaceutical industry is dominated by developed countries, and the share of developing countries in the World's pharmaceutical trade is about 8%. China, Hongkong, Singapore, Korea and India are the major exporters among developing countries. According to the new IMS World Review, in 2002, global audited sales of pharmaceuticals rose 8% (at a constant dollar rate) to reach \$400.6 billion. (IMS World Review tracks actual sales of approximately 90% of all prescription drugs and certain over-the-counter (OTC) products in more than 70 countries. Proprietary data projection methodologies are then used to estimate total global pharmaceutical sales, which grew to \$430.3 billion in 2002.)

Despite economic challenges in the world's leading markets and a lower-than-normal number of new product introductions, the global pharmaceutical industry experienced solid growth in 2002, according to Graham Lewis, IMS Vice President, Strategic Global Solutions. Generic drug sales strengthened in North America and Western Europe due to several patent expiries, while the Japan market continued to show nearly flat growth. Aging populations and the ongoing demand for innovative therapies are expected to effectively sustain pharmaceutical growth in 2003 and beyond.

As sales in Latin America slumped 10% due to the economic problems there, North America, Europe and Japan cemented their position: in total, these regions accounted for 88% of audited worldwide pharmaceutical sales in 2002. North America was yet again the strongest performer, growing 12% at a constant dollar rate to reach \$203.6 billion - 51% of the world's total. Europe grew 8-9%, and Japan, the second-largest individual market, recorded 1% growth. The rest of Asia, Africa and Australia combined showed a healthy increase of 11%.

2002 Global pharma sales by region

World Audited Market	2002 Sales (\$bn)	% Global sales (\$)	% Growth (constant \$)
North America	203.6	51%	+12%
European Union	90.6	22%	+8%
Rest of Europe	11.3	3%	+9%
Japan	46.9	12%	+1%
Asia, Africa and Australia	31.6	8%	+11%
Latin America	16.5	4%	-10%
TOTAL	\$400.6bn	100.0%	+8%

Source: IMS World Review 2003. Sales cover direct and indirect pharmaceutical channel purchases in US dollars from pharmaceutical wholesalers and manufacturers. The figures above represent 52 weeks of sales data, and include prescription and certain OTC data and represent manufacturer prices.

Leading therapy classes

Showing little change from 2001, the top ten therapy classes accounted for 31% of the total audited world market in 2002. Anti-ulcerants were again the largest class, but this situation may change in 2003 given the generic competition for market leader **Prilosec/Losec** (omeprazole), from AstraZeneca, now present in the United States.

Cholesterol & triglyceride reducers were a close second, and could surpass ulcer drugs thanks to the continuing strong performance of Pfizer's **Lipitor** (atorvastatin), which eclipsed Prilosec as the top selling individual product in 2001, and the imminent arrival of Shionogi and AstraZeneca's 'superstatin' **Crestor** (rosuvastatin).

Perhaps reflecting the loss of exclusivity and new OTC status for Schering-Plough's blockbuster **Claritin** (loratadine) in the USA, the systemic antihistamine class dropped out of the top 10 in 2002, to be replaced by the erythropoietins - which came straight in at number seven. This class is dominated by products such as **Epogen**, **Aranesp** and **Erypo/Procrit**, from Amgen and its licensee Johnson & Johnson.

Just ahead of the EPOs, the strongest growth, of 19%, again came from antipsychotics, led by Eli Lilly's **Zyprexa** (olanzapine) and J&J's **Risperdal** (risperidone), and now also including **Abilify** (aripiprazole), the new schizophrenia therapy from Otsuka and Bristol-Myers Squibb.

Leading therapy classes in 2002 global pharmaceutical sales*

Rank	Audited World Therapy Class	2002 Sales (\$bn)	% Global sales (\$)	% Growth (constant \$)
1	Antiulcerants	21.9	6%	+9%

2	Cholest. & Triglyceride Reducers	21.7	5%	+12%
3	Antidepressants	17.1	4%	+5%
4	Antirheumatic Non-Steroidals	11.3	3%	+1%
5	Calcium Antagonists, Plain	9.9	3%	-1%
6	Antipsychotics	9.5	2%	+19%
7	Erythropoietins	8.1	2%	+18%
8	Oral Antidiabetics	8.0	2%	+2%
9	ACE Inhibitors, Plain	7.8	2%	0%
10	Cephalosporins & Combinations	7.6	2%	-3%
	Total Leading 10 ATCs at Level 3	\$122.8bn	31%	+6%

Source: IMS World Review 2003

*Note: The figures above reflect 52 weeks of US sales data, but are compared with 53 weeks of US sales data in 2001, an adjustment that is made every five years to bring IMS' data tracking methodology into line with the calendar year. As a result, 2001 US figures used to calculate the percentage growth year-over-year (constant dollar) in this table incorporate five additional days of sales.

Leading products

In 2002, the world's top ten best-selling drugs accounted for \$44.7 billion in sales, an 11% increase over 2001. Within the total audited world market, Lipitor was again the top-selling drug in 2001, with a massive \$8.6 billion in sales, up from \$7.0 billion in 2001. Merck & Co's statin, **Zocor** (simvastatin), overtook Prilosec as the number two product, with sales of \$6.2 billion. Prilosec's sales dropped 19% to \$5.2 billion, thanks to the generic competition mentioned above and AstraZeneca's promotion of its follow-up product, **Nexium** (esomeprazole).

After being the top ten drug with the most impressive growth in 2001, Merck & Co's coxib for arthritis, Vioxx (rofecoxib), dropped out of the top ten in 2002, possibly due to lingering concerns about its safety. The other coxib, Pharmacia and Pfizer's **Celebrex** (celecoxib), fell from seventh to ninth place.

The new arrival was Pfizer's SSRI antidepressant **Zoloft** (sertraline), which registered 12% growth to reach tenth position. Lilly's antipsychotic Zyprexa saw the highest growth, of 21%, and climbed to fourth place from sixth in 2001

Leading products in 2002 global pharmaceutical sales*

Rank	Audited World Product Sales	2002 sales (\$bn)	% Growth (Constant \$)
1	Lipitor	8.6	+20%
2	Zocor	6.2	13%
3	Losec/Prilosec	5.2	-19%
4	Zyprexa	4.0	+21%
5	Norvasc	4.0	+6%
6	Erypo	3.8	+18%
7	Ogastro/Prevacid	3.6	+3%
8	Seroxat/Paxil	3.3	+13%
9	Celebrex	3.1	- 1%
10	Zoloft	2.9	+12%
	Total 10 Leading Products	\$44.7bn	+11%

Source: IMS World Review 2003

*Note: 53 weeks US sales data as above.

IMS World Review is compiled using IMS' MIDAS™ global analysis system, which captures pharmaceutical activity from more than 70 countries. Growth in sales is measured in constant dollars, enabling analyses without the influence of fluctuating currency exchange rates. Pharmaceutical sales figures include prescription and certain OTC data, and represent manufacturer prices.

IV. PHARMACEUTICAL INDUSTRY-INDIAN SCENARIO

The Indian pharmaceutical industry is one of the fast growing sectors of the Indian economy and has made rapid strides over the years. From being an import dependent industry in the 1950s, the industry has achieved self-sufficiency and gained global recognition as a producer of low cost high quality bulk drugs and formulations. Leading Indian companies have developed infrastructure in over 60 countries including developed markets like USA and Europe. In the last few years, several pharmaceutical companies have demonstrated that they possess the ability to engage in commercially viable research and development activities and become significant players in the international market. The number of units, which was about 2200 in 1969-70 has grown to more than 20,000 units in 1999-2000.

INDUSTRY SCENARIO

The pharmaceutical industry comprises 20,053 manufacturing units and provides employment to approximately 33 lakh people. The total production in the country in 1999-2000 was Rs.19,737 crores with formulations accounting for Rs.15,960 crores and bulk drugs contributing Rs.3,777 crores. The total capital investment in the pharmaceutical industry was Rs.2,500 crores with R&D expenditure being Rs.320 crores. The country's exports stood at Rs.6,631 crores in 1999-2000, imports were Rs.3,441, a net surplus of Rs.3,190 crores. (Source : OPPI)

Number Of Units

Years	Units
1969-70	2,257
1979-80	5,156
1989-90	16,000
1999-00	20,053

The leading 250 pharmaceutical companies control 70 per cent of the market, with the market leader having a share of around seven per cent. Over 60 per cent of India's bulk drugs production is exported and the balance is sold locally to other formulators. With more than 85 per cent of formulation production in the country sold in the domestic market, India is largely self-sufficient in the case of formulations, even though some life saving, new generation, under patent formulations continue to be imported, especially by MNCs.

Growth indicators of pharmaceutical industry in terms of capital investment, production, import, export and expenditure on R&D are reported in the following table:

GROWTH OF PHARMACEUTICAL INDUSTRY (Rs.Crores)

		1965-66	1980-81	1997-98	1998-99	1999-2000
Capital Investment		140	500	1840	2150	2500.00
Production	Formulations	150	1200	12068	13878	15960.00
	Bulk Drugs	18	240	2623	3148	3777.00
Import		8.20	112.54	2868.00	3128.00	3441.00
Export		3.05	46.38	5353.00	5959.00	6631.00
R & D Expenditure		3	14.75	220.00	260.00	320.00

Source : OPPI

McKinsey-FICC-CII Report- Highlights:

The combined market size of pharma and biotech sectors will reach \$ 21-25 billion by 2010. The domestic segment will reach \$ 10-12 billion by 2010 from the present \$ 4.2 billion. In global generics, Indian players can expect a market share of 8-10 percent of the total market size of \$ 50-70 billion by 2010. The country can hope a 5-6 % share of the \$ 27 billion market in the global bulk.

The domestic market will see a shift in generics exports towards value added and regulated markets, driven by drugs worth \$ 80 billion going off-patent in the next 10 years.

India is one of top five manufacturers of bulk drugs in the world and is among the top 20 pharmaceutical exporters in the world. The industry manufactures almost the entire range of therapeutic products and is capable of producing raw materials for manufacturing a wide range of bulk drugs from the basic stage.

