

DRAFT DIAGNOSTIC STUDY REPORT

**PHARMACEUTICAL CLUSTER
HYDERABAD, AP**

Submitted to

**PMD DIVISION
SMALL INDUSTRIES DEVELOPMENT BANK OF INDIA**

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BY



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Abbreviations & Acronyms

APIIC	Andhra Pradesh Industrial Infrastructure Corporation Pollution Control Board
APPCB	Andhra Pradesh Pollution Control Board
APSFC	Andhra Pradesh State Finance Corporation
BDS	Business Development Services
BDSP	Business Development Service Providers
BDMA	Bulk Drugs Manufacturers Association
CCMB	Center for Cellular and Molecular Biology
CDM	Clean Development Mechanism
CETP	Common Effluent Treatment Plant
cGMP	Current Good Manufacturing Practices
Col	Commissioner of Industries
CRAMS	Contract Research And Manufacturing Services
CRM	Customer Relation Management
CTL	Common Testing Labs
DIC	District Industries Centre
DFID	Department of International Development, UK
DMF	Drug Master File
DOD	Department of Drug Control
ESR	Enterprise Social Responsibility
FACCI	Federation of Andhra Pradesh Chamber of Commerce of India
FCs	Financial Consultants
FIs	Financial Institutions
GMP	Good Manufacturing Practices
GLP	Good Laboratory Practices
GOI	Government of India
GTZ	Deutsche Gesellschaft Fur Technische Zusammenarbeit German Technical Cooperation
HCU	Hyderabad Central University
ICT	Information Communication Technology
IDA	Industrial Development Area
IE	Industrial Estate
IICT	Indian Institute of Chemical Technology
IPR	International Patents Regulations
KFW	Kreditanstalt Fur Wiederaufbau (a Development Bank owned by the Government of Germany)
MSME DI	Micro Small And Medium Enterprises Development Institute
NAC	National Academy of Construction
NDMA	Nalgonda Drugs Manufacturers Association
NIN	National Institute for Nutrition
NIPER	National Institute Of Pharmaceutical Education & Research
NSIC	The National Small Industries Corporation Ltd
OPM	Organisation of Pharmaceuticals Manufacturers
OU	Osmania University
PACA	Participatory Appraisal for Competitive Advantage
PASS	Pashamylaram Area Service Society
Pharmexcil	Pharmaceutical Export Council
PTL	Public Testing Laboratories
SME	Small & Medium Enterprises
SIDBI	Small Industries Development Bank of India

Executive Summary

With intent to facilitate increased flow of credit to MSMEs and support other developmental initiatives, SIDBI is implementing a multi-agency / multi-activity flagship project on financing and development of Small and Medium Enterprises in India.

The objectives of this Project is to, inter-alia, improve MSME access to finance (including term finance) and market oriented BDS, thereby fostering MSME growth, competitiveness and employment creation. The project is designed to achieve this objective through a multi-pronged approach that will address key bottlenecks to MSME financing and development in India.

APITCO has emerged as preferred bidder for Pharmaceutical sub-sector by SIDBI-PMD after evaluating the competencies of the organization in technical and commercial areas. The total project period is 32 months.

As a part of pre-implementation phase the core team of APITCO, comprising of cluster manager, net work expert and subject expert, besides HO team officials, have conducted a detailed diagnostic survey in cluster, through detailed questionnaire survey of core cluster firms and BDS providers, interviews with support institutions and focus group discussions with associations, workers. The primary and secondary data thus collected was compiled and a comprehensive analysis was made regarding status of the cluster, BDS providers, key issues and required interventions. Based on the compiled data and analysis a draft DSR was thus prepared as per the specification given by Monitoring & Evaluation Agency which is to be submitted to SIDBI.

Status of the Cluster

Table shows details of SMEs with ownership, capacity, investment, employment and turnover details in Hyderabad Pharma cluster: **(Rs. In Crores)**

S.No	Type of Manufacturer	Type of firm	No. of firms	Ownership				Invest	Emp	T.O.
				Pvt	Pub	Par.	Pro..			
1	Bulk Drugs	Small	86	56	-	25	5	344	3500	1462
		Medium	180	150	30	-	-	1620	12000	5400
2	Formulations	Small	75	-	-	45	30	187	2000	675
		Medium	50	40	-	10	-	275	2500	650
Total			391	246	30	80	35	2426	20000	8187

(T.O.: Turnover, Emp: Employment, Invest: Investment, Pro: Proprietary, Par: Partnership, Pub: Public, Pvt: Private)

Cluster Snapshot

<ul style="list-style-type: none"> ➤ Hyderabad – the Bulk Drug capital of India ➤ It's a naturally evolved Cluster ➤ Shares 90% of the total bulk drug production of A.P. ➤ Age of the Cluster around 25 years ➤ Hyderabad Bulk Drugs are export oriented 	
<ul style="list-style-type: none"> ➤ Cluster Spreads in (Hyderabad, Nalgonda, Rangareddy & Medak Dist.) 	: 60 kms radius
<ul style="list-style-type: none"> ➤ Product Mix 	<ul style="list-style-type: none"> a) Bulk Drugs (Active Pharma Ingredients) b) Formulations (Capsules, Tablets, Syrups, Orals, Ointments, Injectibles)
<ul style="list-style-type: none"> ➤ Total No. of units <ul style="list-style-type: none"> a). Bulk Drugs b). Formulations 	: 391 : 266 : 125
<ul style="list-style-type: none"> ➤ Aggregate employment 	: > 20000 persons
<ul style="list-style-type: none"> ➤ Total investment of the pharma SMEs 	: Rs. 2426.5 Crores
<ul style="list-style-type: none"> ➤ Estimated turnover of the Cluster <ul style="list-style-type: none"> a). Bulk Drugs Manufacturing b). Formulations 	: Rs.8187 Crores p.a. : Rs. 6862 Crores p.a. : Rs. 1325 Crores p.a.
<ul style="list-style-type: none"> ➤ Major Stakeholders 	<ul style="list-style-type: none"> • Bulk Drug Manufacturers • Formulations Manufacturers • Government & support Institutions • Raw material suppliers, M/C suppliers, Support Firms & Financial Institutions and bankers
<ul style="list-style-type: none"> ➤ Major BDS Providers 	<ul style="list-style-type: none"> • GMP Consultants, Technology Consultants, Transporters, Energy and environment consultants, Lean Consultants, ICT consultants, Safety Consultants, IICT, Testing Labs, CCMB, NIPER, HCU etc.

Overview of BDS Services

Cluster has grown with the help and support from the Business Development Consultants in and around Hyderabad. There is a large market potential for BDS. Some of the BDS providers are established as consultancy organizations and some as professionals, who work as individual consultants. Most of the pharmaceutical units prefer experts in each domain to solve their problems than to deal with a single BDS provider.

A few of the BDS providers are more expensive as small enterprises cannot afford the fee. It is a major problem in the Hyderabad pharmaceutical cluster (mainly for small units). There is a need to develop BDS services to reach the small units.

Demand side constraints

- High cost of Business Development Services
- Poor networks among the units resulting in lack of utilization of services
- Fear of leak of technical know how

Supply side constraints

- Weak penetration of BDS providers due to poor marketing techniques.
- Information of services not known to the units as specially regarding individual consultants.
- BDS providers are preferred to cater to large & medium units

Key issues and suggested interventions:

S.No.	BDS Area	Key interventions	Suggestive Interventions
1	Quality	Poor adoption of GMP practices by majority of the firms	<ul style="list-style-type: none">• Interface with GMP consultants• Organize pilot quality audits
2	Finance	Poor credit facility to tide over any urgent / short term financial requirements	<ul style="list-style-type: none">• Organizing Bankers meet
3	Energy Management	Poor adoption of energy saving measures	<ul style="list-style-type: none">• Organizing workshops on energy efficiency• Organize pilot energy audits

S.No.	BDS Area	Key interventions	Suggestive Interventions
4	HRD	Limited availability of Skilled man power	<ul style="list-style-type: none"> Organize skill development programmes in the areas of quality assurance, quality control, production etc Linkage with ITI / technical educational Institutions
5	Pollution & waste management	Problem in disposal of hazardous waste and effluents	<ul style="list-style-type: none"> Organize training programme on pollution and waste management Organize water audits on pilot basis
6	Information Communication Technology (ICT)	<ul style="list-style-type: none"> Lack of awareness on advanced usage of software Low computer literacy levels 	<ul style="list-style-type: none"> Organize training programmes on usage of software applications
7	Safety	Non compliance to safety standards in handling of hazardous waste	<ul style="list-style-type: none"> Organize awareness programmes on safety standards
8	Marketing	<ul style="list-style-type: none"> Limited access to export market 	<ul style="list-style-type: none"> Interface with market consultants Participating in trade fairs Creation of web portal and BDS directory
9	Raw Material (RM)	<ul style="list-style-type: none"> Few basic raw material and excipients sourced from imports are very costly and faces its quality & timely delivery Scarce quality water required for either processing or purification of the final drug substance. 	<ul style="list-style-type: none"> Facilitate to create raw material bank for essential and regular raw materials Facilitating supply of treated or potable water
10	Technology	Non availability of literature and facing problem in literature search	<ul style="list-style-type: none"> Sensitize to create an online search facility for journals like SCI finder

Chapter - 1 Introduction

MSMEs play a vital role in the Indian economy. The sector has proved to be appropriate to address the national priorities of employment, removing poverty and regional imbalances. Government of India has been taking proactive steps in the direction of strengthening the competence of Indian MSMEs. The Tenth five-year plan of the Government placed heavy reliance on the MSME sector for achieving various growth parameters. Recently notified MSME Act 2006 has been another proactive step in creating enabling environment.

1.1 Project background

With the intent to facilitate increased flow of credit to MSMEs and support other developmental initiatives, SIDBI is implementing a multi-agency, multi-activity flagship project on financing and development of Small and Medium Enterprises in India.

The project covers number of sub sectors like Engineering, Carpets and Floor covering, pharma, etc. to cover the project implementation SIDBI has selected experienced facilitators for which sub sector through a tender process.

APITCO has emerged as the preferred bidder for Pharmaceutical sub-sector after evaluation of its competencies by SIDBI-PMD in technical and commercial areas. The total project duration is 32 months and is planned to be implemented in the following phases:

a). Pre Implementation Phase

- Establishment of Project Office with necessary infrastructure
- Preparation of Diagnostic Survey Report
- Preparation of Action Plan
- MoUs with Network Partners

b). Implementation Phase

- Implementation of the activities as per the action plan

c). Sustainability Phase

- Assuring sustainability of interventions
- Setting-up of National and International regulatory requirements through current Good Manufacturing Practices (cGMP), Systems & Processes in-place.

d). Exit Phase

- Formation and strengthening of Governance mechanisms for sustainability of interventions
- Project Impact Assessment & Preparation of End of Project Report (EOR)

1.2 Methodology

As part of the pre-implementation phase, the Core Team of Hyderabad Pharmaceutical Cluster with the support of Project Manager and other In-house consultants has conducted a rapid Diagnostic Survey and prepared the Diagnostic Study Report as per the guidelines given by MSME Foundation for Cluster Development, the Implementing and Monitoring & Evaluation Agency.

The following methodology is followed for preparation of the Diagnostic Study Report.

- a) Collection of secondary data
- b) Collection of primary data
- c) Data processing and analysis
- d) Preparation of draft report

40 cluster firms from manufacturers of bulk drugs (APIs), formulation, intermediates, 8 BMOs and 22 BDSPs were contacted and detailed interactions were held. The outcome of the interactions has helped in understanding the working of the SMEs, their turnovers, total number of personnel employed, their product mix, industry and institutional linkages, key issues affecting their growth, mode of marketing of their products, etc.,

Chapter 2 Frame work

2.1 The cluster

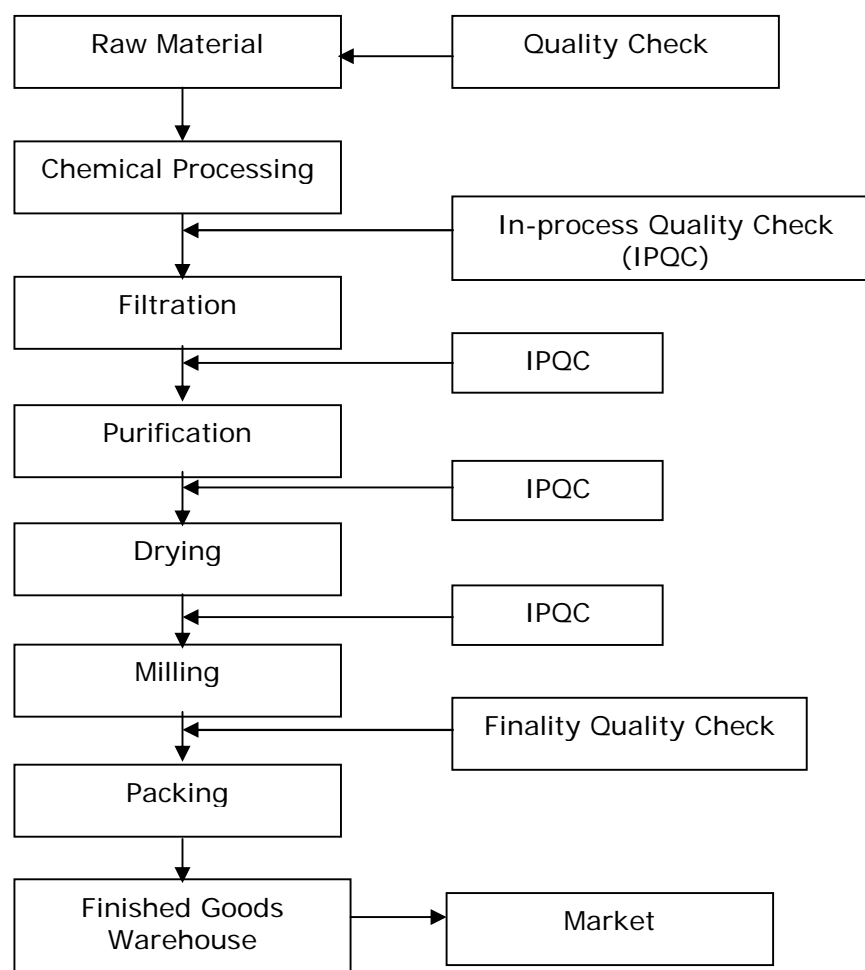
The pharmaceutical cluster of Hyderabad is located in and around Hyderabad city and is spread in a radius of 60 kms in the adjacent districts of Rangareddy, Medak and Nalgonda. The cluster has 125 formulation (F) and 266 bulk drug manufacturing (BDM) units in SME sector. Bulk drugs are active pharmaceutical ingredients (APIs) and formulations are tablets, syrups, capsules, ointments, etc. Location map of the cluster appears as annex 1.

