MANAGEMENT REVIEW

Pricing of Pharmaceutical Products in SME Pharma Units

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Abstract

Small and medium pharmaceutical units contribute to a large extent in making formulations and bulk drugs for meeting domestic pharmaceutical requirement of the country. This research article evaluates one of the key parameters influencing the pricing of drugs in SME Pharma units after implementation of the current GMP, GLP & GCP. It studies in details the processes and mechanism involved in pricing of the SME Pharma units.

Different functional areas like manufacturing, distribution, marketing, R & D, Finance and Information technology in practice of GMP, GLP and other Quality system like ISO were studied for elaborate costing and its effect on pricing of drugs and pharmaceuticals.

For operational economy many of the small scale pharmaceutical units of Odisha have adopted cluster approach, which is a well developed strategy for technological upgradation to meet GMP/GLP requirement.

Keywords

SME (Small & Medium Enterprise) Pharma, GMP- Good Manufacturing Practice, GLP- Good Laboratory Practice, GCP- Good Clinical Practice, Bulk Drugs, Formulations, R & D, Product patent, Contract manufacture, Cluster, BDSP- Business Development Service Provider, Marketing, WTO- World Trade Organisation, DPCO- Drug Price Control Order

Introduction

The study is focused mainly on bulk drug and formulation manufacturing units in SME sector.

(a) Bulk Drugs & Phytochemicals

The bulk drug is the parent chemical entity, excipient or drug substance which is used in formulation making for consumption by patients. Phytochemicals are plant derivatives or extracts which are prepared by processing of crude medicinal plant materials like leaf, bark, root, etc

The Indian Bulk drug Industry is highly competitive with a number of global and Indian companies present in the market now. The foreign companies are present in India through Joint Venture, Equity participation or with technology tie-ups. Between 1965-66 and 1997-98 the production of bulk drugs rose from Rs.180 million to Rs.26230 million.

The total production of drugs and pharmaceutical in India is 40% of the world production with formulation and bulk drug ratio as 55:45. The industry has the potential to emerge as one of the largest in the world. India ranks and the country is expected to make to the top five bulk drug producer segment by 2020.

(b) Formulations (Allopathic/Ayurvedic/Homeopathic)

Various formulations consist of Tablets, Capsules, Ointments, Liquid orals, Powders, etc in allopathic and Indian system of medicine. There are hundreds of brand available in a particular category of drug formulation, whether in specific or combined dosage form.

The Indian pharmaceutical industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacturing and technology. It is a front-runner in the third world in terms of technology, quality and range of medicines manufactured. Almost all types of medicines - ranging from simple pain relieving pills to sophisticated antibiotics and complex cardiac compounds - are now made in the country.

These have made India fairly self-sufficient in this field. A large domestic market and relatively inexpensive trained manpower have also enabled the country to emerge as a low cost production centre. Between 1965-66 and 1997-98 the production of formulations rose from Rs.1500 million to Rs.120680 million. In 2003 the OTC market stood at Rs. 35 billion.

Drugs Prices Control Order (DPCO):

The Drugs (Prices Control) Order, 1995 has been in effect, which puts a cap on the pricing of various Scheduled and non-scheduled drugs & their formulations. The retail price of a drug or formulation shall be calculated in accordance with the following formula:

R.P. = (M.C. + C.C. + P.M. + P.C.) x (1+ MAPE/100) + E.D.

Where R.P. means retail price, M.C means material cost, C.C. means conversion cost, P.M. means cost of packing material, P.C. means packing charges, MAPE is maximum allowable post manufacturing expenses including trade margin and E.D. means excise duty.

There are 75 items in the essential drug list, which come under price control. MAPE includes all costs incurred by a manufacturer from the stage of ex-factory cost to retailing including trade margin which should not exceed 100% of ex-factory cost for medicines. While fixing the sales price a post-tax return of 14% on net worth or 22% on capital employed is taken in to consideration for bulk drugs. For a new plant it is 12% based on long term marginal costing. Where a drug is produced from basic stage the tax is 18% on net worth or 26% on capital employed. Excise duty for all narcotic drugs, drugs containing alcohol, Patent and Proprietary medicine is 16% ad valorem.