The government has taken measures to give impetus to domestic production of drugs and formulations, creating an environment conducive for chanelising new investments into the pharmaceutical sector. However, the industry and experts feel, that time has come for the government to announce new policy initiatives, particularly relating to the research and development and pricing regime, in order to propel the industry into a new growth orbit as well as to face the challenges of a WTO-led trading system and a TRIPS-driven product patent environment.

KEY PLAYERS

The Indian pharmaceutical industry comprises both MNCs as well as domestic companies. While at one time, MNCs dominated the market; their market share has declined steadily from 75 per cent in 1971 to about 35 per cent. In order to boost the domestic industry, the government introduced process patents in the Indian Patent Act of 1970. Domestic pharma companies were quick to take advantage of this and developed expertise in process development and manufacturing of pharmaceuticals. As a result, Domestic companies had a robust pipeline of products, large

therapeutic width and depth and were able to provide masses with the low priced quality pharmaceuticals.

Out of the ten top pharmaceutical companies in India, there are three MNCs. The top ten pharmaceutical companies operating in India are:

(Rs.Crores)		
Company	Finance Year	Net Sales
Ranbaxy Laboratories	Dec 1999	1559
Glaxo Limited	Dec 1999	888.3
Wockhardt	Dec 1999	841.72
Novartis	March 2000	793.13
Cipla	March 2000	704.28
Aurobindo Pharma	March 2000	692.13
Lupin Laboratories	March 2000	485.23
Hoechst Marrion Roussel	March 2000	479.86
Cadila Healthcare	March 2000	447.86
Dr Reddy's Laboratories	March 2000	436.01

Source : Prowess-CMIE

EXPORTS

Exports form a vital component of the growth strategy of most Indian pharmaceutical companies. The industry has made rapid strides in this area in the last few years and export sales of companies such as Ranbaxy have been growing at a faster rate than their domestic sales. The compounded annual growth rate of pharmaceutical exports over the last five years has been more than 20 per cent although in 1999-2000, exports grew by 11 per cent.

Upgraded manufacturing facility:

Increasingly companies are in the process of upgrading their manufacturing facilities, adopt GMP standard and getting international regulatory approvals from USFDA UKMCA. Approvals from these agencies would facilitate export to developed countries

In 1999-2000, on a region-wise basis, India's biggest export markets are East Asia (Rs.1527 crores); West Europe (Rs. 1488 crores); Africa (Rs.780 crores); North America (Rs.766 crores) and East Europe (Rs.670 crores). On a country-wise basis, India's five largest export markets are USA (Rs.671 crores); Russia (Rs.493 crores); Germany (Rs.325 crores); Hong Kong (Rs.356 crores) and Nigeria (Rs.257 crores).

Exports

(Rs.Crores)					
YEAR	Finished Formulations	% of Total	Bulk Drugs including Quinine Salts	% of Total	Total
1997-98	3180	59	2173	41	5353
1998-99	3194	54	2764	46	5959
1999-2000	-	-	-	-	6631
2002-03					11,925*

Source : OPPI

* source: Directorate of Commercial Intelligence & Statistics.

While overall pharmaceutical exports have grown in 1999-2000, India's exports to a few of its leading markets have declined. For instance, according to a CHEMEXCIL Report, India's pharmaceutical exports to USA have declined to Rs.671.8 crores in 1999-2000 from Rs.724.5 crores in 1998-99; Germany to Rs.325 crores from Rs.375 crores; Hong Kong to Rs.356 crores from Rs.404.5 crores and exports to China has declined to Rs.179.5 crores from Rs.137 crores.

Notwithstanding the decline in exports to some key markets, India's export prospects remain bright. As against a global pharmaceutical industry of over \$400 billion, India's export sales are in the region of \$1.5 billion. The potential for growth is enormous, a 20 per annual growth in exports over the next five years will take the overall export figure to \$4 billion by 2005. The next five years will witness a spate of patent expires of blockbuster drugs that will accord opportunities to supply bulk drugs and formulations to advanced markets.

Pharmaceutical exports have crossed the five digit figure in the financial year 2003, clocking exports worth Rs.11,925 , crores, registering a growth rate of 21 percent according to the **Directorate General of Commercial Intelligence & Statistics (DGCIS)**. The higher growth rate is due to increased exports to regulated markets such as the US, Germany, Canada, the UK, Russia, Mexico and Spain. The US market was the most preferred destination for Indian Pharma exports, touching Rs. 2,023 crores during 2002-03 with an increase of 25% over the previous year. Exports to Germany were to the tune of Rs. 727 crores, a 40% increase over the previous year.

Exports to China accounted for 397 crores and Russia accounted for 497 crores. In Asia, China is the leading importer of Indian Drugs.

TOP COUNTRIES OF EXPORTS OF INDIAN PHARMACEUTICALS

(Rs.Crores)

Name of the Country	1999-2000	2002-2003
USA	672	2023*
RUSSIA	493	497*
GERMANY	325	727*
HONG KONG	356	
NIGERIA	258	
U.K.	257	
SINGAPORE	245	
NETHERLANDS	219	
IRAN	180	
BRAZIL	163	
VIETNAM	141	
CHINA	137	397*
ITALY	151	
SPAIN	129	
NEPAL	123	
SRI LANKA	124	
JAPAN	120	
THAILAND	118	

Source : CHEMIXCIL

* DGCIS

RESEARCH & DEVELOPMENT

In a country where research and innovation have traditionally been neglected by domestic industry, the pharmaceutical industry is realising the importance of R&D. The successes enjoyed by a few companies such as Ranbaxy and Dr Reddy's in the R&D field have shown the way for others. Several Indian pharmaceutical companies including Cipla, Lupin, Wockhardt, Nicholas Piramal and Torrent are today engaged in R&D activities.

Investment in pharmaceutical R&D has been rising steadily. From Rs.220 crores in 1997-98, R&D expenditure rose to Rs.260 crores in 1998-99 and to Rs.320 crores in 1999-2000. This figure is projected to jump up to Rs.1500 crores by 2005. At present, R&D spend accounts for two per cent of the pharmaceutical industry's turnover. This is estimated to rise to five per cent by 2005.

Notwithstanding the increase in R&D expenditure, the R&D spend of domestic industry will remain a fraction of the amount invested. Experts, however, point out that R&D costs in India are much less than those in the developed world and it is possible to conduct both New Drug Discovery Research and Novel Drug Delivery System programmes at competitive rates. The Investigational New Drug stage may cost \$100 to 150 million overseas but costs only around Rs.40 to 60 crores in India, says the Mashelkar Committee report. The report adds that while clinical trials cost approximately \$300 to 350 million abroad, they cost about Rs.100 crore in India.

Apart from comparative cost advantage, Indian R&D efforts are also aided by the presence of a well-established network of research laboratories and a skilled pool of scientific personnel. These need to be leveraged and utilized in an effective manner. Greater collaboration between Industry-Government and academia in this area is required to achieve this.

Most Indian companies realise that it will be difficult for them to commercialise their discoveries on an international basis on their own. Therefore they are entering into licensing deals and strategic alliances with international companies. This way their development costs will get shared and returns will accrue faster.

R & D Expenditure

Year	(Rs. Crores)
1998-81	14.75
1997-98	220.00
1998-99	260.00
1999-2000	320.00
R & D Expenditure as % of Sales	2.0%

Source : OPPI

V. HISTORY AND GROWTH OF PHARMACEUTICAL INDUSTRY IN GOA

Goa, the 25th state, with a geographical area of 3702 sq. kms, is one of the smallest states of Indian Union. The state lies along the western coast (Konkan Coast) 600 kms south of Mumbai; and 300

kms north of Mangalore. The state is bounded, on the north, by the river Teracol, which separates it from Sindhudurga District of Maharashtra; in the east and south by Belgaum and Uttar Kannada Districts of Karnataka respectively; and in the west by the Arabian Sea

As per the 2001 Census, the population of Goa is 13.43 lakhs with decadal growth rate of 14.89 percent.

Beaches, temples, churches and wild life sanctuaries are famous tourist spots and attract a number of Indian as well as foreign tourists. In fact, Goa can boast of some of the most beautiful beaches in South East Asia.

Though India became independent in 1947, Goa continued to be under the Portuguese rule and was liberated on 19th December 1961. The beginning of 19th Century saw rigorous conditions being implemented in the European countries including Portugal. Goa was ruled by the Portuguese for about 5 Centuries and was referred to “Estado da India Portuguesa” meaning Portuguese state of India. The Portuguese instituted the system of Pharmacy in Goa in the middle of 19th Century. It was in 1842 by Ministerial Portaria No. 1410 dated 5th November 1842 that the Portuguese started a Higher Educational Institution to qualify Physicians cum Surgeons and Pharmacists. This Institution was initially named ESCOLA MEDICA DE GOA, with a course of 4 years in Medicine and 3 years in Pharmacy.

On 11th January 1847, the Government recognised the Institution as a permanent organisation under the name ESCOLA MEDICO-CIRURGICA NOVA GOA for preparing students in Medicine, Surgery, Pharmacy and Nursing. This Institution is recorded (in the Directory published by the Goa State Association of Chemists & Druggists-) to be the oldest and the first of its kind in Asia, with courses for graduation in Pharmacy (Farmaceuticos) and Medicine (Medico Cirurgio) as in Portugal.

After Independence in 1947 and up to early 1950's all medicine supplies used to come from various parts of India (Goa being still under the Portuguese regime), mainly Bombay and Cochin. Hence, all medicines available in India were available in Goa as well. In 1952 came the BLOCKADE. The Indian Govt., with an intention to drive out Portuguese out of Goa, imposed blockade on trade with Goa. The trade between Goa and the rest of India, in 1952, came to a standstill. Along with other commodities, medicines stopped coming to Goa and Goa had to depend on medicines imported from USA, UK, France, Italy etc. The main importers in those days were Andrade Sa, Cosme matias Menezes, Drogaria Menezis & Cia, Drogaria Salcete, Drogaria Prakash, Drogaria Central, Innocencia Fernades and Drogaria Raikar.