2.2 Production process

2.2.1 Bulk Drug

Bulk drug manufacturing process comprises of 9 stages starting from raw material procurement to dispatch to the market.

Flow Diagram for Bulk Drug Manufacturing



The step – by-step manufacturing process is as follows:

Raw Materials: All raw materials – solvents, catalysts and other chemicals are procured from approved vendors. Material received in the ware house are tested as per set standards and prescribed test procedures. Approved materials are shifted to designated areas whereas the rejected materials are sent back to the vendors.

Chemical Processing: All approved raw materials are charged into a reactor for chemical processing. Depending on the product, the duration, the type of reaction is altered. After completion of chemical processing, the reaction is stopped.

Filtration: The reaction mixture from the previous stage is filtered through suitable filtering equipment to separate drug substance from the liquid chemicals. The solid drug substance is taken for further process.

Purification: The wet crude drug substance obtained from the previous stage is subjected for purification to obtain the pure drug substance which must meet to the set standards.

Drying: The wet pure drug substance obtained in the previous stage is dried at suggested conditions to obtain dried pure drug substance.

Milling: The dried pure drug substance obtained from the previous stage is milled to obtain drug substance in the powder form.

Packing: Activity of packing consists of two levels – Primary packing and secondary packing. Powdered pure drug substance obtained from the previous stage is packed in the primary packing material finally and in secondary packing material. The primary packing material is normally poly bags and secondary packing materials normally are either fiber drums or HDPE containers. After packing in the secondary packing material, proper label is affixed with all particulars such as name of the product, batch no, expiry date, etc. During packing operation in-process testing is undertaken for weight, etc.

Finished Goods ware house: After completion of packing, the sample taken from the product is subjected to a complete testing, on approval the lot is transferred to finished good ware house for onward market transmission

Marketing: Depending on the organization, they may market their product either through direct marketing or through trader network.

2.2.2 Formulations

2.2.2.1 Tablets:



Tablet manufacturing, starting from raw material procurement to dispatch for marketing, involves 10 stages. As per the regulatory requirements, all the incoming raw materials are to be tested to set standards and as per prescribed procedures. The approved materials are charged into a mixing machine for dry mixing.



The dry mixed raw materials Binding agents are added to make dough. The dough is spread on trays for drying. Dried material is milled to obtain granules. To these granules, preservatives, lubricants are added and mixed. These final granules are charged to tableting / compression machine to produce tablets. These tablets are tested before proceeding for final packing. Packed product finally dispatched for marketing.

2.2.2.2 Capsules :



Capsules manufacturing, starting from raw material procurement to dispatch for marketing, involves 11 stages. As per the regulatory requirements, all the incoming raw materials are to be tested to set standards and as per prescribed procedures. The approved materials are charged into a mixing machine for dry mixing. To the dry mixed raw materials binding agent is added to make a dough. The dough is spread on trays for drying. Dried material is milled to obtain granules. To these granules, preservatives, lubricants are added and mixed. These final granules are filled in the empty gelatin capsules. Capsuling is done in an automatic/semiautomatic process. After filling, the same are subject to polishing to remove adhered materials and give a glow. Then these capsules are tested before proceeding for final packing. This finally packed product will be dispatched for marketing. (A sample of each batch is retained as 'retained samples' for any future cross reference).

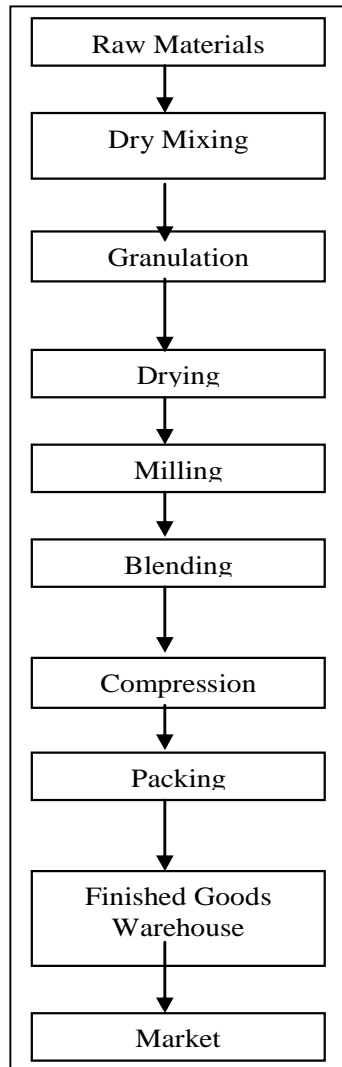


2.2.2.3 Liquid orals.

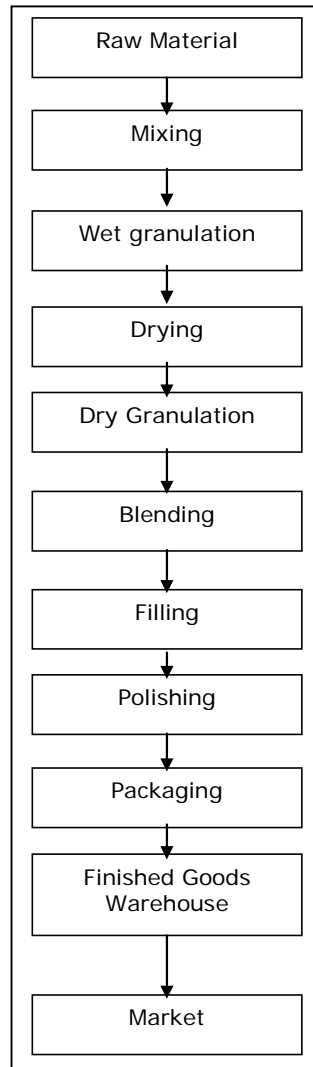
Liquid syrup manufacturing, starting from raw material procurement to dispatch for marketing, involves 9 stages. As per the regulatory requirements, all the incoming raw materials are to be tested to set standards and as per prescribed procedures. In a tank, prepared sugar syrup / take sweetening agent such as liquid glucose, sorbitol, etc., to sugar syrup/ sweetening agent, add the approved materials and mix. After completion of mixing, fill into a washed & dried bottles, sealed the cap, affix the label and proceed for final packing. Finally approved product will be dispatched for marketing.

The flow charts of manufacturing tablets, capsules, and liquid orals are as below.

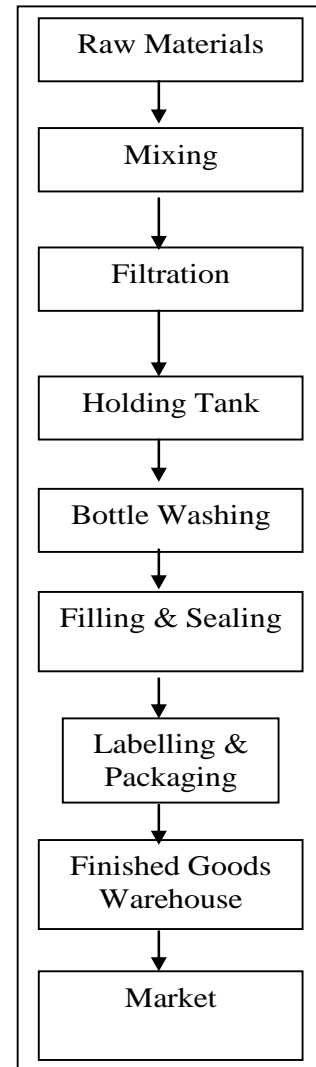
Tablets Mfg. Process



Capsules Mfg. Process



Liquid Orals Mfg. Process



2.3.1 Milestones / Turning Points

- The key factor for the growth of drugs and Pharma industry in Andhra Pradesh was the establishment of Indian Drugs & Pharmaceutical Ltd. (IDPL), by the Govt., of India with a main aim of providing essential drugs at a competitive cost. IDPL acted as the incubator for the growth of technical manpower, many of whom graduated as successful entrepreneur.
- Services of reputed scientific & research institutions such as Centre for Cellular and Molecular Biology (CCMB), Indian Institute of Chemical Technology (IICT), University of Hyderabad, Osmania University, etc, were made available for the industry for its rapid growth in the area of pharmaceutical sector. These institutions also gave birth to pharma entrepreneurs.
- In 1977 the government of Andhra Pradesh established an industrial estate at Jeedimetla to develop ancillary units for IDPL. This started off a growth phase of the pharma cluster here. This along with the shift from product process patent during the 70 by the government gave a big boost to the growth of drugs and pharmaceutical industry in the region too.
- The proactive steps and availability of infrastructure has attracted lot of technical talent into the industry. The units started in small way and graduated to the next level by recruiting technically qualified personnel to promote the industry in a big way, resulting in establishment of large firms.
- Dr. Reddy's Lab , Aurabindo Pharma , Natco, Divi's Lab, Matrix, Suven Pharma, Vimta Lab, Neuland Laboratories are now internationally recognized names concentrating on bulk drug, drug formulations , generics and CRAMS. Bharat Biotech and Shanta Biotech are two leading pioneers that have developed and marketed several vaccines replacing high cost MNC products. Suven has emerged as a contract R&D focused company; Divi's Lab produces of a range of generic active pharmaceutical Ingredients (APIs), intermediates for generics and also does, custom synthesis for MNCS and peptides and contract manufacturing. Matrix is an API manufacturer with focus on central nerve system (CNS), anti-retroviral, Anti – fungal and anti histamine drugs. Natco Pharma Company has taken to three speciality

segments of anti – migraine, anti – depressant ant anti – cancer. Generic players in advanced markets such as the US and Europe are now looking at reshaping their own models to source from independent API manufactures in India

- Large of late number of current MSME entrepreneurs here are technocrats who have working experience with large or medium pharma firms and organizations. With large number of technocrats starting small and medium pharma firms the growth spread to newer industrial areas in and around Hyderabad.
- Post 2004, the cluster faces a shift challenge as the country has once again resorted to product patent as India is a signatory to WTO norms.

2.3.2 Overview of Past and Ongoing Interventions:

GTZ has organized the following training programmes / work shops/ interaction Meets in Hyderabad Pharma Cluster:

- Participatory Appraisal for Competitive Advantage (PACA) with SMEs and their Associations
- Institutional Initiatives for Pharma MSME Exports
- Customer Relation Management Training
- Export Market Facilitation event
- Seminar On Performance Improvement On six Sigma Implementation
- Workshop for Financing of Pharma Entrepreneurs
- Workshop Financial Consultants

Table 1: GTZ Intervention in Cluster

Area wise intervention	Agency	Agenda	Outcome
Lean manufacturing	GTZ	The value adding activities remain as before, only waste is minimized.	GTZ identified 3 units for implementing lean manufacturing practices on pilot scale. The intervention was successful in all the units. Scope for upscaling

GMP Compliance	GTZ	Addresses the quality compliances and implementation of current good manufacturing practices (cGMP) in SMEs.	GTZ worked with 5 units each at Pashamylaram and Nalgonda Industrial Areas to meet Schedule – M complaint. Out of 10 units, 6 units obtained Schedule – M certification and rest due to their internal reasons has not applied for certification Scope for up scaling
Energy Management	GTZ	Initiated awareness creation in energy audit for energy management	Unfinished Scope for upscaling
Pollution	GTZ	Common treatment plant in Nalgonda Industrial Area.	GTZ assisted for the formation of SPV. The report by a consultant has been submitted to Andhra Pradesh Pollution Control Board (APPCB) for its approval Scope for completion
Information Communication Technology in SMEs	GTZ	Sensitized unit holders towards ICT applications and implementation under process.	GTZ assigned M/s Santa Soft to assess the ICT interventions in SMEs. The assessment report was submitted to GTZ. Scope for upscaling
Marketing	GTZ	GTZ has sensitized the field consultants towards Pharma marketing requirement	Unfinished Scope for upscaling

Financial Assistance	GTZ	GTZ had sensitized the financial consultants towards financial assistance & schemes with financial Institutions & Banks.	Created awareness of the Banks & FIs towards understanding the requirements of Pharma industry. SBI released a financial product with the name "VITA-M" a special package to Pharma SMEs to update their facilities requires to meet the GMP compliances. Scope for upscaling
BDS Providers Linkage	GTZ	Sensitized and identified certain Business Development Service Providers in the cluster. Provide Linkage with some cluster firms	GTZ is introducing an innovative concept of formation and registration of combined services of BDSPs under one-umbrella called CAPSULE (Consortium of Service Providers for Up gradation on enterprises). Now GTZ submitted documentation for the registration of the CAPSULE. It is under process. Scope for upscaling
Infrastructure	HPITL	HPITL is a Special Purpose Vehicle (SPV) for the development infrastructure in the specific areas of Pharma Cluster under IIUP scheme with a budget of Rs. 66.6 Crores.	Up gradation facility of Jeedimetla Effluent Treatment Plant is in progress Setting up common Testing Laboratory and HRD training Centers at Jeedimetla Industrial Area is in progress Laying 22.5 kms pipe lines from Patancheru to Balanagar for the disposal of treated effluents , is under progress Development infra like roads/drains in Jeedimetla, Pashamylaram, Uppal, Kazipally industrial Areas is in progress

2.4 Global, National Scenario and features of Benchmark Cluster:

2.4.1 Global Scenario

Although the origins of the modern pharmaceuticals industry can be traced back to the late 19th century, the real development started in 1960^s due to some new and innovative discovery with permanent protection. Next couple of decades saw tightening of regulatory control in the sector all across the world. It was during this period that drugs got laws for patent protection, leading to the appearance of generic drugs.