Every year newer drugs are added to the list which makes it difficult to manufacture and market the products with cost competitiveness at par with MNCs. The National List of Essential Medicines 2003 as well as the WHO List of Essential Medicines mentions 27 categories of drugs. Of these for the purpose of price control 17 categories have been selected. The categories chosen represent drugs required for the public health problems, for common conditions in health care, categories in which drugs are at present expensive or there is evidence of overpricing. All drugs included in these therapeutic categories are proposed to be covered by price control.

I. ANTIINFECTIVE MEDICINES : (including Antihelminthics, Antibacterials including betalactam and other antibacterials, antileprosy , antituberculosis, Antifungals, Antivirals, Antiprotozoals)

II. MEDICINES AFFECTING THE BLOOD : (Antianemia medications and medicines affecting coagulation)

III. CARDIOVASCULAR MEDICINES : (Antianginal , antiarrhythmics, antihypertensives, medicines used in heart failure, antithrombotic medicines)

IV. MEDICINES ACTING ON RESPIRATORY TRACT : (Antiasthmatic medications, antitussives)

V. HORMONE, OTHER ENDOCRINE MEDICINES, CONTRACEPTIVES: (including Antidiabetics and thyroid and antithyroid medicines)

VI. IMMUNOLOGICALS : (including sera and immunoglobulins, and vaccines)

VII. GASTROINTESTINAL MEDICINES : (including Antacids and anti-ulcer medications, antiemetics, antiinflammatory medicines, medicines used in diarrhea)

VIII. PSYCHOTHERAPEUTIC MEDICINES : (including medicines used in psychotic disorders, mood disorders, generalised anxiety and sleep disorders)

VIII. ANTICONVULSANTS/ANTIEPILEPTICS :

IX. ANTINEOPLASTIC, IMMUNOSUPPRESIVES, AND MEDICINES IN PALLIATIVE CARE

X. ANALGESICS, ANTIPYRETICS, NSAIDS, DISEASE MODIFYING AGENTS USED IN RHEUMATOID DISORDERS

XI. ANTIALLERGICS AND MEDICINES USED IN ANAPHYLAXIS.

XII. BLOOD PRODUCTS AND PLASMA SUBSTITUTES

XIII. DERMATOLOGICAL MEDICINES

XIV. DISINFECTANTS AND ANTISEPTICS

XV. DIURETICS

XVI. OPHTHALMOLOGICAL PREPARATIONS

XVII. VITAMINS AND MINERALS

Most of the small scale pharmaceutical units of Odisha manufacture patent and proprietary medicines in either one or two therapeutic categories and compete with similar branded formulations available from MNCs in the market. Some of the units also cater to the government and other institutions. Most the units prefer to be away from the purview of DPCO due to low margin of profit.

However the licensing procedure has been stringent after implementation of Schedule M of Drug Rules i.e. GMP (Good Manufacturing Practice), which makes it difficult for the units to price their products for a tough competitive local market. Introduction of new formulations, new

therapeutic groups to the portfolio on experimental basis is becoming a costly affair with limited success.

Literature Review

The studies relating directly or indirectly to the present subject have been reviewed (Year wise) in order to determine the research gap and to establish the need for this study.

Wani, V.P. (1993) conducted a study on "Quality Consciousness in Small Scale Sector". According to him Small Scale Entrepreneurs should be quality conscious about their product. Today productivity means goods of better quality at less cost, which has less chance of rejection, good profitability with less alteration.

Ramaswamy, K.V. (1994) in his study on "Small Scale Manufacturing Industries" found that the performance of Small Scale Industries was good in terms of employment, export and value added because of the basic characteristics of the industry.

Chadha Vikram (1995) found that the use of outdated technology by SSI Units is the critical obstacle in the way of growth and modernization of the small industries. Small Industries can be modernized by improving productivity, enhancing quality, reducing cost and restructuring product mix through up-gradation of technology and enlarging the skill of the workers. The liberal fiscal and monetary incentive should be given to these units so that they can carry out R & D particularly in technology intensive industry.

Mukherjee, Neela (2002) evaluated the performance of Small Scale Industries in India and World Trade Organisation. According to him small and medium enterprises occupy a crucial position in the Indian Economy, not only because they contribute to GDP, income, exports and employment but they also provide self employment, livelihoods and small business and it is important to create and ensure space and more opportunities for such a sector.