Among the above importers/traders of pharmaceutical products, Mr. Pascoal Menezes of CMM group and Mr. Govind Kare are recognised to be the pioneers of Pharmaceutical industry in Goa. Mr. Pascol Menezes started the first pharmaceutical manufacturing unit at Curti, Ponda, in the

name and style of 'Calter Wallace', in 1963. Then Mr. Govind Kare started his unit in 1970 by name 'DCI Pharmaceuticals', in the outskirts of Margao.

After setting up of Calter Wallace (now renamed as Wallace Pharmaceuticals), many new companies came and became Menezes group of companies. Such companies are: CFL Pharmaceuticals, Cosme Remedies, Cosme Pharma, Colfax Labs, Menezes Chemicals, etc. Now, with the division in the family, these companies are managed by different members of the family.

Another oldest Pharma Company is DCI Pharmaceuticals established in 1970. The founder being the trader in pharmaceuticals earlier, he was having pharmacy shops, named as Pharmacia Slacete in Margao. To expand this promising business to the entire Bombay Presidency, he opened a branch in Bombay under the name 'Indoco Continental Trading Company' Capitalising the expertise as trader in pharmaceutical products, Govind Kare incorporated, on 23rd August 1947, 'Indoco Remedies' to establish a small scale unit to manufacture drug formulations and an organisation to market them in **Thane**. The unit became sick in the early 1960's due to various reasons. Then in 1963, Suresh Kare, son of Govind Kare, took over Managing Director of the Indoco Remedies, who revived the company to new heights. The Indoco is having plants in Mumbai, Aurangabad and set up plant for oral liquid and solid dosage formulations in Verna, Goa in 1997. The separate dedicated state of the art sterile manufacturing plant was set up recently in 2002 for injectibles at Verna, Goa. This year, the combined turn over of Indoco remedies is reported to be around 140 crores.

Growth Trend:

There are 43 (50 if sub-units of Cipla are included) pharmaceutical formulating units in the State. Even though number is small, we find exponential growth of pharmaceutical formulating units in Goa in the late 1990s. There were hardly 3 units before 1970. The no. of units before 1980 was less than 10 and about 17 units were there up to 1990 and 21 units up to 1995. After 1995, more than 50% of the total number of units have come up in Goa. These units are large units, having their units in other parts of India. Following table gives an idea about the growth trend of pharmaceutical units.

Table:

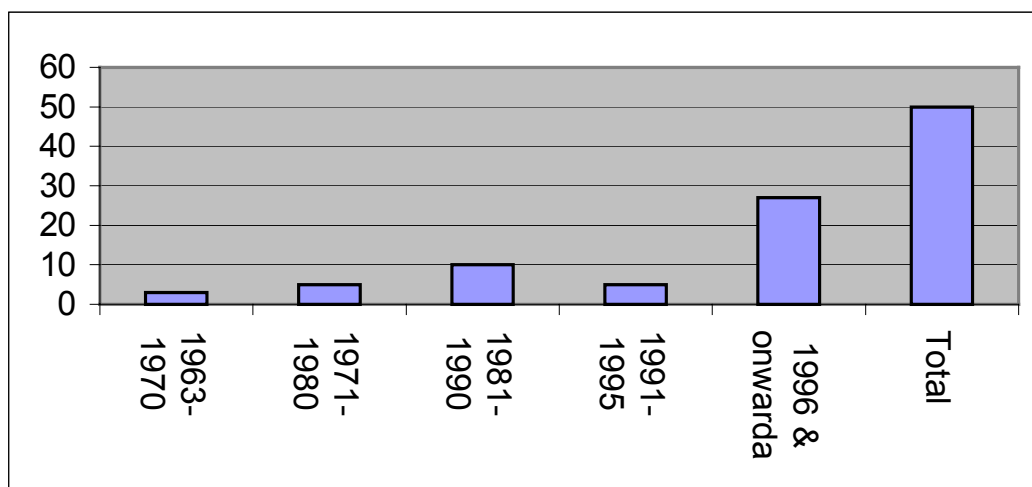
Period	No. of firms
1963-1970	3
1971-1980	5
1981-1990	10
1991-1995	5
1996 & onwards	20 (27*)
Total	43 (50*)

* including sub-units of Cipla

It is understood that another 4-5 large scale units are in the pipeline including Indian Pharma Majors like Dr. Reddy,s Laboratory, Lupin, Micro Labs, Glenmark etc. It is interesting to note that all the units which have come up after 1995 are large firms and multinationals.

The industry is not location specific. In fact it is not a natural cluster. Units are spread across the state. However, there is concentration of pharmaceutical industries in selected pockets like Verna Industrial Estate, Tivim Industrial Estate, and around Ponda. The Govt is giving preference to locate the new units in Verna Industrial Estate.

Chart: Yearwise growth of pharmaceutical industries



Following are the main reasons attributed for sudden growth of pharmaceutical industries in recent years.

- **Income Tax Holiday:**

After 1995, the Union Government is extending Income Tax Holiday Scheme for 5 years to new units coming up in Goa. Traditionally, the Goan economy was tourism and mining based. In order to attract the investment in industrial sector also, the Govt extended Income tax holiday for 5 years for the units. Under the Scheme, new units are fully exempted from payment of Income tax on their income for a period of 5 years. The Scheme in operation till now and will expire by the end of this financial year, i.e, March 2004. For Pharmaceutical industry, being capital intensive with high turnovers this acted as a big boost and relief for the new units. During the filed survey, Income tax holiday was pointed out by the units to be the main driving force to establish their units in Goa.

- **Sales Tax Exemption Scheme:**

In order to attract the investment in the State, the State Govt. also offered sales tax exemption scheme initially for a period of 15 years for SSIs and for 12 years for Large firms. This was subsequently reduced to ten years for both SSIs and non-SSIs. The Scheme has been withdrawn now w.e.f 1st April 2003.

- **Capital Investment Subsidy:**

The above incentives were further complimented by the State Govt. with the Capital Investment Subsidy Scheme. The said scheme has been stopped from this financial year. Under the scheme, the State Govt. was reimbursing 25% of the fixed investment subject to a ceiling of Rs. 25 lakhs, which was subsequently reduced to Rs. 10 lakhs.

- **Infrastructure:**

The Goa Industrial Development Corporation has developed 18 industrial estates in the State. Industrial plots are given to the entrepreneurs on hire purchase/ long lease basis at competitive rates and payable in installments. Basic amenities like power, water, roads, post and telephone, banking facilities are given. Besides, even though Goa is not having any power generating plants of its own (except 48 MW naphtha-based plant which came up recently), power tariffs are very competitive compared to that of neighbouring states. The State gets power from the NTPC through southern and western grids. In fact the State is selling the excess power to other states because, the State's requirement of power is estimated to be 200 MW against available power supply of 407 MW. However, due to poor distribution network, industries are facing the problem of power interruptions.

The State has well-developed transport and communication facilities. Railways are comparatively well developed with propre linkages. National Highway No.17 passes through the State connecting major towns. The Konkan Railway, connecting Bombay to Mangalore traverses the entire length of the State, which is considered to be blessing for the growth of trade and industry in the State. There are daily trains to Delhi, Trivendrum, Bangalore, Vijayawada and a number of trains daily to Mumbai.

There are regular air services to Delhi, Mumbai, Bangalore, Cochin by Indian Airlines and other private airlines. Goa,s Dabolim Airport happens to be one of few destinations where International Chartered flights are allowed to land.

Banking facilities are also well developed in the State. There are about 450 branches of commercial banks, private and cooperative banks throughout the State. In addition, other financial institutions like SIDBI, IDBI, NSIC, KVIC, NABARD etc are having their presence in the state.

Literate labour force and peaceful atmosphere with communal harmony are the other positive points to attract investment in the State.

All the above factors together influenced the flow of investment in the pharmaceutical industry and thereby setting up of new plants.

In the following table, data on investment, employment, turnover, exports etc is given.

(Rs. Crores)	
No. of units	50
Investment (Rs. Crores)	775

Turn over	1600
Exports	350
Employment (Tech)	1500
Employment (Non-tech)	4089
Total Employment	5589

From the above table it can be seen that, the total turn over of the cluster is about 1,600 crores, employing more than 5,500 people. The average turn over of the cluster works out to be about 32 crores. The total investment in the cluster is about 775 crores. Exports form about 21% of total turnover, with about 350 crores.

Growth Trend in Turn Over

The trend in the growth of units in terms of turn over in respect of **19 surveyed units** is reproduced in the tabular form.

Year	Turn Over (Cr)	% Increase
2000-2-01	305.23	
2001-02	336.81	10.52
2002-03	456.67	35.58
2003-04 (estimated)	525.81	15.14

There has been increasing trend in the turn over of the cluster units. The exponential growth to the tune of more than 35% during 2002-03 is mainly because, one of the units selected for survey came up in 2002, which happens to be a large firm (MNC). Otherwise, the growth trend would have been around 16%. Data was collected from the surveyed firms in respect of turn over for 2003-04, based on the present trend. The units are expected to grow at the rate of over 15%.

It may be noted that, the above results are in respect of 19 firms, out of them small firms are in majority. Out of 19 firms surveyed, 9 firms were small and tiny firms with an annual turn over of less than 5 Crores, 6 were medium with annual turn between 5-50 crores and 4 were large firms with annual turn over of 50 crores. Since large firms dominate the cluster, growth trend for the cluster as a whole is estimated to be 18-20%.

The 19 surveyed units employ 2360 persons, out of which 748 i.e., about 31% are female. Thus, involvement of women work force is considerable.