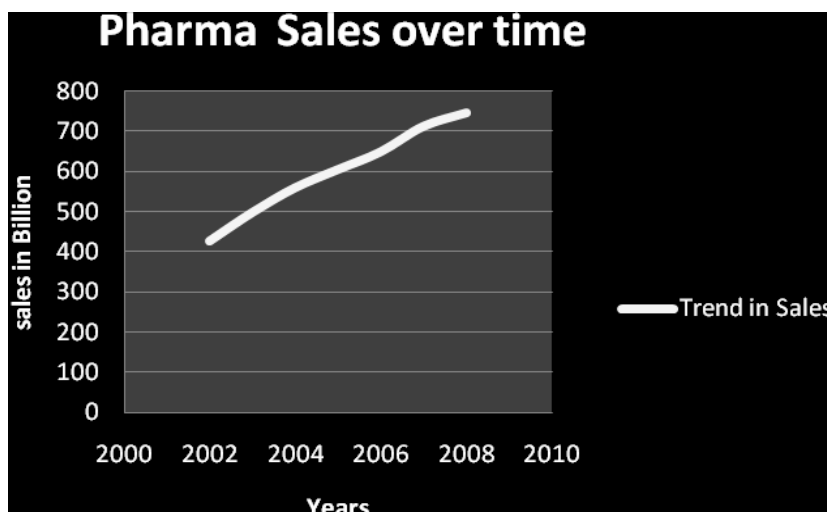
The introduction of generics was very beneficial for society as the valuable medicines became extremely cheap. 1980s and 1990s saw the introduction of venture capital in the pharma and biotech industries. Due to worldwide reforms in the healthcare sector, several regulations were passed to control the pricing of the drugs and deliverance of genuine product innovation. By the turn of the century, all the leading drug companies were spending reasonable amount of their revenue in research and development (R&D).

Today, the global pharmaceuticals industry is more than USD 550 billion and has grown at a compound annual growth rate of more than 6% in last 5 years. Geographically, north America is the biggest pharmaceuticals market with a share of almost 50%, followed by Europe 30% and Japan 9%. Around 20% of all retail prescriptions filled today are related to Medicare. Of those only 31% are for branded drugs and rest are filled generics.

At present there are over 1,000 drugs under development, with companies diverting increasingly large proportions of their revenue streams into R&D, the primary driver of competitiveness in the industry.

Having traditionally enjoyed strong growth rates, the industry's operating environment is becomingly increasingly complex. Volume growth is, currently, negligible, the primary driver of industry value being rising per-unit values, whilst the rise of generics is eroding sales growth. Under these circumstances, the global pharmaceutical market is expected to show slightly slower growth in coming years and is predicted to

be in the range of USD712 billion to USD 745 billion by the end of 2008 which is depicted below.



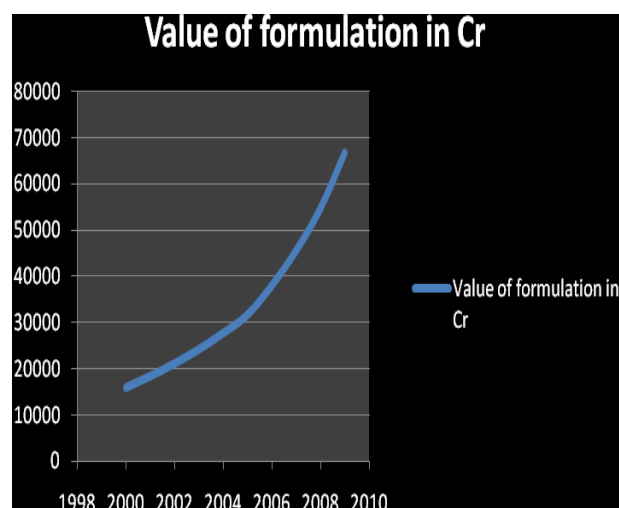
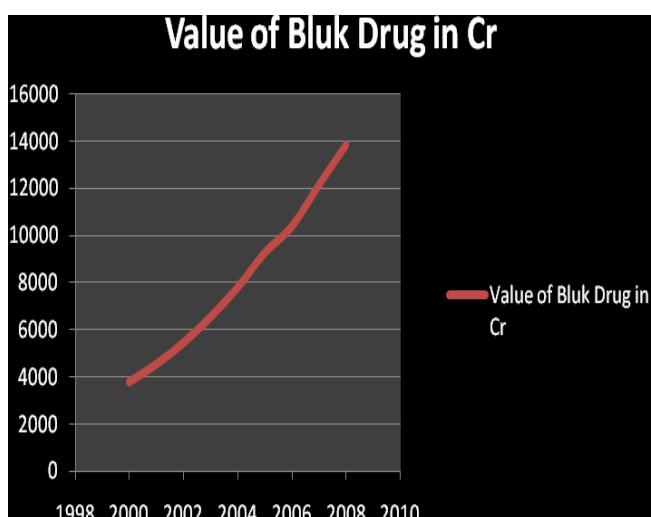
In recent years, pharmaceutical companies in Asia, particularly in China, South Korea and India, have been a success due to their ability to retain their cost advantage while matching the quality standards of the west. Despite an impressive growth, foreign drug makers are particularly concerned with issues on corruption, governmental bureaucracy and intellectual property (IP) protection in these countries. These issues are important particularly when growing drug counterfeiting activities pose a major global public health risk as well as a financial and reputation threat to pharmaceutical manufacturers. Drug pricing pressures are challenging the pharmaceutical industry like never before, with governments resorting to drug price controls and other measures to manage spiraling pharmaceutical costs.

2.4.2 National Scenario

2.4.2.1 Overall

A highly organized sector, the Indian pharmaceutical industry is estimated to be worth \$5-10 billion and growing at the rate of 8-9% annually. It ranks very high in the third world in terms of technology, quality and ranges of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. It plays a key role in promoting sustainable development in the vital field of medicine. Indian pharmaceutical industry boasts of quality producers and many units are approved by regulatory authorities in USA and UK.

The Indian pharmaceuticals sector is highly fragmented with more than 20,000 registered units. It is an extremely fragmented market with severe price competition and government price control. The Indian industry meets around 70% of the country's demand in bulk drugs, drugs intermediates, pharmaceuticals formulation, chemicals tablets, capsules, orals and injectables. There are 250 large units and about 8000 small scale units which form the core of pharmaceutical industry in India (including 5 central sector units). These units produce the complete ranges of pharmaceuticals formulations i.e., medicines ready for consumption by patients and about 350 bulk drugs, i.e. chemicals having therapeutic value and used for production of pharmaceuticals formulation.



Source: Indian Drug Manufacture Association

The pharmaceutical sector is distributed through various pharmaceuticals clusters in the country.

The Details of Pharmaceutical Clusters in India (Turnovers & Employment) are as follows:

S.No.	State	Production value per annum (Rs in Crores)	Estimated Employment
1	Maharashtra (Mumbai ,Pune and Aurangabad)	12000 - 15000	65000
2	Gujarat (Ahmedabad and Baroda)	10000 – 12000	55000

3	Delhi , UP and Haryana	5000	25000
4	MP (Indore Cluster)	2500	15000
5	Uttarakhand (Dehradun Cluster)	2000	20000
6	AP(Hyderabad cluster)	8186	20000

The Pharmaceuticals sector has been able to attract FDI amounting to USD 1401.60 million in the sector during 2000-01 to 2008-09 (up to September). In so far as domestic industrial proposals between August 1991-March 2008 are concerned, total IEMs[2] filed including LOI[3] & DIL[4] add up to Rs. 31257 crores in Drugs & Pharmaceutical Sector. The Pharmaceutical sector is estimated to have created 2.20 lakh employment opportunities

Indian exports rising from a negligible amount in early 1990s to US\$ 11183.49 million by 2007-08. The exports of drugs, pharmaceuticals, & fine chemicals from India grew at a compounded annual growth rate (CAGR) of 17.8% during the five year period 2003-04 to 2007-08.

(In USD Million)

S.No	Importer	2003	2004	2005	2006	2007	2008
1	USA	455.66	492.27	603.93	715.54	989.27	1,375.42
2	Germany	161.68	211.17	206.52	253.01	296.78	337.41
3	Russia	107.17	140.05	172.15	242.84	291.88	297.97
4	UK	89.05	109.10	130.41	187.75	199.12	267.82
5	China	92.96	102.33	121.21	177.04	151.62	203.40
6	Brazil	76.07	87.09	108.96	140.39	171.60	187.03
7	Canada	52.94	90.09	110.20	118.56	124.22	183.41
8	South Africa	25.29	38.26	48.19	101.02	110.77	161.62
9	Nigeria	76.00	82.78	102.99	118.69	139.09	160.06
10	Other countries	2986.84	3857.01	4669.76	5788.92	6824.73	8009.35
Total		4123.66	5210.15	6274.32	7843.76	9299.08	11183.49

(Source: Pharmexcil, Hyderabad)

At present India ranks 4th in volume terms and 13th in value terms. The country accounted for 8 percent of global production and 2 percent of world markets in

pharmaceuticals in recent year .According to Ministry of Commerce & Industry pharmaceutical sector is estimated to have created employment of 2,20,000 people.

2.4.2.2 Impact of product patent

In 2004 India shifted from process to product patent. Under the product patent regime, Indian companies cannot manufacture and market products under patent. Companies interested in the products have to get license from the innovator company (patent holder). Majority share of the profits will go to the patent holder. Thus Indian companies will not be able to produce or export patented drugs. The competition in the off patent products area will increase. The effect will be felt in 5 to 10 years time. During this period Indian companies have to get into the drug discovery area.

Indian pharma known to support customers with DMFs for bulk drugs for their dosage form approvals/ abbreviated new drug application (ANDA) Filings fore formulations.

Apart from the large units mentioned above the Hyderabad cluster of nearly 125 formulations and 266 bulk drug manufacturing units in SME sector. These units together produce bulk drugs valued at Rs. 6862 Crores and formulations valued at Rs. 1325 Crores.

2.4.3 Future outlook of Pharma Industry in India

Pharma Policy 2006 states that “ It is estimated that by the year 2010 industry has the potential to achieve Rs. 1 00 000 Crores in formulations with the bulk drug production going up from Rs. 8000 Crores to Rs. 25 000 Crores”. This is a reasonable target considering the opportunities in the domestic and export marketing. The trends which will influence the growth of Indian pharma industry are:

- Increasing R&D costs will lead to more consolidation among international companies with in 5 years, the top 10 pharma companies are expected to control over 60% of the world market (in value terms)
- Indian pharma companies are expected to move up the value chain from merely being reverse engineering to developing of proprietary products
- MNCs will make an aggressive bid for the Indian market , as India moves from TRIPS, and international companies will register their new drugs for patents

- All SMEs have to comply with GMP requirements and supportive human resource base
- Smaller companies, which had so far benefited from the protective regime, need to become niche contracting units, niche players (geographic/ technology based)

2.4. Benchmark Cluster

Ahmedabad pharmaceuticals cluster in Gujarat is considered as a benchmark in parameters like, Quality, Pollution, and waste management, Skilled Manpower, Energy conservation, safety, Industry and Institutional linkages and Comparison has been done between the firm belongs to the benchmark cluster with the firms belongs to the Hyderabad cluster.