Jong Wook Ha, Soon-Gwon Choi and Sungwoo Jung (2007) analysed the Korean firms "on When, how and where do SMEs start global business".

Daiva Radzeviciene (2008) analysed the role of knowledge management in small and medium-sized enterprises in Lithuania by looking at information and knowledge resources, the development of information technology which supports the business process and the main processes of KM inside companies. There appears to be a strong awareness of KM.

Objective of the Study

The objective of the study was:

- To conduct Value Chain analysis and evaluate the competencies of the SME Pharma units in techno-commercial areas.
- To evaluate the factors affecting pricing mechanism of drug products of SME.

Methodology

This study attempts to present and analyse the business dynamics of the pharma industry and also to understand its pricing policy. The objective is to explore the areas of intervention, cost competitiveness for development of the pharmaceutical industry. A diagnostic Survey was conducted in various Drugs and Pharmaceutical units of Odisha, through detailed questionnaire, survey of core individual and cluster firms, BDS providers, interviews with proprietors, managers, support institutions and discussions with associations, workers. The primary and secondary data thus collected was compiled and a comprehensive analysis was made regarding status of the cluster/independent units, BDS providers, key issues and required interventions.

The principal basis of information and perspectives detailed in this study derives from primary sources, mainly, structured surveys of pharma enterprises and detailed issue based discussions/interviews with a number of individuals directly or indirectly concerned with the industry in the state. At various stages of the study, we had interactions with drugs, pharmaceuticals producers, repacking units, loan licensees, office bearers and members of industry associations, bankers, officials of the concerned state departments, R and D specialists, academics, policy makers and other knowledgeable and experienced persons in the field. A selective list of persons consulted/interviewed as part of this study appears as below:

Primary & Secondary data source - Though Questionnaire and Interview

Sample: Basic Features of the Sample Units

- For the purpose of the study, we have surveyed mainly 20 Small and Medium industrial units producing drugs and pharmaceuticals located at Bhubaneswar and Cuttack.
- All production operations and quality functions are carried out either by manual, semi-automatic, or auto-controlled machines by technical staff.

Table 1:
Profile of Survey Respondents (Category of Persons/ Organisations Interviewed)

Medium pharmaceutical units:1	Small pharmaceutical units: 17
Medical disposables units: 2	Loan licensees: 1
Industry Associates: 1	Policy making and regulatory bodies: 1

Table 2:
Number of units according to sales turnover

Table 3:
Parameters under study

Production Process

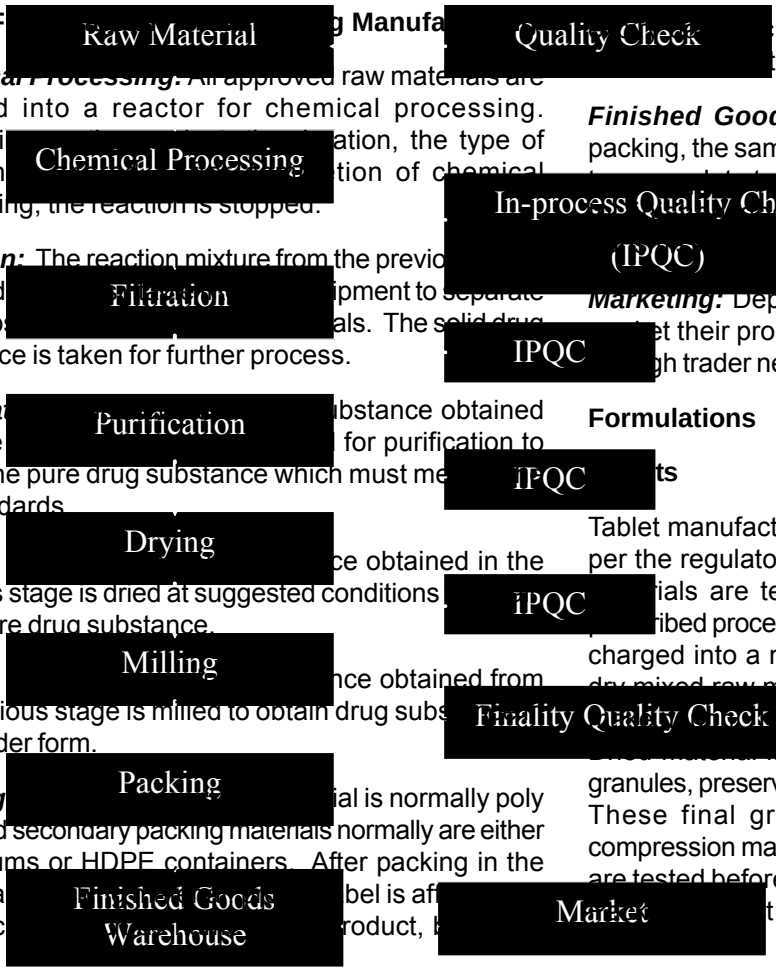
Bulk Drug

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

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.