New Industrial Policy

The long awaited industrial Policy was announced by the Chief Minister, in the presence of Industries Minister, Power Minister, and the Chief Secretary and Secretary (inds), on **4th August 2003**. The policy gives top priority to accelerate industrial development through sustainable employment to local youth. Following are the salient features of the New Industrial Policy:

- Proposal to set up an Investment Board, replacing the High Power Coordination Committee and thereby introduce the Single Window Clearance System. The mandate of the Board to include identification of investment requirements of the State, prioritisation of public investment in specific projects, decision on funding modalities, clearance of investment proposals and review of implementation of projects.

- Thrust areas include pharmaceuticals, drugs & bio-tech industries, food processing and agro based industries, IT and IT enabled services, eco-tourism, heritage, adventure, medical tourism
- The policy offers employment subsidy to the extent of Rs. 6 lakhs per annum for SSIs and Rs.12 lakhs per annum for specified categories of Medium and Large Scale units
- The policy proposes to support local entrepreneurs to venture out and expand their units. The capital contribution will be for 5 to 10 years with guaranteed return of 6% p.a. and it is applicable to units in operation in the preceding three years.
- Share capital to self employed local entrepreneurs to start income generating activities in various trades. The share capital to be repaid to the government over a period of 10 years, without interest.
- Interest subsidy scheme to investors
- Preferential purchase incentive scheme for SSIs
- Preference to women entrepreneurs by giving 5% additional benefit under the local employment subsidy scheme and priority in share capital contribution and special contribution schemes.
- Interest free loans up to Rs. 5 lakhs repayable over period of 5 years for Goan industry under Export Market Financial Assistance Scheme.

These proposals are to be supported by the actual issue of notifications for effective implementation.

VI. MAJOR LEGISLATIONS

Manufacture and sale of drugs and pharmaceutical products are governed by a number of legislations. Some of these legislations are very important and having a direct bearing on working of pharma units, which are briefly analysed below:

Schedule 'M' of the Drugs and Cosmetics Act (1940)

The Schedule 'M' classifies the various statutory requirements mandatory for all drugs, pharmaceuticals and medical disposable industry relevant as per current good manufacturing practices (CGMP). Schedule 'M' was last revised in 1986, when the concept of GMP was first introduced. The Central Government is now revising the Schedule 'M' to get it "harmonized with that of the various developed and developing countries and also to the level of the well established international organizations such as the World Health Organisation (WHO)".

The WHO guidelines on GMP for pharmaceutical products urge that:

- all manufacturing processes are clearly defined, systematically reviewed, and shown to be capable of consistently manufacturing pharma products of the required quality that comply with their specifications;
- all necessary facilities are provided including qualified trained personnel, adequate premises and space, suitable equipment and services, correct materials, containers and labels, approved

procedures and instructions, suitable storage and transport and adequate personnel, laboratories and equipments for in process controls;

- instructions and procedures are written in clear and unambiguous language;
- operators are trained to carry out procedures correctly;
- records are made (manually and/or by recording instruments) during manufacture to show that all the steps required by the defined procedures and instructions have actually been taken and that the quantity and quality of the product are as expected and any significant deviation fully recorded and investigated;
- records covering manufacture and distribution are retained in a comprehensive and accessible form;
- a system is available to recall any batch of product from sale or supply; and
- complaints about marketed products are examined, the causes of quality defect investigated, and appropriate measures taken.

A special sub committee constituted by the Government of India has proposed revamping of the Schedule M, covering specifications such as general requirements in case of buildings and premises, personal sanitation and hygiene, training, production and operation controls, quality control and assurance, stability and validation studies, documentation, complaints and self-inspections; and special requirements for individual formulation categories. Among other things, the amendment calls for the following:

- to maintain a ratio of 1:2 between the constructed area and surrounding premises to prevent environmental pollution;
- to install a validated water system to aid monitoring and control of bio-burden levels;
- to have a good disposal system, in the absence of which to have arrangements to recycle rejects;
- to have proper environmental control, with emphasis on buildings, till the primary packaging is complete;
- to ensure supply of filtered air in all production areas to prevent environmental pollution;
- to have specifically designed areas for production, quality control, storage and ancillary areas;
- to take adequate precautions to segregate the manufacture of highly potent drugs to avoid cross contamination;
- to design adequate operational and process controls to ensure reproducible quality of drugs;
- to ensure total quality control from raw materials procurement till the retail counter;
- to undertake detailed stability studies to establish the quality of drugs in different climatic and storing conditions; and
- To evolve clear and realistic documentation procedures.

DRUG PRICE CONTROL ORDER (DPCO)

Drugs and formulations have been subjected to price control for more than three decades now. The economic reforms initiated by the Government of India in July 1991, trickled down to the

Pharmaceutical Industry only in 1994 and that too partially. Price control in a large number of industries has already been abolished.

The DPCO came into existence in 1970 and thereafter amended in 1979, 1987 and 1995. The main objectives of the Drug Policy after the modifications in the Policy of 1987 announced in September 1995 are

- to ensure availability, at reasonable prices, of essential and life saving and prophylactic medicines of good quality;
- strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;
- creating an environment conducive to channelizing new investment into the pharmaceutical industry to encourage cost-effective production with economic sizes and introducing new technologies and new drugs;
- and strengthening the indigenous capability for production of drugs.

The Drugs Price Control Order (DPCO), 1995 is an order issued by the Government of India under Section 3 of the Essential Commodities Act, 1955 to regulate the prices of drugs. The Order inter alia provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Government and penalties for contravention of provisions among other things. For the purpose of implementing provisions of DPCO, powers of the Government have been vested in the National Pharmaceutical Pricing Authority (NPPA). Drugs are essential for health of the society. Drugs have been declared as essential and accordingly put under the Essential Commodities Act. Only 76 out of 500 commonly used bulk drugs are kept under statutory price control. All formulations containing these bulk drugs either in a single or combination form fall under the price control category. However, the prices of other drugs can be regulated, if warranted in public interest.

The NPPA was established on 29th August 1997 as an independent body of experts following the Cabinet Committee's decision in September 1994 while reviewing the Drug Policy. The Authority, inter alia, has been entrusted with the task of fixation/revision of prices of pharmaceutical products (bulk drugs and formulations), enforcement of provisions of the Drugs (Prices Control) Order and monitoring the prices of controlled and decontrolled drugs in the country.

The Indian Patent Act, 1970

The Patents Act, 1970 which came into effect in 1972, was instrumental in providing the impetus for laying foundations of a strong manufacturing base for both formulations and bulk actives (as well as intermediates) in India. Provisions of the 1970 Act helped the National pharma industry to grow at a double digit pace. Special amended provisions for pharmaceuticals, deleting, reduction of patent protection period from 14 years to 7 years (from date of application) and 5 years (from date of sealing) in the Patent Act, 1970, virtually kept pharma patents out of protection and open for

commercialization for anyone at will. Consequently, there was no interest for international applicants to file pharma patent applications in India.

With the advent of WTO and TRIPs, the entire scenario has changed. Developing countries like India have been given time till 2005, to change their Patent Legislation. India availed of this and made the 1st Amendment to Patent Act 1970 (earlier on 1.1.95 through notification and later through the 1999 Amendment effective from 1.1.95). This enabled applicants to file for product patents. Since 1.1.95, it is understood that in excess of 4700 product patent applications have been received and accepted by the Indian Patent Office. These applications will be taken up for examination on or after 1.1.2005 to grant Exclusive Marketing Rights (EMRs) Following table in the next page gives an idea about proposed changes in the Patent Law

Comparing the Indian Patent Law with Proposed Changes

Indian Patent Law	Proposed Changes
Provides only process patents	Provides product patents
Duration of patents is 7 years	Duration of 20 years of all patents
Provides for automatic compulsory licensing without the patent holder being heard	Permits compulsory licensing on the merits of each case, but the patent holder will have to be heard
No system for protection of plant varieties in India	Sui generis for the protection of plant varieties
Does not allow patenting of life forms	Requires micro-organisms to be patented
Importation does not amount to working of the patent	Does not permit discrimination between imported and domestic products
The burden of proof is on the plaintiff	The burden of proof is on the alleged infringer

VII. ANALYSIS OF BUSINESS OPERATION

Any manufacturing and commercial activity cannot be carried on in isolation. It is a process in which many operations are linked together. The linkages may be with the firms, raw material suppliers, machinery suppliers or with regulatory bodies, financial institutions, technical institutions etc. One can get a fair idea about the working of a firm or a cluster of firms, when the business operations are looked and analysed from the macro point of view. How the pharmaceutical firms in the cluster are operating in relation to these linkages is briefly analysed in this section.

The Pharmaceutical industries are required to obtain the Licence from the Directorate of Food & Drug Administration, Govt. of Goa, under the Drugs & Cosmetics Act, 1940. The licence may be own, loan or both own and loan. Own licence holders will be having their production plants and manufacture the products. Loan licencees will not be having their own production facilities. They utilise the excess production capacity of other units and market the products. In this case, sometimes (as per the agreement entered into) the raw material and packaging materials etc., are supplied by the parent company and the sub-contracting firm will get the job-charges or conversion charges as per the DPCO. The units having both own and loan licences will be manufacturing at their own premises and also utilise the production facilities of other units. Some units are operating

on P2P (Proprietor to proprietor) basis, wherein, there will be an agreement between two units- 'A' company manufacturing the product for 'B' company for marketing under the brand name of company B.

There are 50 formulating units in the cluster. There are tiny units with an annual turnover of hardly Rs. 10 lakh to large units having turn over of more than one hundred crore per year. Out of this only 13 units are having a turnover of less than Rs. 5 Crore p.a. Out of these 13, three units are entirely doing sub-contracting for other companies. So, their turn over is in terms of job charges received. The actual turnover may be 20-25 times more than the job charges. And a couple of units are operating on P2P basis. There are 13 medium scale companies with annual turnover ranging from more than 5 Crore to 50 crore. And the number of large firms with more than 50 crore turn over is 24.

Table: Classification of units

Small firms	Medium firms	Large firms	Total
13	13	24	50

It can be seen that about 74% of the total units are medium and large firms and small firms constitute only 26% of total units.