The findings are as follows:

Areas (In Bulk Drug Manufacturing)	Benchmark Cluster firms	Hyderabad Cluster firms	Likely agenda for implementation
Adherence to Current Good Manufacturing Practices(cGMP)	High	Medium	Strengthening the practice of current good manufacturing practices
Pollution and waste management practices	high	Medium	Facilitate to improve facilities to meet set norms
Availability of skilled Manpower	high	Medium	Improve availability of trained manpower
Energy conservation Measures	high	Low	Awareness generation of the entrepreneurs and facilitate energy audits
Adherence to safety norms	High	Low	Awareness generation of the entrepreneurs and facilitate safety audits
Industry and Institutional linkages	High	Medium	Assess requirements and facilitate in linkage with institutions

Areas (In Formulation Manufacturing)	Ahmedabad	Hyderabad	Agenda for intervention
Adherence of Current Good Manufacturing Practices	High	Low	Strengthening the practice current good manufacturing practices
Availability of Manpower	High	Medium	Improve the availability of trained manpower
Presence of Pharma manufacturers associations			
<ul style="list-style-type: none"> • Information Dissemination • Own office infrastructure 	High	Low	Capacity building of Associations
	High	Medium	
Business Development Service providers	High	Medium	Capacity building of BDSPs to their services and availability
Industry and Institutional linkages	High	Medium	Assess requirements and facilitate in linkage with institutions

Conclusion:

Adoption of Quality control norms, Industry linkages, good testing labs are the major advantages of Ahmedabad formulation cluster which are found lacking in formulation SMEs of Hyderabad pharmaceutical cluster.

2.5 Vital Statistics

The total number of SMEs in the cluster is 391 out of which 226 are producing Bulk Drugs (APIs) and 125 are producing formulations (Tablets, Syrups, Capsules, ointments, etc). The total investment of the SMEs is Rs. 2426 Crores out of which Rs. 1964 Crores in Bulk drugs (APIs) and Rs. 462 Crores in Formulations. The total investment in Small Pharma Enterprises is Rs. 531.5 Crores where as Medium Pharma Enterprises contribute Rs.1895 Crores. The total turnover of the SMEs is Rs. 8187 Crores out of which Rs. 6862 Crores by Bulk drugs (APIs) and Rs. 1325 Crores in Formulations. The total turnover of Small Pharma Enterprises is Rs. 2137 Crores

and Medium Pharma Enterprises contribute Rs.6050 Crores. The average investment for Small & Medium enterprises in Bulk Drugs /APIs are Rs. 4 Crores & Rs. 9 Crores respectively. The average investment for Small & Medium enterprises in formulations are Rs. 2.5 Crores & Rs.5.5 Crores respectively.

Table: Industrial area wise units' distribution

S.No.	Location/ Industrial Estates (District)	Type of firms						Total
		Large		Medium		Small		
		BDM	F	BDM	F	BDM	F	
1	Jeedimetla (Rangareddy)	4	2	27	16	6	31	86
2	Kazipally / Bonthapally / Gaddapotharam (Medak)	7	1	48	8	10	17	91
3	Bolaram (Medak)	5	4	14	4	8	2	37
4	Choutuppal (Nalgonda)	2	0	42	10	14	0	66
5	Mallpur / Nacharam (Rangareddy)	0	0	7	2	6	4	19
6	Pashamylaram / Patancheru (Medak)	5	0	29	9	40	16	99
7	Uppal (Rangareddy)	0	0	12	2	3	4	21
Total		23	7	179	51	87	74	421

(BDM: Bulk Drugs Manufacturing units, F: Formulations units)

Table: Units Distribution with Category Type of Product:

S.No.	Name of the Large firms	Bulk Drug	Formulation	Total
1	Large	23	7	30
2	Medium	180	50	230
3	Small	86	75	161
Total		289	132	421

Table: Type, Ownership, Investment, Employment, and Turnover

(Rs. In Crores)

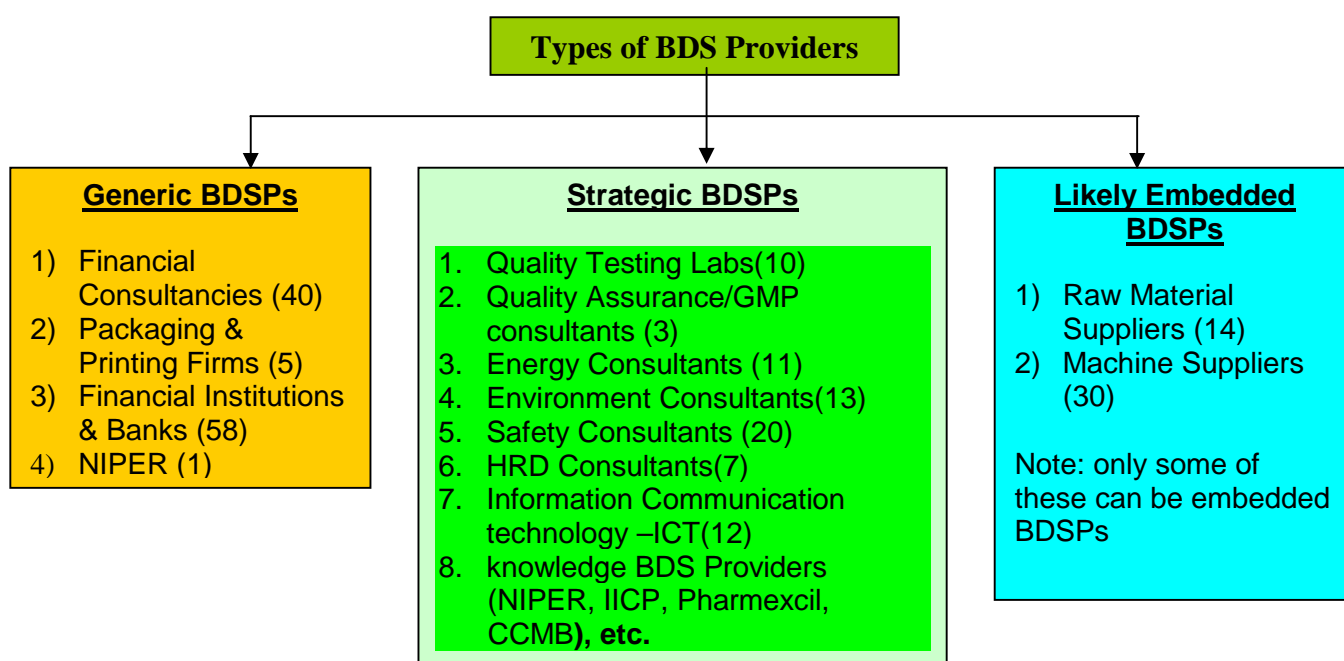
S. No	Type of Manufacturer	Type of firm	No. of firms	Ownership				Invest	Emp	T.O.
				Pvt	Pub	Par.	Pro..			
1	Bulk Drugs	Small	86	56	-	25	5	344	3500	1462
		Medium	180	150	30	-	-	1620	12000	5400
2	Formulations	Small	75	-	-	45	30	187	2000	675
		Medium	50	40	-	10	-	275	2500	650
Total			391	246	30	80	35	2426	20000	8187

(T.O.: Turnover, Emp: Employment, Invest: Investment, Pro: Proprietary, Par: Partnership, Pub: Public, Pvt: Private)

2.5.1 Business Development Service Providers

Broadly BDS can be classified into three types as Generic BDS, Strategic BDS and Embedded BDS. Generic BDS are generic services like Strategic BDS are that issues that affect typical business growth like marketing energy, environment training, regulatory requirements, etc. Embedded services are packaged or bundled within commercial transactions without fee e.g. designs advice to a manufacturer from buyer knowledge on appropriate machinery use from a raw material supplier. The embedded BDSPs are value chain partners providing backward and forward linkages. However only a handful of them are may be embedded BDSPs.

Major BDS Providers in Cluster



2.5.2 Who Does Who Pays Matrix

S.No.	BDS Function	Who Does	Who Pays	Payment Mechanism	Remarks
1	Quality Compliance	GMP Consultants	Entrepreneur	Direct	Providing current GMP services
2	Quality Testing	Testing Laboratories	Entrepreneur	Direct	Testing the quality of the product
3	Capacity Building	NIPER	Entrepreneur	Direct part, Subsidy part	Skill development programmes for unskilled, semi-skilled and skilled persons
4	Financial services	Financial Advisors / Chartered Accountants	Entrepreneur	Direct	Providing Auditing, filling of Tax returns, Report preparations, etc
5	Energy Management Services	Energy Management Consultants	Entrepreneur	Direct part, Subsidy part	Providing energy saving measures
6	Environment Managerial Services	Environmental Management Consultants	Entrepreneur	Direct	Providing effluent treatment solutions and waste reduction solutions
7	Safety Management	Safety Consultant	Entrepreneur	Direct	Providing safety related solutions
8	Infrastructure Facilities	Facilitated by to BMOs	PPP model	30% BMOs and 70% government	Providing Common testing laboratories for product and raw materials, PHCs, Fire stations, Banks, etc
9	Marketing	Marketing Consultants	Entrepreneur	Direct	Providing market potential details with location wise, packing type, weight, etc details

Chapter -3

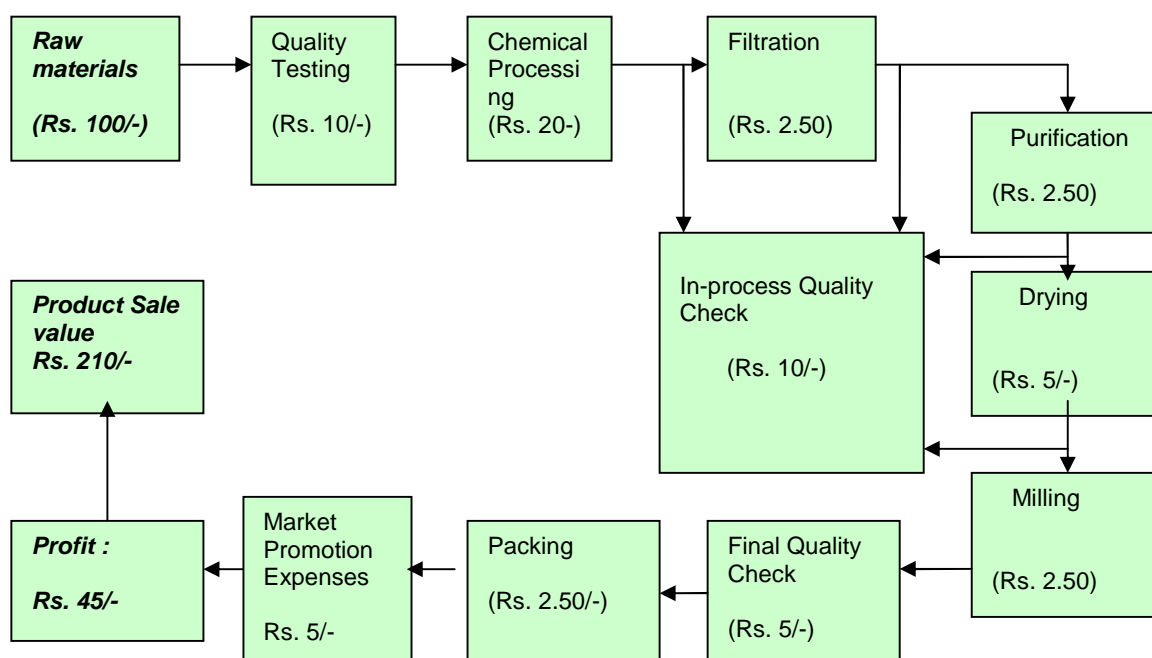
Analysis

3.1 Comparative Value Chain Analysis:

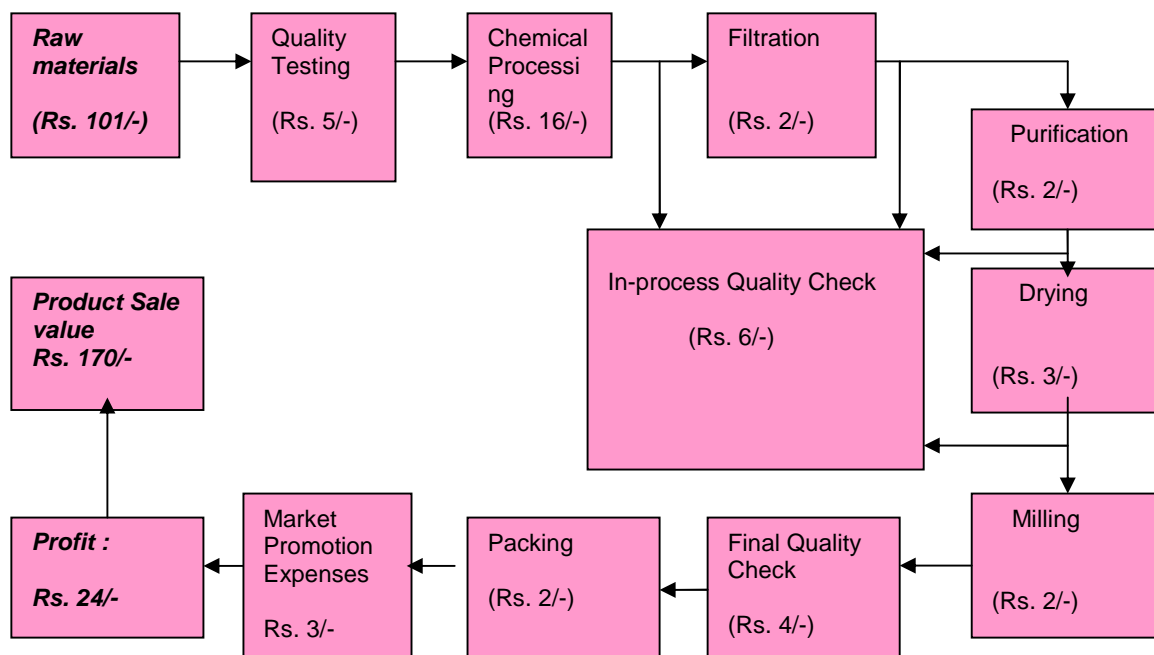
The comparative value chain analysis of SMEs which are practicing cGMP norms with the SMEs which does not practicing. cGMP norms are explained below:

A). For Bulk Drug Manufacturing:

A.1) Diagram: value chain for a bulk drug unit which is implementing GMP compliances (Assumption: cost of raw material for manufacturing of a product is assumed as Rs. 100/-)

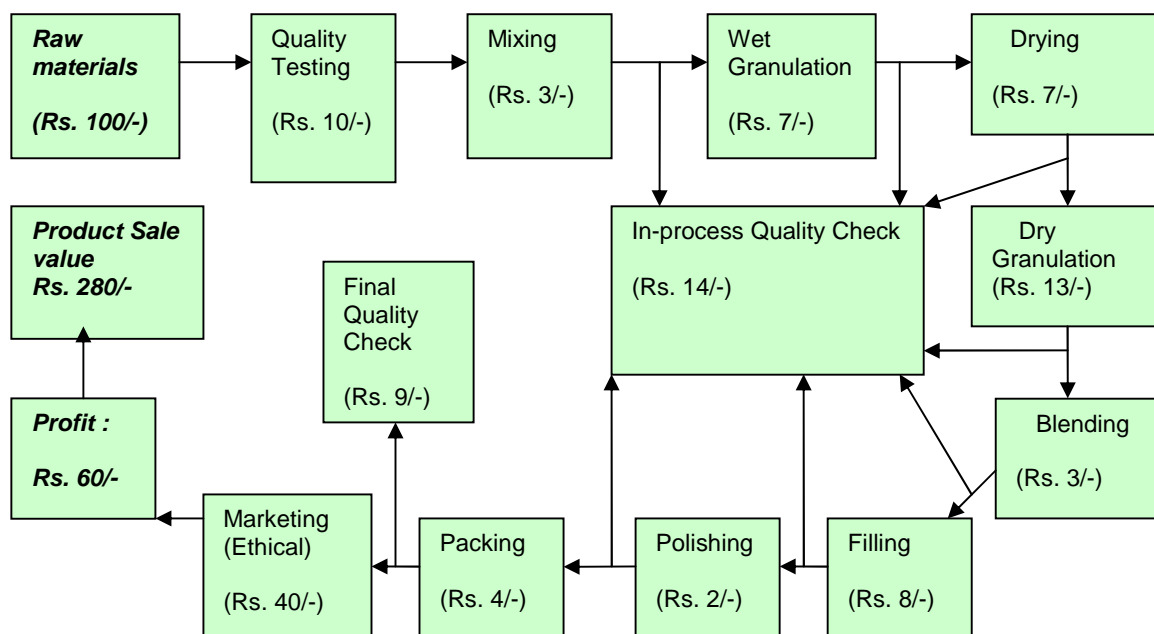


A.2) Diagram: value chain for a bulk drug unit which is not implementing gmp compliances (assumption cost of raw material for manufacturing of a product is assumed as Rs. 101/-)

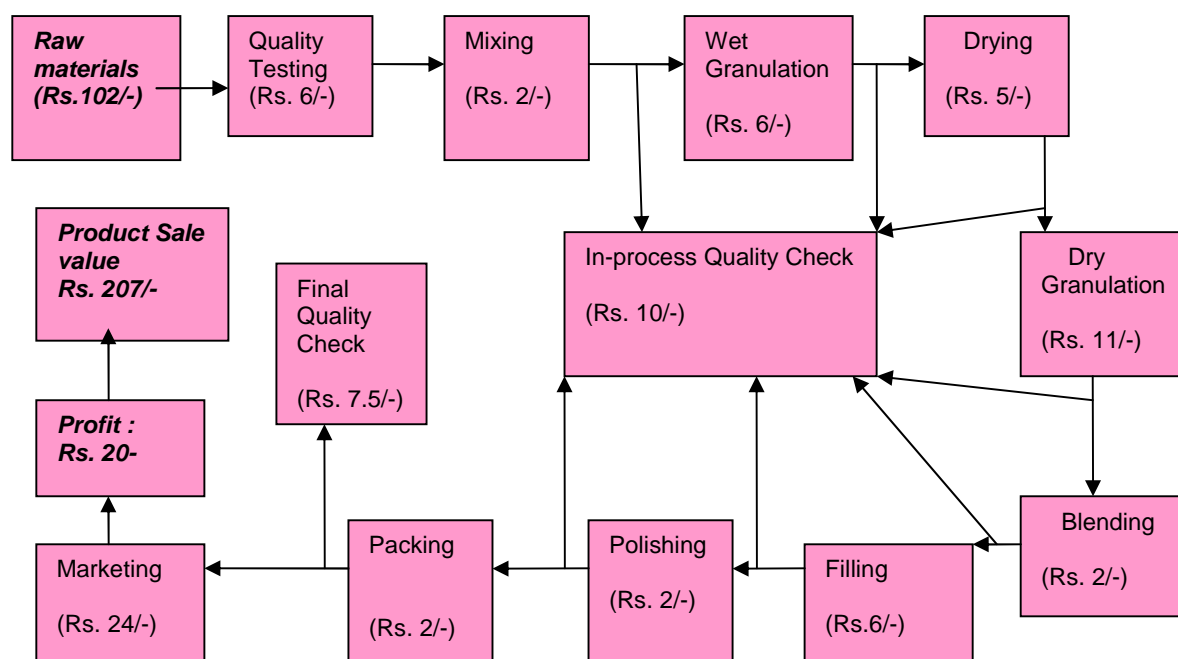


B). For Formulations Manufacturing:

B.1 Diagram: value chain for a formulation unit (capsules) implementing gmp compliances (assumption: cost of raw material for manufacturing of a product is assumed as Rs. 100/-)



B.2 Diagram: value chain for a formulation unit not implementing GMP compliances (assumption: cost of raw material for manufacturing of a product is assumed as Rs. 102/-)



Based on the study of value chain analysis of bulk drugs and formulations, manufacturing process of two units which are of different quality compliance state, considering that the other activities and facilities are near similar; the following conclusions can be drawn.

3.1.2 Conclusions:

Out of the two cluster firms one is following good manufacturing practices as prescribed whereas the other is not following. The cluster firm which follows GMP norms procures its raw materials from an approved vendor whereas the other cluster firm is procure raw materials from open market, which normally is at a higher price

The cluster firm following GMP norms follows prescribed test methods to test the quality of its raw materials whereas the other firm does not follows as prescribed. This provides some cost saving for non-GMP firms.

However the firm that follows the GMP standards is able to sell their product through profitable mode, whereas the firm that does not follow the standards needs to depend on local traders to market their product. This difference in market model

leads to higher profit margins than the non-compliant firms which sell through trader network.

Hence, considering the overall situation, even though the firm which follows suggested norms is higher on production cost, the final profit realization is higher compared to a non-compliant firm. The later also commands better market respect. The chances of product failure and product return are very less. Due to same reasons, if the product fails during its life time, the reasons for failure can be investigated very easily. The other firm which is not practicing the norms in full does not enjoy similar advantages.

3.2 BDS Analysis

3.2.1 Overview of BDS market

As the regulatory requirements and technology of pharmaceuticals are fast changing on a regular basis, to understand and adopt the same is difficult for pharma SMEs as they can't afford to employ qualified personnel exclusively for this purpose. Hence, the pharma SMEs has to depend on BDS service provider to meet some these requirement. To address these changing requirements, the pharma SMEs can improve their productivity, profitability, and sustainability, some time even the existence.

As the demand for various categories of BDSs providers are increasing due to presence of large base of small and medium enterprises in Pharma sector, the service providers are inadequate in certain areas to the cater the industry. Due to short of service providers and high demand of available service providers, many a times these service providers are not in the reach of pharma SMEs. Therefore to make the BDS affordable by SMEs, it is suggested to empower existing BDS service providers.

The BDS supply comes from public, private organized and private unorganized BDS providers. This analysis does not include embedded BDS provider, who will be identified during the process of implementation

3.2.1 Public BDS Providers

The Public BDS providers available in the cluster are:

3.2.1.1 Indian Institute of Chemical Technology (IICT)

Indian Institute of Chemical Technology (IICT) offers services including technology transfer design for plant, analytical services, trouble shooting, process improvement quality and productivity improvement. At present about 8% of medium & small enterprises are utilizing its services in process improvement and library facilities. There is a scope for better action of utilize IICT services in technology transfer, testing facilities, process improvement and literature search.

3.2.1.2 Small Industries Development Bank of India (SIDBI)

SIDBI provides financial support to SMEs under various schemes. Linkage with SIDBI by most of the cluster firms is poor. There is a scope for availing the services of SIDBI under Credit Guarantee Scheme. Even new products may also be launched.

3.2.1.3 District Industries Center (DIC)

At present, the services of DIC are issuing the SSI registration for cluster units and providing incentives like power rebate, sales tax rebate and other incentives providing from the Government. DIC provides single window service to units in getting approved clearances. All the cluster firms are utilizing the DIC services like registration, approvals and incentives.

3.2.1.4 Andhra Pradesh Pollution Control Board (APPCB)

The APPCB will monitor the effluents releasing by the units. Cluster firms utilize its services like getting approvals, guidance to waste disposals, etc. The Pollution Control Board provides the service to the firm for testing or effluents and gives awareness for norms for waste and environment management. They assist the units with suggestions for proper treatment of effluent. There is a scope for its intervention to give more awareness and support on modified rules and regulations to all the cluster firms

3.2.1.5 Financial Institutions (FIs) & Banks

They provide term loans, working capital loans to the units. Units have good linkage with the banks / financial institutions and availing term loan, Cash / credit facilities. 60% of the

cluster firms avails the services like financial assistance to start the firm, term loans and working capital requirements. 15% of medium enterprises and 32% of small enterprises requested for the financial assistance to upgrade their facilities to meet the cGMP compliances and working capital requirements. Baring SBI, none has any such product.

3.2.1.6 Pharmexcil

Pharma Export Promotion Council (Pharmexcil) has been set up for the purpose of export promotion in Pharma industry in 2004. Pharmexcil organizes trade delegations and Buyer-seller meet India and abroad it also organizes the seminars on exports related issues and makes suggestions to Government of India on the policy issues relating to Pharma Exports.

Pharmexcil deals in bulk drugs and its intermediates, formulations, ayurvedic, homeopathic, unani, diagnostics, surgicals and pharma industry related services, contract like manufacturing, clinical trials, etc

Pharmexcil provides information and services to all the cluster firms. Any pharma SME who is either in exports or intends to enter into exports business avails Pharmexcil services. Currently about 20% cluster firms are utilizing its services. Remaining cluster firms may utilize the provided services gradually.

3.2.1.7 National Institute of Pharmaceutical Education and Research (NIPER)

National Institute of Pharmaceutical Education and Research (NIPER) imparts training to the entrepreneurs and provides skill up gradation training to unskilled, semiskilled, and skilled personnel of the industry. It also gives support in research and development. The institute commenced its operations in Hyderabad an year ago and is slowly upgrading its facilities to cater the industry need and presently the usages of its services are meager. In future once the Institution is fully equipped and operational geared up then there is a great scope for utilization of the facilities and services by the cluster firms.

3.2.2 Private BDS Providers (unorganized)

Unorganized Private BDS providers are providing services in the areas of GMP, US, FDA, DMF, ISO certification, marketing, human resources development, energy management, environment, and safety management. Such Private BDS providers available in the cluster are: details below:

3.2.2.1 Good Manufacturing Practices (GMP) Consultants

GMP consultants are available in the Hyderabad Pharmaceutical Cluster. GMP consultants deal with the schedule – M, ISO certification, cGMP and DMF services to the Pharma Cluster. About 25-30% of medium enterprises and about 50-60 % of small enterprises are utilizing consultant services.

3.2.2.2 Marketing Consultants

Marketing consultants advises the Pharma SMEs in product selection, location, packing mode and suggest retail price for both national & international markets. 12 % cluster firms are utilizing marketing consultant services. 40 % of the cluster firms requested for marketing consultant services in launching and promoting their products in other countries. Hence there is shortfall in appropriate services.

3.2.2.3 Safety Consultants

Safety consultants have an active role in pharma cluster by giving training on safety management and providing the safety devices for the cluster firms. 13 % cluster firms are utilizing consultant services. There is a big scope for promotion safety of consultant services.

3.2.2.4 HRD Consultants

HRD consultants giving services like skilled man power supply to the Pharma cluster for successful functionality of the Industry. 40 % medium enterprises and 5 % small enterprises utilize HRD consultant services. Remaining cluster firms need to adopt their services.

3.2.2.5 Energy Consultants

The Energy Consultant has to conduct both the electric and thermal energy audits, which helps the industry in reducing the production cost, minimizes the resource losses. The availability of consultants across the cluster is low, and their services not competitive. 50 % medium enterprises utilize the energy consultant services. Remaining medium enterprises and all small firms need to aware energy conservation methods and adopt in practice.