Fig. 1 F **g Manufa**



Chemical Processing: All approved raw materials are charged into a reactor for chemical processing. Dependi ation, the type of reaction tion of chemical processing, the reaction is stopped.

Filtration: The reaction mixture from the previo is filtered ipment to separate drug subs als. The solid drug substance is taken for further process.

Purificat ubstance obtained from the for purification to obtain the pure drug substance which must me set standards.

Drying: ce obtained in the previous stage is dried at suggested conditions dried pure drug substance.

Milling: nce obtained from the previous stage is milled to obtain drug subs the powder form.

Packing ial is normally poly bags and secondary packing materials normally are either fiber drums or HDPE containers. After packing in the seconda bel is aff all partic roduct, b

. During packing operation in-process aken for weight, etc.

Finished Goods ware house: After completion of packing, the sample taken from the product is subjected approval the lot is transferred house for onward market

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

Formulations

ts

Tablet manufacturing process involves 10 stages. As per the regulatory requirements, all the incoming raw ials are tested to meet the standards, As per ribed procedures (SOP) the approved materials are charged into a mixing machine for dry mixing. To the dry mixed raw materials, binding agents are added to dough is spread on trays for drying. 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 in strips. t is finally dispatched for marketing.

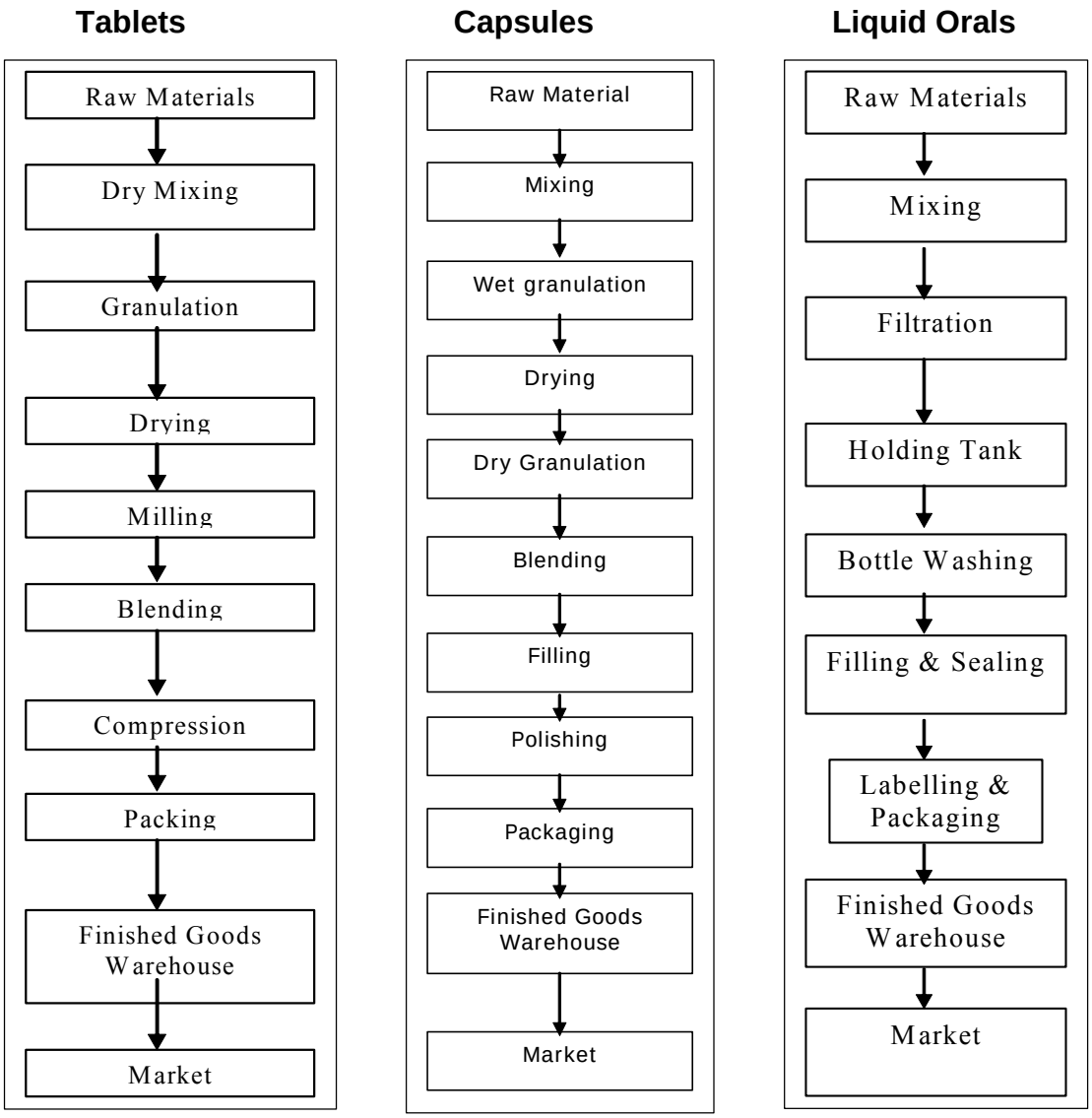


Fig. 2: Flow Chart for Manufacturing Process of Formulations

Capsules:

Similarly Capsules manufacturing, which starts from raw material procurement to dispatch for marketing, involves 11 stages. As per the regulatory requirements, all the incoming raw materials are tested to set standards and stored as per prescribed procedures. The approved materials are mixed, dried and milled to obtain granules. To these granules, preservatives, lubricants are added and mixed. These final granules are filled in the empty gelatin capsules, which is done in an automatic/ semiautomatic process. After filling, capsules are subject to polishing to remove adhered materials and give a glow. Then these capsules are tested before proceeding for final packing in strips. This finally packed product is dispatched for marketing.

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 containing prepared sugar syrup / sweetening agent such as liquid glucose, sorbitol, etc., other approved materials are added and mixed. After completion of mixing filtration or milling is done to obtain the desired quality. Then the product is filled into washed & dried bottles, sealed, visually inspected, labeled and finally packed in to cartons. After test and QC approval, product is dispatched for marketing. A sample of each batch is retained as 'control/ retained sample" for any future cross reference.

Distribution Process

In a geographically diverse and extremely competitive market where sales volumes are high, distribution plays a crucial role. Further, the common incidence of brand substitutions makes it imperative for a company to make available its brands at all times and at various levels of distribution. The distribution channel for pharmaceutical products is given below:

Fig. 3 Distribution Channel for Pharmaceuticals

The cluster map of pharmaceutical units is outlined below. The cluster consist of 10-12 individual formulation units of Cuttack and Bhubaneswar.