Many large firms have their corporate offices outside the State, mainly in places like Mumbai. As these units have some more units in other parts of the country, they have centralised marketing, purchase, personnel departments outside the state. Even big local companies have their marketing offices in places like Mumbai.

BUSINESS LINKAGES:

The business linkages for any manufacturing activity will be at two levels- **forward** and **backward**. In the forward linkages, C& F agents, Stockists, Wholesalers and retailers come into picture. Machinery and raw-material suppliers form the backward linkages. Both machinery suppliers and raw material suppliers are not located within the geographical limits of the State. Details of raw materials and its suppliers are analysed below:

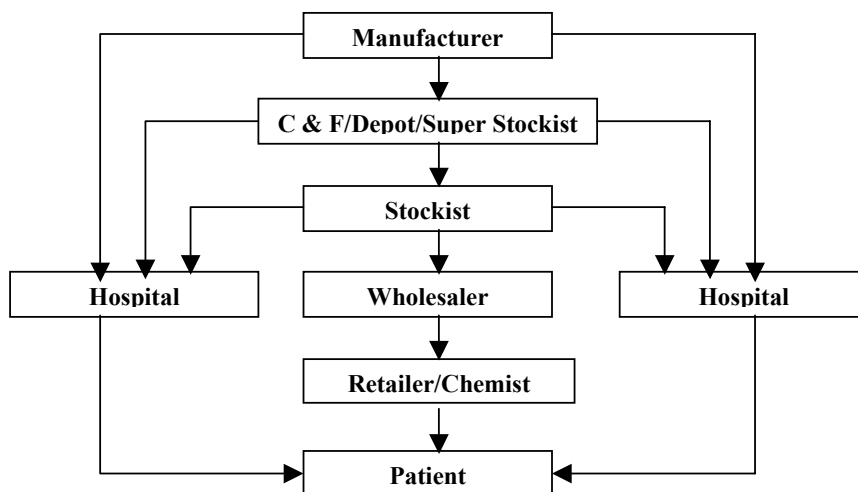
Forward Linkages:

Distribution Channel: Linkages at the forward level can be seen at two levels for domestic marketing- Institutional Sales, and prescription sales.

In case of Institutional Sales, open tender system is being followed and the products are supplied without intervention of intermediaries. In recent years, Institutional sales are guided by quality and WHO-GMP is being insisted for supplying to institutions. Unless small firms upgrade their quality, it would be difficult for them to cater to the needs of the Institutions. However, institutional sales form a small part of total turnover of the companies.

The major part of pharma products is through prescription sales and distribution channel occupies a dominant place. Brand name, sales network, product pricing and dealers' margin are the major aspects. The distribution channel for pharmaceutical products is given below:

Channels of Distribution



The distribution margins are governed as per the provisions of DPCO. DPCO allows, for Stockists, a margin of 8% of the MRP in case of controlled drugs and 10% in case of decontrolled drugs. For retailers, the margins are 16 and 20% of the MRP for controlled and decontrolled drugs respectively. There are about 500 retail chemists and 200 wholesalers/Stockists in the state. In recent years, there has been a change in drug distribution. The company owned warehouses and depots are being replaced by C&F Agents, to curtail the overheads. An agent is paid a fee of 4% to 10% depending on turnover. Because of extended transit time, companies can move seasonal products well in advance to C&F Agent without incurring ex-factory excise costs.

Backward Linkages:

Bulk Drug: Bulk drug is the active component main raw material for the formulating units. There are hardly any manufacturer-suppliers of basic drug within the State. The basic drug manufacturing units are not encouraged in the State as a matter of Policy of the Govt. in order to keep the pollution free environment. Even though there are a couple of units manufacturing basic drug, their contribution is negligible to the total requirement. So, bulk drug is mainly procured outside the State from Commission agents/dealers at Mumbai, Hyderabad, Delhi etc.

Excipient: There are no local units making Excipient and procured mainly form Mumbai. The same is the case with other raw materials like, **coating material, empty capsules, preservatives, Glass ampules, vials, etc. including pharmaceutical machinery.** There are no units in the State manufacturing all these items.

Printing & Packaging: The printing and packaging requirement of pharmaceutical units is met partly by local packaging units and partly procured from outside the state. There are units manufacturing printed cartons, collapsible tubes, aluminum foil printing, corrugated boxes etc.

However, some large firms get these materials outside the State through their centralised purchase departments, which works out to be cheaper due to bulk buying.

Even though raw material and part of packaging material are not available locally, but out sourced, all the units visited are satisfied with the regular and consistent quality and supply of raw material. Out of 19 units, all units say that they get the consistent and regular supply raw material. Only one unit reported that the quality of raw material, in respect of empty capsules is inconsistent

Man-power: There is a Pharmacy College under the Goa University, which acts as main source of technical man power for the pharma industry. The college conducts D. Pharma, B. Pharma as well as M. Pharma courses. In some units, technical persons from neighbouring states are also working. Surrounding Villages ensure the supply of semi-skilled work force to pharma units. Female work force constitutes a considerable chunk of the total work force.

LINKAGES WITH INSTITUTIONS AND ASSOCIATIONS

Goa is a very small State with only two districts. Put together, it may even be smaller than a big district of its neighbouring states. The geographical area of the State is 3,702 sq. kms with a population of about 13 lakhs. So, the number of technical Institutions is very less.

Directorate of Food & Drug Administration (FDA):

The Directorate of Food & Drug Administration, Govt. of Goa is a very important regulatory body for the pharmaceutical industries. It is located in Panaji- the capital of Goa. The Directorate issues licences, State GMP Certificates and WHO-GMP certificates in collaboration with Central Drug Authorities, monitors quality control through periodic inspections. As the name itself indicates, it looks after both food and drugs. The Directorate is headed by a Director. For Drug administration, he is assisted by 2 Dy. Drug Controllers, 3 Asstt. Drug Controllers, 7 Inspectors and 1 Technical Officer. The Directorate is having a Drug Laboratory with 1 Senior Scientific Officer, 1 Junior Scientific Officer, 2 Chemists and 5 Asstt. Chemists.

Goa College of Pharmacy:

The antecedents of Goa College of Pharmacy go back to the mid-nineteenth Century. In the year 1842, the Portuguese started a Higher Secondary Educational Institution named as Escola Medica De Goa for training Physicians and pharmacists. This is considered to be the oldest pharmacy institution in Asia.

In 1963, Goa College of Pharmacy was established by upgrading the old Portuguese Pharmacy to a full-fledged degree course of Bachelor of Pharmacy under the University of Bombay. Later in 1970, the college was recognised for Masters Degree in Pharmacy. The college started Diploma in Pharmacy in 1966.

Now, the College is affiliated to the Goa University and approved by Pharmacy Council of India and All India Council for Technical Education. The College is the main source of technical

manpower for the pharmaceutical industry. The College is headed by the Principal and supported by 21 faculties. The intake for D. Pharma is 60 students, for B. Pharma 60 students and for M. Pharma in Quality Assurance and Pharmacology 15 students. The College intends to start Ph.D. Programme in due course.

Goa Pharmaceutical Manufacturers Association (GPMA).

There exists a separate association of pharmaceutical industries viz., Goa Pharmaceutical Manufacturers Association. The Association has 37 members and an Executive Committee. Majority of pharmaceutical industries are members of GPMA. Some Ayurvedic and Cosmetics manufacturing units are also members of the Association. The Association does not have the Secretariat and Secretariat Staff. At present, honorary office bearers/executive committee is handling the affairs of the association. The Executive Committee is expected to meet once in a month, and Annual General Body once a year. However, it is observed that the monthly meetings are not held regularly. It is understood that, since majority of the members of the association are working managers, hardly they find any time to involve in such activities. The Association pursues with Government bodies pertaining to legal and policy matters. Sometimes, the GPMA organises seminars/workshops for its members. It is having representation in some of the Boards and committees like Labour, Excise etc.

Goa Small Industries Association (GSIA), Goa Chamber of Commerce & Industry (GCCCI) and Confederation of Indian Industries (CII), Goa State Council are the other associations in the state. Some of the pharmaceutical units are members of these associations. These associations have significant influence over the formulation of Govt.'s Policy concerning to trade and industry. They have their own secretariat premises and staff.

Indian Pharmaceutical Association (IPA): The Indian Pharmaceutical Association organises seminars and workshops of interest to pharma industry. Any Pharmacy Graduate can be a member of the Association. Entrepreneurs as well as Govt. officials are members of the Association.

Chemists & Druggists Association of Goa (CDAG): There is a Goa State Association of Chemists & Druggists affiliated with the All India Association of Chemists & Druggists (AIOCD). Wholesalers/Distributors and retail pharmacists are the members. The Prescription sales are routed through the channel of wholesalers and retailers. They receive a commission as per the DPCO. For Stockists, the margin is 8% of the MRP in case of controlled drugs and 10% in case of decontrolled drugs. For retailers, the margins are 16 and 20% of the MRP for controlled and decontrolled drugs respectively. In addition, the AIOCD charges Rs. 500/- as Product Information Service, for introduction of any new drug in the market. There are about 500 retailers and 200 wholesalers operating in the State.

Following table demonstrates the nature of linkages with the Associations

Membership to Association

Association	Membership	Percentage
GPMA	17	89
GSIA	3	16
GCCI	4	21
CII	3	16
N=19		

Out of 19 units surveyed, 17 units, constituting 89% of the units, are the members of the GPMA. Some units are members of more than one association like GSIA, GCCI and CII. There is a general feeling among the small firms that the welfare of small firms is not taken care by the GPMA.

This has led some small firms to have separate association. It is found that 8 small firms have joined and informally formed an association of their own. This is association of small/tiny firms mainly concerned with implementation of Schedule M. This association of firms says that the units neither have the resources nor the funds to upgrade their facilities. The amended schedule M requires changes in structures among other things. The existing premises do not permit them to make any structural changes, in addition to huge investments and recurring expenses. A couple of units are operating in rented premises. The association of these small firms is trying to pursue the authorities to exempt such small firms from the ambit of Schedule M. Some units among this association feel that the Schedule M should be implemented in phases. Appreciating the objective of the Govt. to provide quality drugs to the public by implementing Schedule M, some of them feel that concessions to be given to small firms.