3.2.2.6 Environment Consultants

Environment Consultants deals the pollution problems and reduce the pollution. They suggest solutions for the pollution related issues. 30-36 % cluster firms utilizing pollution related consultant services. There is a good scope for consultant services in all the cluster firms as per the norms.

3.2.2.7 Industry Associations

There are 4 associations in the Hyderabad Pharmaceutical Cluster. The details are given below:

- Bulk Drugs Manufacturers Association (BDMA)
- Organization of Pharmaceutical Manufacturers (OPM)
- Nalgonda Drugs Manufacturers Association – NDMA
- Pashamylaram Industrial Services society (PASS)

Bulk Drugs Manufacturers Association (BDMA):

The Bulk Drug Manufacturers Association (India) was formed in 1991 with Hyderabad as its Head Quarters. This is an all India body representing all the Bulk Drug Manufacturers of India. It has memberships of 266 members belongs to Hyderabad pharma cluster. The Association has the permanent office infrastructure and being managed professionally. The Association has 4 employees as full time and one employee as part time and these employees have been entrusted with the day to day administration of the Association. At present the associations is providing the following services /activities

- They assist the newly set-up units to collectively negotiate with the Government regarding disputes on land registration, pollution, labour laws etc.
- They are active in lobbying against the government to solve issues on pollution control
- Representing the Government on tax related issues.
- Organizing periodical meetings with the members and sharing the information on various changes of policies, and welfare issues. Provide information relating to various Pharma exhibitions / trade fairs.

Organization of Pharmaceutical Manufacturers (OPM):

Organization of Pharmaceutical Manufacturers (OPM) is an association for formulations manufacturers. This Association has been formed purely out of necessity to put forth the views and requirements of the members in the area of common concern mainly related to Advocacy. It operates from Hyderabad and has 125 members in the OPM. The association does not have any regular employee on full time basis but have couple of part time employees to maintain the Office and to take of day to day activities of the Association.

Nalgonda Drugs Manufacturers Association (NDMA):

Nalgonda Drugs Manufacturers Association represents bulk drugs and formulations SMEs established in and around Nalgonda. It has a membership of 66 pharmaceutical firms. The Association has no office and don't have regular staff to manage their day to day activities. The Association is being driven by the office bearers and has now taken up an initiation for establishing common facility for Effluent treatment and testing laboratory. The Association now requires facilitation support in establishing the proposed facility and build the capacity for self governance.

Pashamylaram Industrial Services society (PASS):

Pashamylaram Industrial Services society (PASS) is an association which represents from Pashamylaram area of Medak district for both the bulk drugs and formulations manufacturers. It has a membership of 99 pharmaceutical manufacturers. This Association has an office but don't have regular staff to manage the Association affairs. They are active in lobbying against the government to solve their issues on pollution control and other issues of common concern mainly related to Advocacy.

Table: Status of Existing BMOs in the Cluster

S.No.	Business Members Organization (BMO)	Members	News Letter / Website	Separate Office	Staff for Association activities
1	BDMA	266	Website	Yes	Yes
2	OPM	125	No	No	Yes
3	PASS	99	No	Yes	No
4	NDMA	66	Website	No	No

BDSPs	Business Development Services										
	Raw Material	Technology improvement	Marketing	HRD	Quality compliances	Finance	Logistics	Energy	Safety	Environment	Information Communication Technology
Public											
NIPER	0	1	0	1	0	0	0	0	0	0	0
IICT	0	1	0	0	1	0	0	0	0	0	0
CCMB	0	1	0	0	1	0	0	0	0	0	0
HCU	0	1	0	1	1	0	0	0	0	0	0
FIs/Banks	0	0	0	0	0	2	0	0	0	0	0
ITI	0	0	0	1	0	0	0	0	0	0	0
Pharmexcil	0	0	3	0	0	0	0	0	0	0	0
JETL	0	2	0	0	0	0	0	0	0	2	0
PETL	0	2	0	0	0	0	0	0	0	2	0
Private Organised											
Ts	3	0	2	1	0	0	0	0	1	0	0
FCs	1	0	0	0	2	0	0	0	0	0	0
PTLs	0	1	0	0	4	0	0	0	0	0	0
Ramky	0	3	0	0	0	0	0	0	0	3	0
BMOs	3	1	3	1	1	1	2	1	2	2	1
PMs	0	3	0	0	3	0	0	0	0	0	0
CRAMS	1	4	1	0	0	0	0	0	0	0	0
EnvCs	0	0	0	1	0	0	0	0	0	2	0
EneCs	0	1	0	1	0	0	0	2	0	0	0
SCs	0	0	0	0	0	0	0	0	2	0	0
PCs	0	0	0	0	1	0	0	0	0	0	0
ICTs	1	1	1	1	1	2	2	0	0	0	2
Private Unorganized											
FCs	1	0	0	0	1	0	0	0	0	0	0
EnvCs	0	0	0	0	0	0	0	0	0	1	0
EneCs	0	0	0	0	0	0	0	0	1	0	0
SCs	0	0	0	0	0	0	0	0	1	0	0
PCs	0	0	0	0	1	0	0	0	0	0	0

Note: **0** - No linkage, no impact on group, **1** - Poor linkage, very little impact, **2** - Fair linkage, some impact, **3** - Good linkage, significant impact, **4** - Very Good linkage, excellent impact

NIPER – National Institute for Pharmaceutical Education & Research

IICT – Indian Institute of Chemical Technology

CCMB - Center for Cellular and Molecular Biology

HCU - Hyderabad Central University

FIs/Banks- Financial Institutions/ Nationalised Banks

ITI - Industrial training Institutes

Pharmexcil – Pharmaceutical Exports Council

JETL- Jeedimetla effluent treatment plant limited
 PETL- Patancheru effluent treatment plant limited
 Ts -Transporters
 FCs – Financial Consultants
 PTLs – Public Testing Laboratories
 BMOs – Business Members Organisation
 CRAMS – Contract research Manufacturers
 EnvCs – Environment Consultants
 EneCs – Energy Consultants
 SCs – Safety Consultants
 PCs – Pest control Consultants
 ICTs – Information, Communication & Technology Consultants

3.3 BDSP Demand Side Assessment

Pharmaceutical cluster needs different types of BDS providers like GMP, ISO, certification US FDA, DMF (Drug master file) financial consultant, testing Lab and consultants related to marketing, energy, environment and safety & ICT. There is a lot of demand for BDS providers as the cluster across four districts

Table: Demand Side Assessment of BDS:

S.No	Type of the Service provider	Services Offered	Type of units using the service	Present status of usage
1	Quality compliance	<ul style="list-style-type: none"> ▪ GMP ▪ ISO Certification ▪ US FDA & DMF 	Small & Medium Enterprises (SMEs)	Low
2	Technology	Technology Up gradation		Low
3	Chartered Accountants	<ul style="list-style-type: none"> ▪ Financial ▪ Taxation ▪ Audit 		Medium
4	Testing Labs	Analysis report		Medium
5	HRD	Recruitment of Skilled Man power		Medium
6	Marketing	<ul style="list-style-type: none"> ▪ Domestic Marketing ▪ Export Marketing 		Medium
7	Energy Management	Energy Audits		Low
8	Environment	Treatment of Effluents		Low
9	Safety Management	<ul style="list-style-type: none"> ▪ Training On Safety Measures ▪ Supply of Safety Devices 		Low
10	IT Firms	<ul style="list-style-type: none"> ▪ Selling of Software Packages ▪ Maintenance 		Low

(Note: Large firms have internalized most BDS need)

Table: Status of Private BDS Providers

S.No	Type of Area	Services	Aggregate Annual Turnover (in Crores)	No. of Units availing services	Average service charge / pricing (Rs in Lakhs)
1	Quality compliance	➤ GMP	4.50	150	3.00
		➤ ISO Certification	0.50	50	1.00
		➤ DMF	1.20	80	1.50
		➤ US FDA	1.80	60	3.00
2	Chartered Accountants	➤ Financial ➤ Taxation ➤ Auditing	18.00	300	6.00
3	Testing Laboratories	➤ Quality analysis	35.00	275	12.72
4	Marketing Consultant	➤ Domestic ➤ Exports	12.00	50	24.00
5	Energy Consultant	➤ Energy Audits	3.00	140	2.14
6	Environment	➤ Solid & Liquid waste disposal ➤ Pollution control equipment supply	75.00	205	36.58
7	Safety Consultant	➤ Trainings on Safety Measures ➤ Supply of Safety Devices ➤ Supply of fire fighting equipments	2.00	50	4.00
8	Information Communication Technology (ICT)	➤ Selling of Software Package ➤ Maintenance	4.00	195	2.05

3.4 BDS Conclusions

Table: Major problems affecting the BDS market are as below:

The major operational problems affecting the BDS from the Demand side and Supply side:

Demand Side	Supply Side
<ul style="list-style-type: none"> ➤ High cost of Business Development Services ➤ Poor networks among the units resulting in lack of utilization of services ➤ Fear of leak of technical know how 	<ul style="list-style-type: none"> ➤ Weak penetration of BDS providers due to poor marketing techniques. ➤ Information of services not known to the units as specially regarding individual consultants. ➤ BDS providers are preferred to cater to large & medium units

GMP Consultants, Marketing & HR Consultants are the critical BDS providers in the clusters. Approximately 70-75% of SMEs of cluster are not adhering to cGMP compliances. As such GMP consultants are required and most of the GMP consultants are unorganized it leads to the penetration problem to the cluster.

- Supply side constraints are felt in the areas of knowledge BDS providers, BDS facilitation (association) quality, environment, energy & safety consultants
- There is a pent up demand in the areas of quality, technology, IT, energy, environment & safety and finance to lack these up
- Hence the pressure point BDS provision is required in the areas of quality, energy, environment, safety and finance

3.5 Analysis of Business Operations (AOBO) & Pressure Points

A). Raw material Procurement

For many of the pharma products cost of raw materials contributes to over 50% of the total product cost. Any saving in sourcing raw materials will directly impact the income of the pharma SMEs.

Many of the raw materials for formulation are available locally. But still some of latest / novel drugs (e.g:Acylovir) and other special excipients (e.g:Hydroxy ethall cellulose) are sourced from overseas markets. Due to presence of middle men, some time pharma SMEs face with the quality related issues of the material and timely delivery. For the benefit of pharma SMEs, a raw material bank may be created for stocking essential and regular moving raw materials to impact on the overall income of SMes. This will facilities in availability of major materials at a very competitive price and short delivery period.

B). Process Technology

Many of cluster firms have set up their own research and development laboratories, for upgrading their process and also develop newer products. Some are also depending on outside private agencies and/or national laboratories for the same. SMEs are facing lot of problems in literature search, which is the key for success of any R&D activity and are depending on national laboratories such as IICT or local universities for literature search. Alternatively, literature can be obtained by subscribing online paid literature sites, such as “SCI finder” application software to find chemical products across the globe, and the American Chemical Society (“ACS”). Hence these cluster firms have indicated their interest to be part of any such intervention to address this issue.

Some of the cluster firms have indicated that the government should setup a body to identify the technology for newer products from either local technology providers or overseas technology providers and validate the same for the benefit of Pharma SMEs. Some have expressed that government body should guide the Pharma SMEs newer evolving processes and product or processes which may be getting obsolete; such support is being provided by Chinese government for the benefit of their pharma SMEs.

C). Marketing

Marketing is a value delivery system. Bulk drug marketing in SMEs follows:

Own Marketing setup:

Pharma SMEs market their product by themselves by establish a sales set up to identify consumers -domestic and international. Establish contacts with the identified customers. Finalize technical and commercial terms to manufacture and supply. Direct consumer contact will be on long term and helps the company to build strong relationship and consistent business. In many cases the profit realization is more than other mode of marketing.

Through Indenting Agents:

Pharma SMEs identify an indenting agent who can guarantee a specified business on mutually agreed terms. Indenting agent books orders on behalf of the company and material will be dispatched to the consumer directly by SME. Based on the projections of indenting agent, SME manufactures the product. In this mode the SMEs without spending on marketing resources, gets assured business.

Through Traders

Pharma SMEs will identify traders who can guarantee a specified business on mutually agreed terms. Based on projections of traders SME will manufacture and supply to the trader. The traders stock the material in their warehouse and markets in his jurisdiction. In this mode the SMEs without spending on marketing resources, gets assured business, but the fund realization takes long and margins are low comparative to other two modes.

Third Party manufacturing

In third party manufacturing, the SME manufactures the product as per the specifications of third party and supplies. The SME will charge the third party on mutually agreed terms, normally the conversion charges and small margin.

Contract manufacturing

In Contract manufacturing, SMEs gets all raw materials and packaging materials from contracting organization. Material is manufactured using facilities and manpower of SME. SME will be paid for the conversion cost which will be decided on mutual agreed terms. Any liability is to the account of the contractor. Majority of organizations follow combination of all above marketing mode to sale their product. New entrants prefer to tie up with large organization as contract manufacturers.

SMEs formulation manufacturer follows one of the following modes for marketing their products:

Ethical Marketing

In this mode of marketing the pharma SMEs shall employ their own marketing personnel to promote their products. Sales personnel visit the Doctors and provide product information. Sales will be based on Doctor's prescription. Product is distributed from the manufacturer to the stockiest and finally to the retailer (Medical shop). In this mode initial investment is high, returns are high and relationships with the direct users are better

Through Traders

Pharma SMEs will identify traders who can guarantee a specified volume of business on mutually agreed terms. Based on projections of traders, SME manufactures and supply. In this mode the SMEs without spending on marketing resources gets assured business. Normally the payment realization will be delayed and margins are low.