The nature of support from the association:

The role of association is mainly concentrated in pursuing the procedure and policy matters and legal issues. All the 19 units surveyed say that the role of association is concentrated on these two issues. There is no provision of support from the association in terms of marketing, sales promotion, joint training, inputs and services. Some of these issues are not feasible to be carried on in pharmaceutical cluster.

The business linkage among the firms is only through loan licensing, wherein, the loan licensee will be utilising the excess production facility of the other unit. However, we find an interesting networking among the firms belonging to a 'group of companies'. Even though each firm is a distinct legal entity, the units in a group of companies are well networked to achieve the economies of scale. This group of companies will be having common corporate office, marketing, procurement and personnel divisions. Purchases, marketing etc are done through the centralised marketing and procurement division. Even training programmes for the workers are organised by the common personnel departments. These companies also operate on p2p basis, and the products of all

companies are marketed under single brand name. Similarly, large firms and multinationals function under their own network.

There are other Central and State Level Association like Directorate of Industries, National Small Industries Corporation, Small Industries Service Institute, etc. SISI conducts training programmes, organises seminars and workshops for the small-scale industries. SISI organised training programmes like Packaging for exports, Seminars on WTO, Intellectual Property Rights, wherein, pharmaceutical industries took part among others. NSIC also made an attempt to initiate cluster development activities and organised a seminar on CDP in December 2003 in association with Goa Small Industries Association, and made a preliminary survey. However, the initiative did not pick up the momentum.

Current level of cooperation and competition:

Competition among the firms is a necessary phenomenon for the healthy growth of industry. Information was collected from the units during the field survey about the issues of competition, and depicted in a tabular form:

Issues	Response	Percentage
Price	13	86
Brand name	13	86
Quality/technology	12	80
Cost of skilled personnel	2	13
Volume of output	10	67
Sales promotion	13	86
Prompt delivery	3	20
Common product	5	33
Fake drugs	5	33
N=15		

Price, Brand name and Sales promotion are the major issues of competition, followed by quality, technology and volume of output.

Wooing customers by unfair means (through medical practitioners), copying of product, imitation of trade mark, fake drugs and misinformation about products to customers/traders are the ways (in the order of preference) in which the competitors are doing.

During the discussions with entrepreneurs at the time of field visit, it was observed that small firms produce and market their products at competitive costs due to low overhead costs. So, there is a price-competition among small firms to market their products. But these firms are poor in brand building and not in a position to capture a sizeable chunk of the market. Fake drug is another issue of concern, especially for the large firms manufacturing branded products. During the field survey, some units disclosed that they have received complaints about fake drugs, from outside the state.

Sources of Information:

Following are the sources of information on technological change and upgradation, in case of surveyed firms: Internet, Magazines, News, Seminars are the main source of information on technological changes.

Sources of Information	Responses	percentage
Social get-together	2	13
Export Agent	1	7
Machinery Supplier	2	13
Exhibitions/fairs	1	7
Client firms	3	20
Visit to other firms	1	7
Internet/Magazines/News/Seminars	11	73
Own network of firms	4	27
N=15		

Distribution of Sales among surveyed units:

Information on sales regarding their distribution as per the region indicates that, 89% of the sales are at the National level. Local sales (within the state) account for about 8%, while exports are hardly 1%. The low level of sales within the state is mainly due to the fact that, Goa is a very small state, with limited market. It was found that the percentage of sales within the State is more for small and tiny firms, whereas, it is negligible for medium and large firms. The percentage of exports to total sales will be, however, more for the cluster as a whole, because percentage of large firms is more.

Market	% of sales
Local	8
National	89
Export	1
Total	100
N=19	

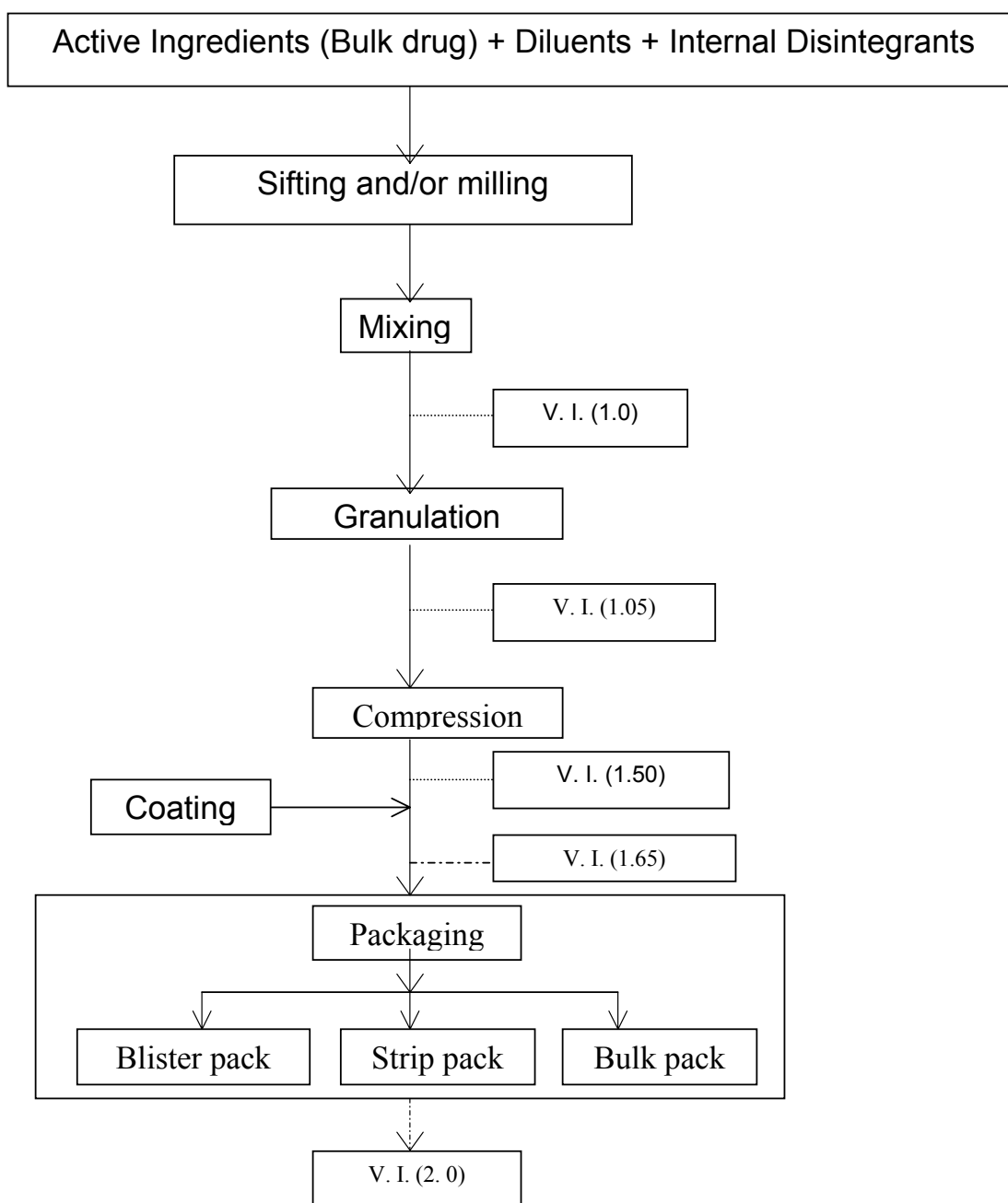
The above figures are with regard to surveyed units only. Sales within the State for the cluster as whole form a negligible part of total sales, for the obvious reason that the state is very small. The percentage of exports is only 1% because, the sample mainly consists of small firms with no exports. However, medium and large firms are in to export and it is estimated that exports to total sales will be over 20%. Even sales within the State forms a negligible part for the cluster as a whole, even though it is 8% in respect of surveyed units.

From the analysis of business linkages and linkages with the Institutions as above, the emerging cluster map is depicted in the as enclosure. The thick line shows the strong linkages whereas the dotted line signifies weak linkages with the units.

VIII. VALUE ADDITION (MANUFACTURING PROCESS) IN FORMULATIONS

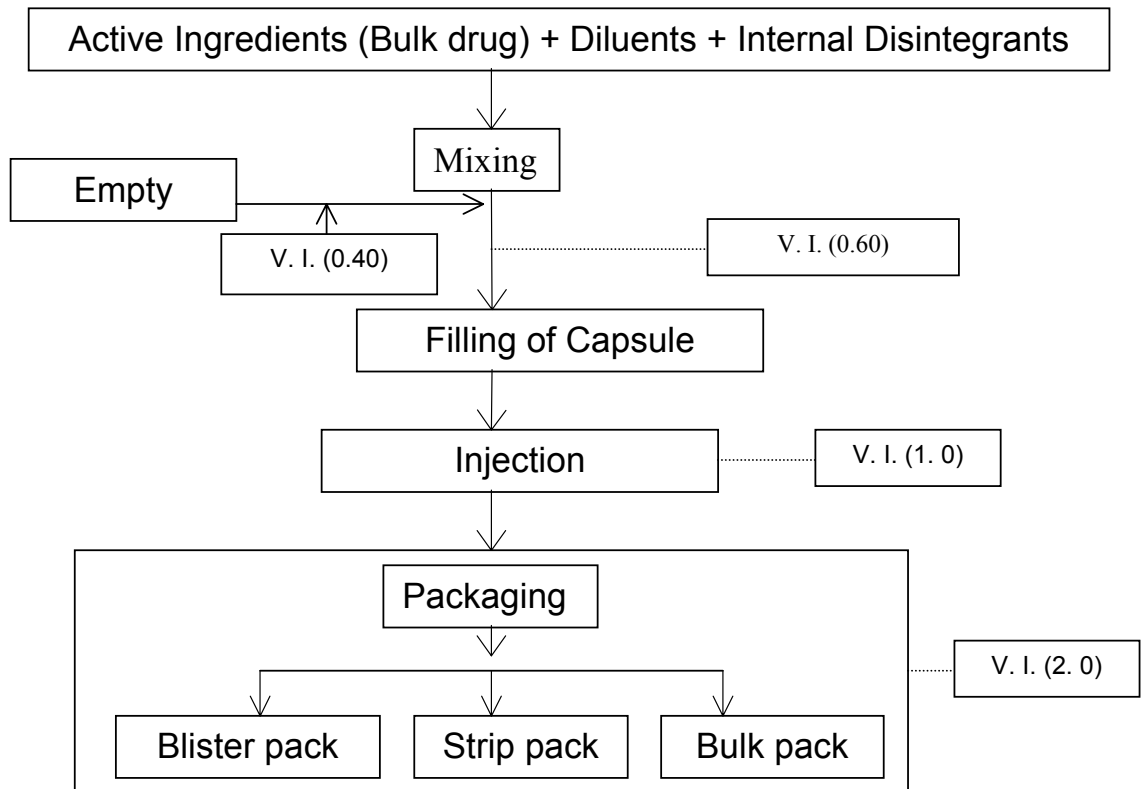
The Value Index for various formulations, viz, tablets, capsules, Liquid orals, injectibles and ointment, given below is only illustrative to give a broad idea about value addition taking place at different stages of production. The exact value addition depends on the nature of basic molecule used for formulation, nature and type of packaging material used.

I: TABLETS

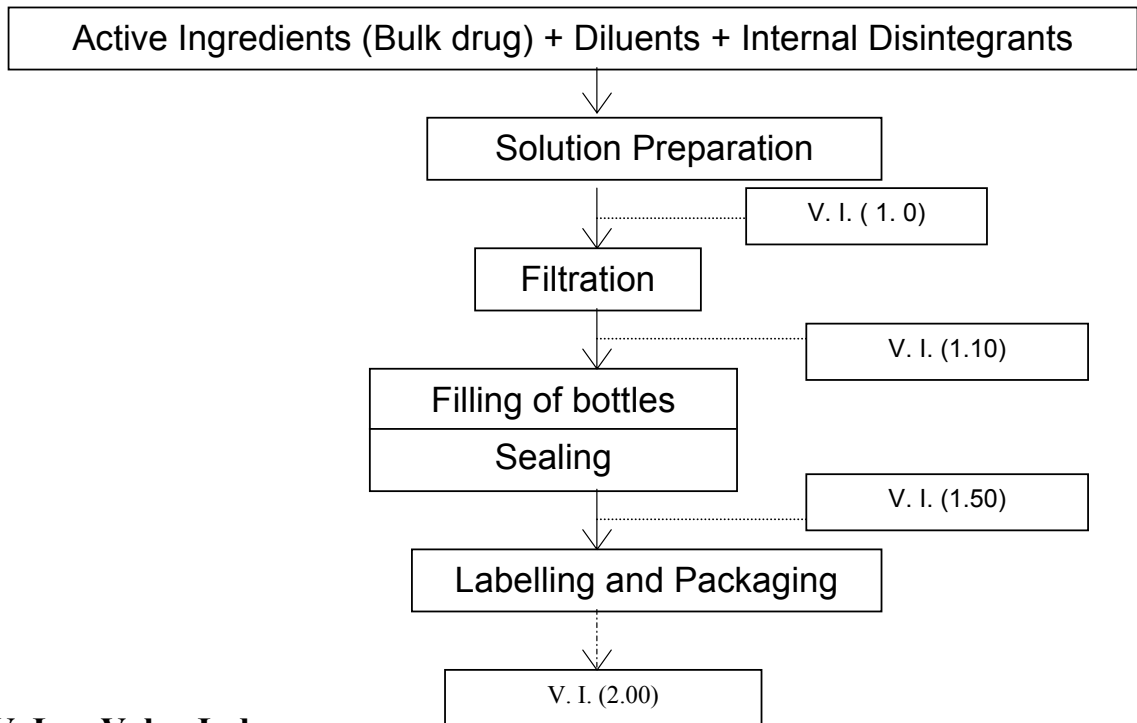


V. I. = Value Index

II: CAPSULES

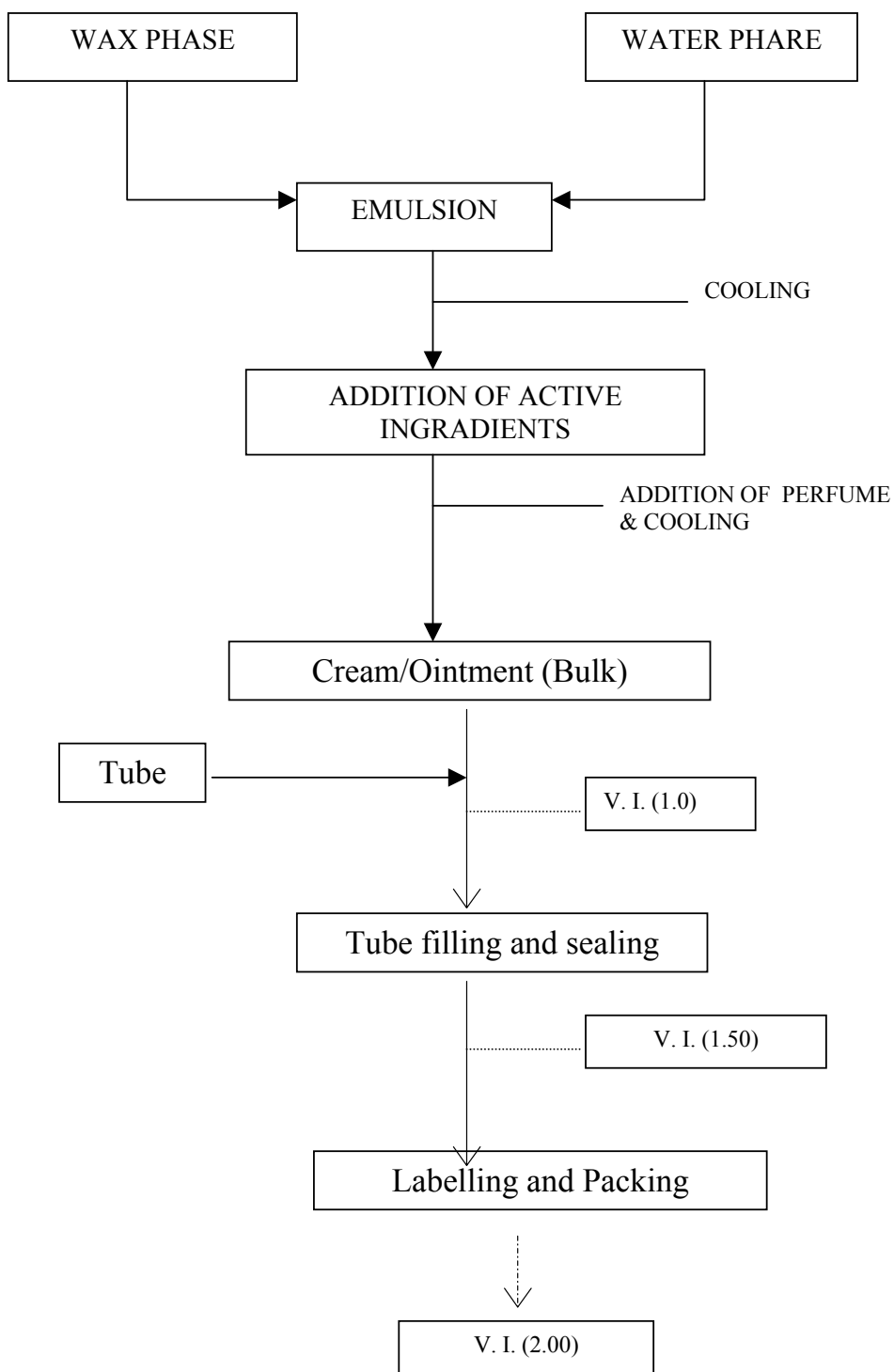


III: LIQUID ORALS



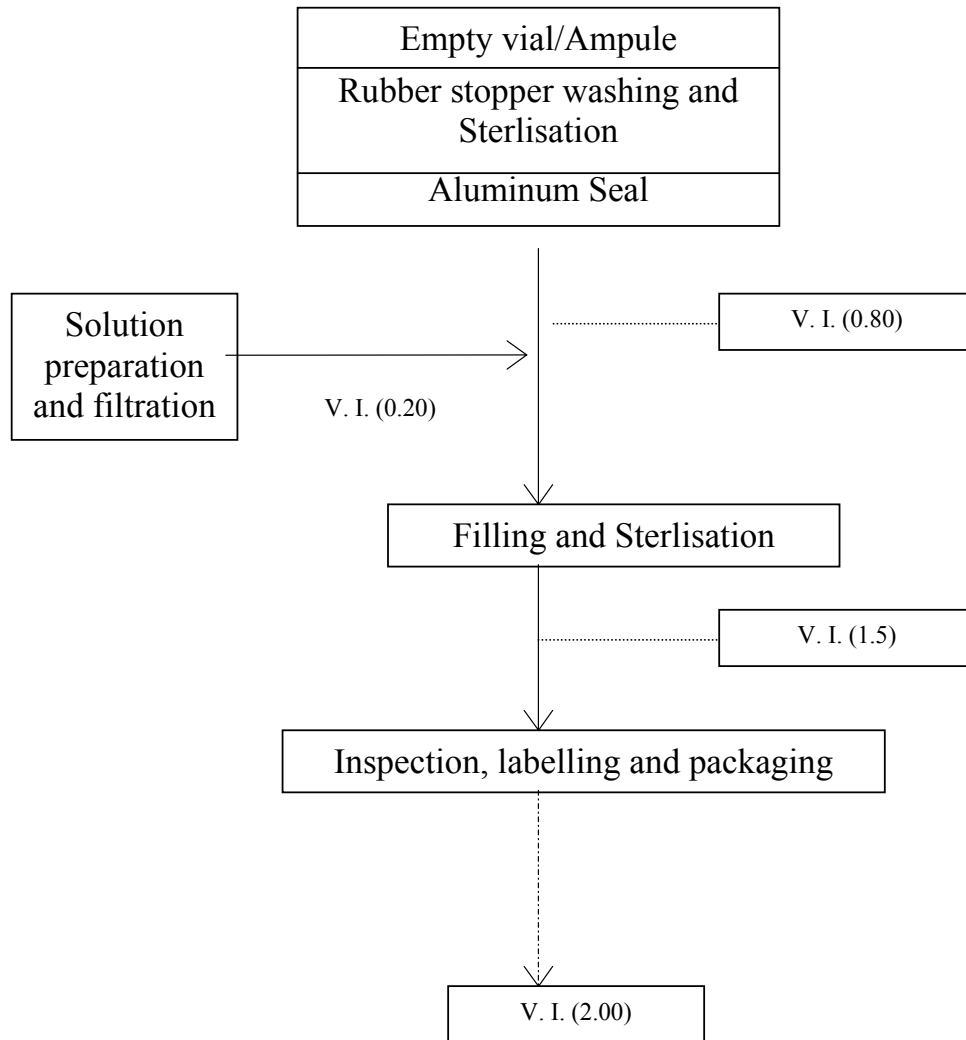
V. I. = Value Index

IV: OINTMENT



V. I. = Value Index

V: **INJECTABLES**



V. I. = Value Index

IX. ISSUES OF MAJOR CONCERN

Quality upgradation as per Schedule M of Drugs and Cosmetics Act, 1940:

Quality is of prime importance for the pharma industry and products manufactured are expected to be of high standard. Any compromise in quality of the product will adversely affect the health of the consumer. Therefore, for ensuring quality, the units have to follow good manufacturing practices as laid down in Schedule M of the Drugs & Cosmetics Act, 1940. The Central Govt. has revised the Schedule M to get it harmonised with that of the various developed and developing countries and also to the level of well established international organisations like WHO.

The Schedule M classifies various statutory requirements mandatory for pharmaceutical manufacturing relevant as per the Good Manufacturing Practices (GMP). The deadline for adhering to Schedule M is 1st January 2004. Before that, all firms have to upgrade their production facilities.

Quality standards for the cluster as whole are in tune with international standards. About 75% firms are WHO-GMP compliant. Some big units have got US-FDA and UK MCA certifications. And most of the WHO-GMP firms will be compliant with the revised schedule M specifications. Some of the non-WHO-GMP firms are in the process of upgrading their production facilities as per amended schedule M. However, Small and tiny firms are facing a very serious problem in this regard. Adhering to Schedule-M, involves huge expenditure and recurring expenses and modifications in the production facilities. Large & medium firms and multinational companies have their production facilities in tune with Schedule M requirements. But small firms, even though their number is very small, are in the doldrums. About 10-12 small firms in the cluster are facing this problem. The main problems in adhering to Schedule M are:

Huge investments to upgrade the production facilities, modifications in the premises. The condition is worse for a couple of units operating in the rented premises. There are a couple of units with an annual turn over of less than Rs. 15 lakhs operating in very small and compact premises. Neither they have the space to carry out modifications nor they have financial resources.

Some entrepreneurs feel that, the value of plant and machinery for the purpose of SSI limit be raised to a minimum of Rs. 5 Crore for pharma industries from the present Rs. 1 Crore, in view of implementation of Schedule M.

For small firms, it is generally felt that, even soft loans are made available and subsidies are offered to upgrade their facilities conforming to Schedule M, the unit will become economically non-viable. The reasons mentioned being: the additional cost incurred cannot be recovered due to price competition and control of prices through DPCO. The Government's commitment to upgrade the quality of drug to the international level and social approach to the pricing of drugs affordable to the general public, with socialistic approach are contrasting. One entrepreneur, with turnover of Rs. One crore pointed that, it requires a capital investment of about Rs. 45 lakhs to make changes as

per Schedule M requirement. In addition, there will be recurring expenditure in lakhs of rupees, only additional electricity charges accounting for about Rs. 60,000/- a month. Hence, closure of the unit is the ultimate result.

Neither the entrepreneurs (some among surveyed units) are inclined to hire Common BDS providers. They feel that, requirements in Schedule M are clearly spelt out and they themselves are competent enough to make their units conforming to Schedule M requirements. The main issue is viability of the unit, which is as good as setting up of a new manufacturing plant, in some cases.

In fact, a group of 8 small firms have informally formed an association, to make a collective representation to the Govt. both the State and the Central, regarding difficulties in implementation of Schedule M. They are pursuing the Govt. agencies that the provisions of Schedule M should not be made applicable to small/tiny firms.

All small firms are hoping that the deadline for Schedule M will be deferred, at least for the time being, for about 2 years. Almost all firms are following the wait and watch policy.

Testing Facilities:

Another issue of concern to small and medium firms is with regard to Testing Laboratory. There is no public testing laboratory in the state. All large firms are having their in-house testing facilities and rarely send their samples for outside testing, to places like Mumbai, Bangalore, Hyderabad. But the frequency is very less. Even small firms do have their in-house testing facilities for regular testing. As some of the tests require installation of costly equipments, they send their samples outside the State. However, number of firms requiring testing facilities is so small that the viability of setting up of a common testing facility, prime fascia seems to be dismal. A lot of technical issues are also involved, in setting up of common testing laboratory and running it by the Industry Association. Some entrepreneurs feel that the information on ingredients/additives used in the product will be divulged, once the testing is being done in the Laboratory run by Industry Association. This may work disadvantageous to the commercial interest of the unit in question, as the information will be leaked to the competitors.. A techno-economic and techno-feasibility study needs to be undertaken, by a research institution of repute to study the viability of a testing laboratory.