Third Party

In third party manufacturing the SME manufactures the product as per the specifications of third party and supplies to them. The SME apart from conversion cost and some % extra is paid. Any liability is to the account of the SME.

Propaganda-Cum-Distribution

Pharma SMEs appoints region wise propaganda cum distributing agents. SME manufactures the product as per the agreed formulation. It is the responsibility of the propaganda cum distributor to promote the product and generate the sale in his jurisdiction. In this mode SME gets assured sale and margins are low.

Institutional Sales

Institutional marketing comprises of:

- To State and Central Govt. hospitals
- To Govt. agencies such as Railways and Defense hospitals
- Hospitals attached to large industrial houses e.g. BHEL, ECIL etc.
- To corporate hospitals like APOLLO, CARE Hospitals etc.

To participate in State and Central Govt. tenders, the pharma SME should have made the products for a minimum of three years. Pharma SME entrepreneur with marketing background would prefer to set up their own market activities and enter into ethical marketing. Entrepreneurs with long stand of manufacturing activities would opt for institutional marketing.

For the development of pharma the marketing consultancy service providers are required to advise the pharma SMEs in identifying the product, packing, area(s) where it can be launched. And these service providers will also advise pharma SMEs in products and marketing.

Bulk Drugs SMEs, who wish to export to other countries, has to prepare and submit a technical document – Drug Master File (DMF), depending upon the country. Preparation of DMF involves lot of cost and require technically competent person in preparation and subsequent activities. Many pharma SMEs are unable to undertake the same due to high cost, in spite of having necessary technical capabilities to manufacture the final drug substance to meet target country’s quality requirement. For that, frequent interaction meets with regulatory bodies can helps SMEs. Hence there is need for financing.

D). Manpower & Employment

As technology and regulations are continuously upgrading, the employable manpower availability for pharma SMEs in Hyderabad is one of the difficult task. To tide over manpower shortage, many cluster firms are interested to associate with any intervention in manpower training in technical subjects covering quality assurance, quality control, production etc. It is suggested to identify potential fresher from educational institutions and train them to cater the need of pharma SMEs.

E). Safety Management

Safety is one of the critical issues for all bulk drug manufacturers where as in formulation manufacturers it is not very critical. Bulk drug manufacturer handles variety of flammable, explosive and other hazardous chemicals during their processes. Unless these cluster firms understand the nature of hazard and deploy suitable fire fighting systems, any untoward incident can cause lot of property and human damage.

Even though, the safety is critical to all API and intermediate manufactures, many of cluster firms either due to their insufficient understanding on these systems or busy with other business related activities or huge cost involved in creating facilities to meet the requirements, enough attention was not given to safety. SMEs interested for any intervention in the form of training to their production personnel, safety audits of the facilities etc. Also advisable to create common fire fighting facilities to meet all types of fire classes in each industrial development area.

F). Quality Compliance

Hence the Pharma industry world over is heavily controlled by regulatory bodies. In India the pharma industry is covered by Drug & Cosmetic act 1945. One of the chapters of the said act – Schedule ‘M’ governs the manufacturing and quality control practices of

the industry. The schedule stipulates the requirements of facilities so that quality is inbuilt in to the systems. Any pharmaceutical manufacturers in any sector – micro, small or large are covered under this act, and any manufacturer without this certification cannot function

Good Manufacturing Practices (GMP) implementation has two fold – system and facilities. System implementation involves identification of all activities, writing down them in sequential manner, practicing them rigorously and document, besides other activities. GMP implementation requires experienced personnel; small and medium enterprises are unable to afford such personnel to employ on a full time basis. Few SMEs are engaging external consultants on retainer basis or few are engaging some of GMP personnel of large organization on informal basis.

Organizations that have complied with the local GMP norms and wish to enter into outside markets, they need to upgrade their GMP norms to meet such regulations, for ex., organization to enter into US market need to meet USFDA GMP norms, to European market it is EDQM norms etc. In general there is no serious difference in any of these regulations, expect how the regulatory bodies evaluate.

Some of the SMEs whom we interacted have shown interested in availing any intervention for implementation of basic Schedule ‘M’ (i.e. regulatory norms of Govt.of India) quality certification and few for upgrading to next level to enable them to enter export markets.

Currently available service providers are well experienced to meet the requirement of the industry. As industry base is growing, and the regulatory requirements are revised on a regular basis, more and more such service providers are entering field. The cost of facility up gradation to meet any of these regulations depends on their present status. GMP consultants can provide inputs by way of plan as per regulatory requirements and to meet the same.

Some of the cluster firms have indicated that some soft loans by way of concessional interest and higher moratorium can help the industry. Also they have indicated that any special products / packages from financial institutions for GMP implementation and up gradation will help the industry in a big way (The pharma policy 2006 has address this need). BDS providers in the area of equipments, for facility up gradation to meet requirements are available in and around Hyderabad. The costs of such equipments are depending upon the level of up gradation the cluster firm is aiming.

Quality Testing Facilities

Pharmaceutical manufacturers have to upgrade their quality testing facilities on a regular basis based on current regulatory requirements. To meet the basic criteria of safety, quality and efficacy, quality testing for raw materials, in-process materials and final products besides packing materials is part of any regulatory requirements.

With increased consciousness of patients and availability of technology, current regulatory challenge of a cluster firm is not to estimate the purity of the active material, but to assess the content of impurities. To estimate this level of concentrations, the cost of analytical equipment will be very high and in many cases it is not in the reach of pharma SMEs. As per Schedule ‘M’ regulations it is expected that entrepreneur has to create all such facilities to test the quality of incoming, in-process and final product besides packing materials. Outside testing labs are catering to local pharma industry in a big way but at time these service are not affordable by Cluster SMEs.

G). Finance

Many of pharma SMEs are first generation entrepreneurs. Many of them have put in lot of work experience with other leading national or international organizations and started their own industry. In view of this, they are strong in technical management, but not so in financial management. Their financial status is also not very strong to tide over any urgent / short term financial requirements.

Lot of these pharma SMEs either work as contract manufacturers to large pharma units or distribute their product through trader, in either cases they are not in a position to bargain terms to their advantage or realization of their bills would take longer period. There is a need to provide financial assistance to SMEs in this area.

H). Energy Management

Tightening capital markets, fluctuating energy prices and increased environmental concerns are factors that are driving pharmaceutical processors to revisit their energy strategies in an effort to optimize cost savings

Table: 4 Energy consumption in pharma industry

S.No.	Application	Bulk Drug units	Formulation Units
A). Power			
	Process needs		
	Reactors, Mixers, pumps, centrifuges , dryers in API units	30%	
	Mixers, tableting machines, packing machines in formulation units		40%
	Utilities		
	Pumps, Refrigeration	45%	5%
	HVAC systems	10%	40 %
	Lighting	5%	10%
	Office and other uses	5%	5%
B). Fuel (Coal & Furnace oil)			
	To generate steam for process needs	100%	100%

The cost of energy is not a major part of the production cost. However spiraling prices of energy and the national prerogative of energy saving has made energy conservation an important parameter in development of this industry. There is considerable scope for energy saving in the pharma SMEs. The industry is aware of the possibilities but shy of making the investment in adopting energy saving equipment.

I). Environmental Management

As Hyderabad is hub for bulk drugs in India, pollution and waste management are one of the toughest tasks for all bulk drug industry. Manufacture of these categories of products involves lot of chemical reactions. Any chemical reaction besides producing targeted product also generates other by-products, side-products, and un-reacted products mixed with other chemicals. Disposal of these unwanted products, which in some cases may be toxic, create lot of problem. Creating facilities for disposal or treating such waste materials are very expensive and in many cases is beyond reach of pharma SMEs.

In order to handle the pollution and waste management, it is essential to provide training to all cluster firms, arrange pollution consultants in the field of water audits, advise them relating to the nature of different streams of pollutants, methods / scheme to reduce the liquid or solid waste generation and means to handle them effectively. This will help the entrepreneurs in higher income, cleaner environment and reduces the water consumption. Many of the cluster firms have shown lot of interest in such services.

J). Information and Communication Technology (ICT)

The export firms are having their own web portals and doing e-commerce in a limited way, where as small export firms and manufacturing units are not doing any e-commerce due to lack of awareness, affordability for local software developers for creation and maintenance. The computer literacy levels are also found wanting in majority of the manufacturing firms and still manually maintaining books, ledgers and other operations leading to employee drudgery. Most of the firms use software for accounting purpose. The employees of the firms have not fully used due to lack of skills. Most of the CEOs of the firms spend much of their time on raw material procurement, inventory but not on business development. Only ICT can solve the most of the problems like to know the details on line about inventory, details of raw materials, manpower, purchase and marketing, etc.

The issues and suggested solutions are given below:

BDS Areas	Issues		Suggested Solutions	Required BDS providers / Facilitators
	In Bulk drugs manufacturing	In Formulations manufacturing		
Raw Material (RM)	<ul style="list-style-type: none"> Few basic raw material and excipients (like Cyclopropylamine, 3, 4, 5 –Trimethoxy benzoldihyde, etc) sourced from imports are very costly and faces its quality & timely delivery problems 		<ul style="list-style-type: none"> Facilitate create raw material bank for essential and regular raw materials 	<ul style="list-style-type: none"> Raw material suppliers Banks BMOs
	<ul style="list-style-type: none"> Scarce quality water required for either processing or purification of the final drug substance. 		<ul style="list-style-type: none"> Facilitating supply of treated or potable water 	<ul style="list-style-type: none"> Banks BMOs
Technology	<ul style="list-style-type: none"> Non availability of literature and facing problem in literature search 		<ul style="list-style-type: none"> Sensitize to create an online search facility for journals like SCI finder 	<ul style="list-style-type: none"> BMOs IICT HCU CCMB
Marketing	<ul style="list-style-type: none"> Limited access to export market 		<ul style="list-style-type: none"> Interface with market consultants Participating in special BSM Creation of web portal and BDS directory 	<ul style="list-style-type: none"> BMOs Market consultants Pharmexcil Web portal developers

HRD & Manpower	<ul style="list-style-type: none"> Limited availability of skilled man power Low labour skills and productivity in existing labour 	<ul style="list-style-type: none"> Organize skill development programmes in the areas of quality assurance, quality control, production etc Linkage with ITI / technical educational Institutions for regular source of human manpower 	<ul style="list-style-type: none"> NIPER BMOs ITI Pharmacy colleges
Safety	<ul style="list-style-type: none"> Non compliance to safety standards in handling of hazardous waste 	<ul style="list-style-type: none"> Organize awareness programmes on safety standards Safety audit, safety seminar Upscale 	<ul style="list-style-type: none"> Fire & Safety Consultants BMOs
Quality	<ul style="list-style-type: none"> Poor adoption of GMP practices by majority of the firms (only bulk drug) 	<ul style="list-style-type: none"> Interface with GMP consultants Organize pilot quality audits GMP & marketing consultancy Upscale 	<ul style="list-style-type: none"> Quality consultants IICT BMOs Banks/FIs
Finance	<ul style="list-style-type: none"> Poor credit facility to tide over any urgent / short term financial requirements Lack of ample credit facility for GMP up gradation 	<ul style="list-style-type: none"> Organizing Bankers meet Create products Promote those 	<ul style="list-style-type: none"> Banks/FIs Financial consultants BMOs
Testing facility	Lack of appropriate machinery for small firms and the testing labs are not capacitated.	<ul style="list-style-type: none"> Need for testing facilities 	Networks, BMOs
Energy Management	<ul style="list-style-type: none"> Poor adoption of energy saving measures 	<ul style="list-style-type: none"> Organizing workshops on energy efficiency Organize pilot energy audits Upscale 	<ul style="list-style-type: none"> BMOs Energy auditors/ Consultants

<p>Pollution & waste management</p>	<ul style="list-style-type: none"> • Problem in disposal of hazardous waste and effluents 		<ul style="list-style-type: none"> • Organize training programme on pollution and waste management • Organize water audits on pilot basis • Upscale 	<ul style="list-style-type: none"> • Environment consultants • BMOs
<p>Information Communication Technology (ICT)</p>	<ul style="list-style-type: none"> • Lack of awareness on advanced usage of software • Low computer literacy levels 		<ul style="list-style-type: none"> • Organize training programmes on usage of software applications • upscale 	<ul style="list-style-type: none"> • IT firms • ICT consultants • BMOs

Pressure Points:

The pressure points in the cluster, which influences mostly as mentioned below:

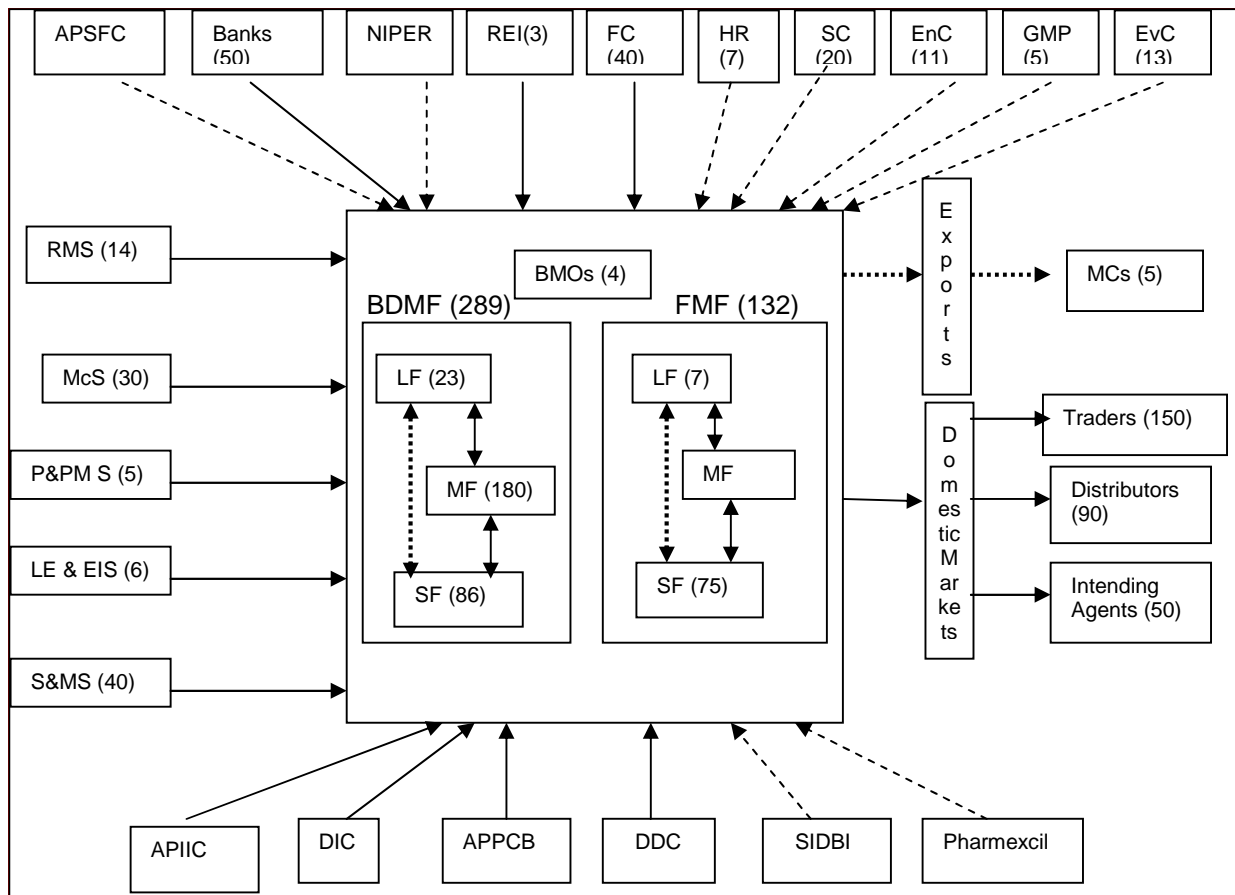
- Create common safety infrastructure for fire and other safety need
- Quality compliances and certification
- Documentation of Drug Master File (DMF) for export market
- Linkage with knowledge institution for knowledge update on technology and products.

4.1 SWOT Analysis

Strengths	Weakness
<ul style="list-style-type: none"> ◇ Strong marketing & distribution network (mainly catering to the larger industries) ◇ High volume domestic and international market ◇ Competencies in chemistry, process development and fast adoption of new technologies ◇ Availability of public testing laboratory services ◇ Developed industry with strong manufacturing base ◇ Access to pool of highly trained scientists ◇ Well established R&D infrastructure in large firms ◇ Most of the entrepreneurs are technocrats ◇ Less over head cost 	<ul style="list-style-type: none"> ◇ Lack of knowledge resources to compete with MNCs for New Drug Discovery, Research and commercialization of molecules on a worldwide basis ◇ Lacking knowledge on the fast technology up gradation taking place in the process ◇ Lack of strong linkage with knowledge network ◇ Lack of financial assistance for up gradation ◇ Long time for sales price realization through traders' network ◇ Retaining talented manpower ◇ Low investments in innovative R&D in small and medium firms. ◇ R&D activity is almost non – existent and limiting the scope for developing new products in Indian medicine due to IPR norms. ◇ Lack of market related skills (marketing product and procurement of raw materials) ◇ Non availability of competent cGMP consultants locally. ◇ Lack of strong linkages between industry and academia ◇ BMOs operating below potential ◇ Small firms do not make full utilization of PHARMEXCIL ◇ Low adherence to GMP

	<ul style="list-style-type: none"> ◇ Most of the units run by single man who may be technically strong but lacks management training ◇ Lack of services for documentation of “DMF” and export promotion
Opportunities	Threats
<ul style="list-style-type: none"> ◇ Significant export potential. ◇ Marketing alliances for MNC products in domestic market and international market. ◇ Contract manufacturing arrangements with MNCs ◇ Strong growth of domestic market ◇ Potential for developing India as a centre for international clinical trials ◇ Scope for completion of CEIP of Nalgonda Institutional Area. ◇ High demand for testing facilities and high yield technologies in Indian medicine ◇ Globally all governments looking for cheaper medical care ◇ Many large companies are depending on small firms ◇ CRAMS offers 	<ul style="list-style-type: none"> ◇ Export effort hampered by procedural hurdles in India as well as non-tariff barriers imposed abroad and fluctuations in Forex market. ◇ Influence of other emerging markets ◇ Product patent regime poses serious challenge to domestic industry unless it invests in research and development ◇ Drug Price Control Order puts unrealistic ceilings on product prices and profitability ◇ R&D efforts of Indian pharmaceutical companies hampered by lack of enabling regulatory requirement

4.2 Present Cluster Map



BDMF	:	Bulk Drugs Manufacturing Firms
FMF	:	Formulations Manufacturing Firms
LF	:	Large Firms
MF	:	Medium Firms
SF	:	Small Firms
BMOs	:	Business Members Organizations
APSFC	:	Andhra Pradesh State Finance Corporation
NIPER	:	National Institute for Pharmaceutical Education & Research
REI	:	Research & Educational Institutes
FCs	:	Financial Consultants
HR	:	Human Resource Consultants
SC	:	Safety Consultants
EnC	:	Energy Consultants
EvC	:	Environment Consultants
GMP	:	Good Manufacturing Practicing Consultants
RMS	:	Raw material Suppliers
P&PMs	:	Printing & Packaging Material Suppliers
McS	:	Machinery Suppliers
LE & EIS	:	Laboratory Equipment & Engineering Item Suppliers
S&Ms	:	Stationary & Miscellaneous Suppliers
MCs	:	Marketing Consultants

4.3 Vision of the cluster

Position the Hyderabad drugs and Pharmaceutical cluster as a vibrant and competitive cluster by meeting the global regulatory practices and strong linkages with knowledge network by linking with a vibrant and self propelling BDS framework and creation of appropriate PPPs.

4.4. Long and Short- Run Objectives

4.4.1 Long-run Objectives

- Strong linkage with knowledge networks
- Creation a system for preparation of drug master file (DMF) to register product in overseas markets
- Creating common testing facilities under PPP model
- Formation of consortia for raw material bank
- Creation of fire fighting system/ safety consultancy services
- Adherence to regulatory requirements by at least 30% of the total SMEs
- Increase in BDS turnover by 8 to 10%
- Increase in turnover and exports by 15% of proactive firms by 5 to7%
- Facilitation for establishing a Common Effluent Treatment Plant and testing facilities with the support of DC-MSME for Nalgonda Bulk Drug SMEs.

4.4.2 Short-run objectives (for first year)

- Perpetration of proposal for common testing facilities
- Perpetration of proposals for fire fighting systems in all industrial Development Areas (IDAs)
- Awareness on current and emerging regulations by drug authorities
- Skill improvement programme for existing employees working in QC / QA / Prod / Maintenance / personnel departments of cluster firms
- Preparation of DMF
- Awareness on benefits of energy auditing and conducting pilot energy audits
- Awareness on safety management and conducting pilot safety audits in Bulk drugs
- Creation of cluster level web portal & BDS directory

4.5 Suggestive Action Plan

A). Proposed Interventions with Tentative Time lines Hyderabad Pharma Cluster

S.No.	BDS Areas	Suggested Intervention	Time Line (Quarter wise)												
			1	2	3	4	5	6	7	8	9	10			
1	Technology	<ul style="list-style-type: none"> Sensitize to create an online search facility for journals like SCI finder 													
2	Market access	<ul style="list-style-type: none"> Interface with market consultants 													
		<ul style="list-style-type: none"> Participating in trade fairs 													
		<ul style="list-style-type: none"> Creation of web portal and BDS directory 													
3	HRD & Manpower	<ul style="list-style-type: none"> Organize skill development programmes in the areas of quality assurance, quality control, production etc 													
		<ul style="list-style-type: none"> Linkage with ITI / technical educational Institutions 													
4	Quality	<ul style="list-style-type: none"> Interface with GMP consultants 													
		<ul style="list-style-type: none"> Organize pilot quality audits 													

S.No.	BDS Areas	Suggested Intervention	Time Line (Quarter wise)											
			1	2	3	4	5	6	7	8	9	10		
5	Pollution & waste management	• Organize training programme on pollution and waste management												
		• Organize water conservation efforts on pilot basis												
6	Energy	• Organizing workshops on energy efficiency												
		• Organize pilot energy conservation efforts												
7	Finance	• Organizing Bankers meet												
8	Information Communication Technology (ICT)	• Organize training programmes on usage of software applications												
9	Raw materials	• Facilitate to create raw material bank for essential and regular raw materials												
		• Facilitating supply of treated or potable water												
10	Safety	• Organize awareness programmes on safety standards												

B). Proposed Annual Action Plan for the year 2009 -10

S.No	Activity	Required BDS Providers	Funding Agencies	Expected Outcome	Time Frame
1	Organize three cluster coordination committee meets		SIDBI	Successful execution of first year action plan	M4, M7, M10
2	Creation of Web Portal and BDS directory	Web portal developer	SIDBI	Brand promotion of cluster and increased awareness on BDS providers	M4/M5
3	Facilitating the SMEs to establish a common facility with the help support Institutions to source on line data / e-journals	ICT, BMOs	SIDBI, BMOs CCMB IICT NIPER	SMEs utilize online paid literature sites, for ex., SCI finder, ACS etc. which has key for the success of any R&D activity and also upgrading their process and develop newer products.	M9
4	Workshop with GMP consultants of Jeedimetla, Pashamylaram and Choutuppal areas	GMP consultants	SIDBI	SMEs aware in implementation of basic Schedule - 'M' quality certification, IPR related issues, WHO – GMP norms and upgrade to next level and enter into export markets.	M5/M6

5	Organize pilot quality audits for the implementation of cGMP in first 5 units at each location of Jeedimetla Pashamylaram Choutuppal areas	GMP consultants	SIDBI, Cluster firm	GMP consultants provide inputs by way of plan as per revised regulatory requirements and to meet the same on regular basis. Assessment in roadmap for achieving WHO-GMP	M7, M8, M9
6	Workshop with market consultants	Marketing consultants	SIDBI	Marketing consultant advises SMEs in identifying the product, packing, area(s) where it can be launched	M8
7	Organise skill development programmes in the areas of quality assurance, quality control, production, etc	Public or private training institutions	SIDBI Cluster firms	SMEs train the personnel in technical subjects covering quality assurance, quality control, production etc.	M8, M9, M10
8	Organise training programme on pollution and waste management	Environmental Consultants	SIDBI	SMEs aware on pollution and waste management and handle the hazardous wastes	M7
9	Organise water conservation efforts on pilot basis in 5 cluster firms	Environmental Consultants	SIDBI, Cluster firm	Environmental consultants advise and train SMEs in the field of water audits and different streams of pollutants, methods to reduce liquid or solid waste generation	M9, M10, M11

				and means to handle effectively. Helps the entrepreneurs in higher income, cleaner environment and reduces the water consumption.	
10	Organise workshop on energy efficiency	Energy Consultants	SIDBI	SMEs are aware on the possibilities of energy conservation and adopt methods	M9
11	Organise pilot energy conservation efforts	Energy Consultants	SIDBI, Cluster firm	SMEs are aware and adopt energy conservation and saving equipments	M10, M11, M12
12	Organise bankers meet	FIs/ Bankers	SIDBI BMO	SMEs aware on special products / packages like soft loans, concession on interest and higher moratorium from financial institutions & banks for GMP implementation & up- gradation	M5/M6
13	Sensitization workshop for formation of consortia for raw material bank	BMOs	SIDBI BMO	Helps in stocking essential and regular moving raw materials will facilitates in availability of major materials at a very competitive price and short delivery period.	M11
14	Workshop/pilot on testing needs	BMOs	SIDBI BMO	Road map for common testing facilities.	M10
15	Workshop/pilot on DMF		SIDBI BMO	Road map for common testing facilities.	M10

16	Participating in trade fares	BMOs Pharmexcil	SIDBI, Cluster firms	SMEs can avails the opportunity to enter into western countries market	M11/M12
17	Organize awareness programmes on safety standards at different locations (4 No.s)	Safety Consultants	SIDBI	SMEs understand how to handle variety of flammable, explosive and other hazardous chemicals during processes and also understand the nature of hazard to deploy suitable fire fighting systems. SMEs train their production personnel and conduct safety audits facilities to meet all types of fire classes.	M6, M12