Some units say that, as per schedule M, all the testing facilities should be in-house. If that is the case then there is hardly any chance for a testing laboratory.

New patent Regime:

There is going to be radical change in the patent regime with India becoming member of the WTO. India has to be TRIPs compliant by 2005, by changing from process patents to product patents. Under the Product patent system, EMRs will be given to the companies filing patents, and no other company can manufacture and market the patented products. This will be a serious issue for the

Indian companies, as they have a very weak patent base. However, entrepreneurs are not that much concerned about this fact. This is because many products, worth millions, will be going to be off-patent and thus Indian companies can concentrate on generic market. However, there is need for the Indian Companies to concentrate on R&D activities to expand its business.

SPURIOUS DRUGS:

Another major issue of concern not only for the pharmaceutical industry but also for the general public as a whole is the menace of spurious or fake drugs. The problem of fake drug has becoming an issue of prime concern, especially for large firms making branded-fast moving products. The menace is posing severe threat to the credibility of pharma companies and playing with the life of consumers. It is reported that the mafia is worth Rs. 4,000 crore. In order to counter the problem of fake drugs, many companies are adopting preventive measures. The Associated Capsules Group, the Mumbai based manufacturer of empty gelatin capsules, have introduced oriented circular two-colour printing of capsules to help consumers to distinguish genuine from the fake. The traditional method was linear printing of the brand and the manufacturer's name on the capsules. The new technique is called brand shield- a high tech, complicated and expensive process, which the mafia would not be able to duplicate. Now, brand shield is being used by over 300 companies, including Glaxo, Medley, Neimeth, Lupin, Cadila, Jackson and Pfizer. E-Merck, for example has devised a unique design-a different type of cap on which the company's name and the product's name are engraved in various colour combinations- for the bottles of its vitamin syrups, particularly the fast moving Polybion. Now, Indian Companies are using two dimension and three dimension holograms. In the west, pharma giants have gone in for high cost and high quality packing, which cannot be duplicated without investing huge sums. Some of them are using aluminum foil packing which are ten times more expensive than the traditional packing. Indian Companies are looking at this option. The fake drug manufacturers reportedly located mainly in the North Indian States of Delhi, Bihar, Uttaer Pradesh, Haryana and slowly spreading to Madya Pradesh, Himachal Pradesh, Rajasthan and punjab.

Non-availability and high cost of essential and life saving drugs is another factor attributed to the growth of fake and spurious drugs and the Government should look into this aspect. Stringent action against the offenders is another measure to check the fake drugs, for this a concerted effort from the pharmaceutical companies, drug authorities and enforcement wings is urgently needed. According to Dr. RA Mashelakar, Director General of CSIR, '... penalties to be sure, swift and severe. Today fines are as less as Rs. 10,000/-, which is definitely not fair, considering the problem. ... it should be a minimum of Rs. 1 lakh or three times the value of goods confiscated. To make it more severe, we also suggested the death penalty because these are habitual offenders.'

X. SWOT ANALYSIS

Strengths:

- Conducive Policy Environment with incentives and concessions for new investment
- Developed Industrial Infrastructure including availability of power, water etc.
- Peaceful Social Climate
- Existence of Packaging industries
- Network of transport facilities- Road, Railway and Air
- Presence of Banks and financial institutions

Weaknesses

- Outsourcing of raw material
- Weak Association Base
- Absence of R&D facilities and Public Testing Laboratory
- Weak capital base of small firms for quality upgradation
- Production of spurious/fake drug- major problem for large firms making branded products
- Lack of exposure to export marketing for small firms

Opportunities

- Expanding demand both in the domestic and international market.
- Expansion of Generic market with drugs worth millions are going to be off-patent
- Development of R&D facilities
- Developing consortium of small firms for exploring export marketing

Threats:

- Product Patent regime w.e.f. 2005
- Quality upgradation as per Schedule M requiring initial investment and recurring cost, especially for small firms
- Ceilings on product prices and profitability preventing the companies from generating investible surplus
- Procedural hurdles for export marketing
- WTO led global trading system to lower the import-tariffs, paving the way for cheap imports and thereby price competition. This will lead to reduction in profits by domestic firms.