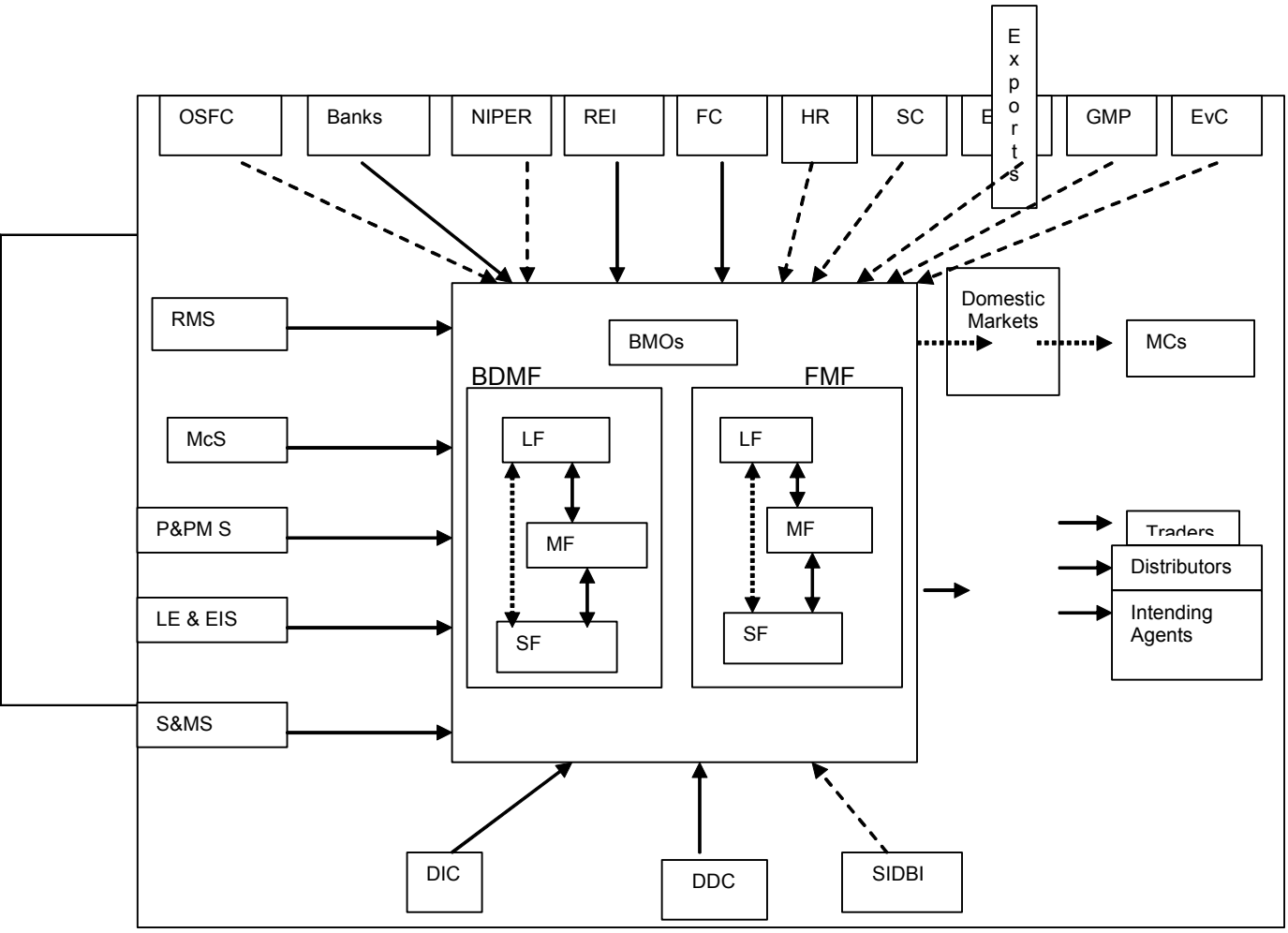


Fig. 4 Present Cluster Map for Drugs & Pharmaceutical units

BDMF : Bulk Drugs Manufacturing Firms
LF : Large Firms
BMOs : Business Members Organizations
SIDBI : Small Industrial Development Bank of India
OSFC: Odisha State Finance Corporation
REI : Research & Educational Institutes
EnC : Energy Consultants
GMP : Good Manufacturing Practicing
RMS : Raw material Suppliers
P&PMs : Printing & Packaging Material Suppliers
S&Ms : Stationary & Miscellaneous Suppliers
FMF: Formulations Manufacturing Firms
MF/SF: Medium Firms/Small Firms
FCs: Financial Consultants
SC: Safety Consultants
DIC: District Industry Center
HR: Human Resource Consultants
EvC: Environment Consultants
MCs: Marketing Consultants
McS: Machinery Suppliers
DDC: Directorate of Drugs Control
LE & EIS: Laboratory Equipment & Engineering Item Suppliers
NIPER : National Institute for Pharmaceutical Education & Research

Organisation Structure of individual SME unit:

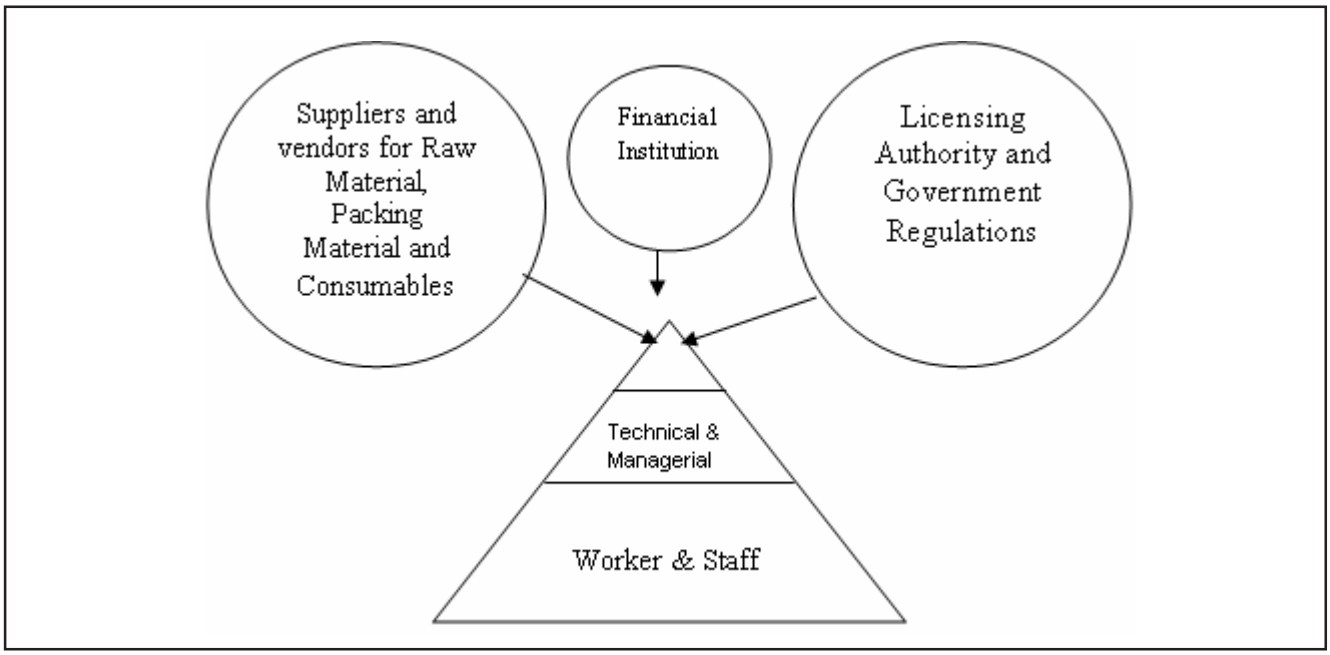


Figure 5 SME (Pharma) Organisation: 3 Tier Pyramid Structure

Most of the units under study have a simple organization structure with either the proprietor or partner as the chief decision making authority, who controls a small team of administrative staff, technical staff and marketing staff. The bottom of the pyramid consists of workers and field staff. Some of the functions like GMP/GLP are outsourced due to lack of technical personnel.

Besides the technical GMP/GLP consultancy service, consultants in the area of Finance, Safety, Environment (Polution control), Marketing are available, who help the cluster group in overcoming procedural obstacles.

Limitations Of The Study

(i) This study primarily looks on the past, current and future of Pharma SMEs as well as service providers without much revelation on financial data. But more views of many shareholders for the SME systems need to be taken in consideration which exposes study's Limitation.

(ii) The present study has not covered the units of Odisha having investment of less than Rs. 1 lakh or units outside Odisha owing to a number of problems.

Analysis And Interpretation Of Data

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:

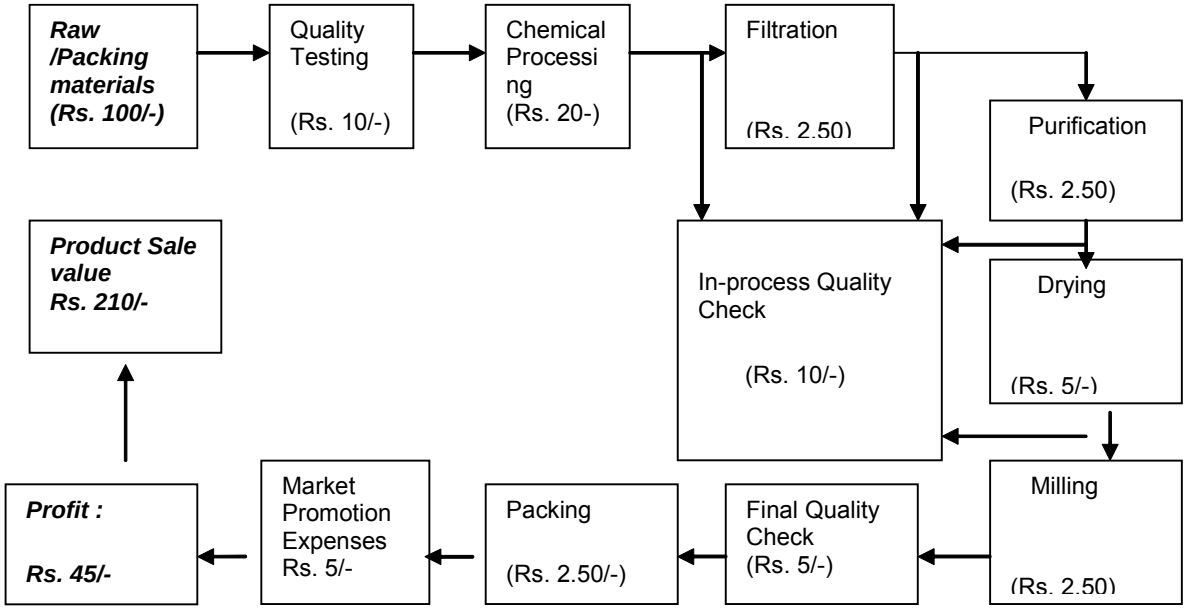


Fig. 6 Value chain for a bulk drug unit which is implementing GMP and GLP compliances

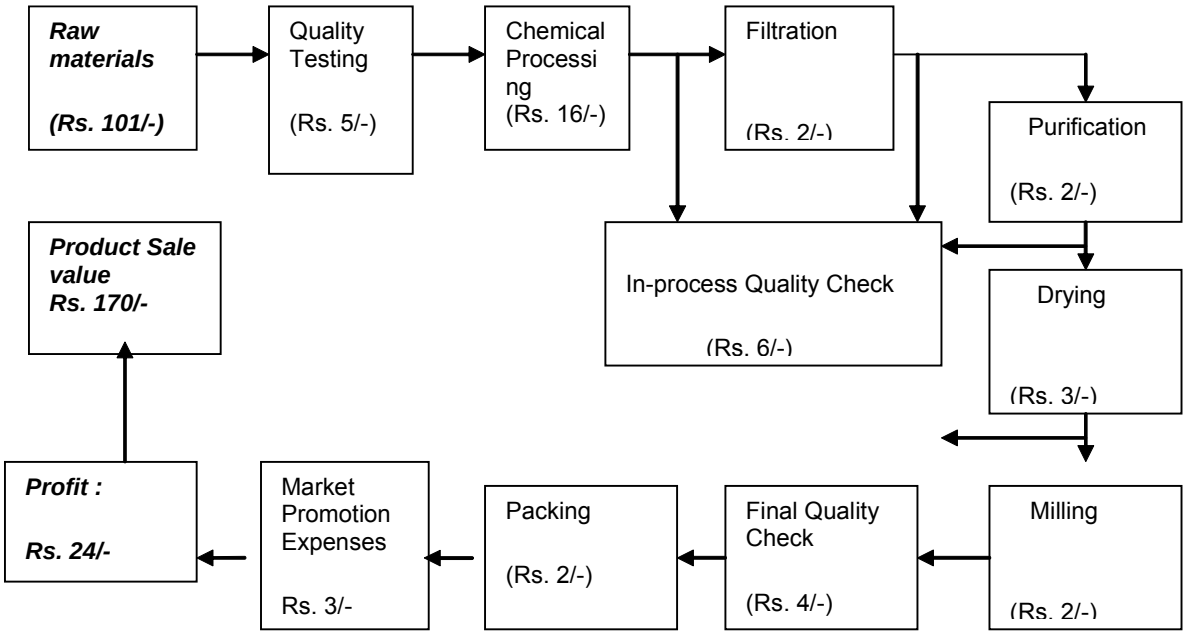


Fig. 7 Value chain for a bulk drug unit which is not implementing GMP/GLP compliances

(Assumption: cost of raw and packing material for manufacture of a product is assumed as Rs. 100/- and Rs.101/- for GMP complied and non-complied units respectively)

B) For Formulations Manufacturing:

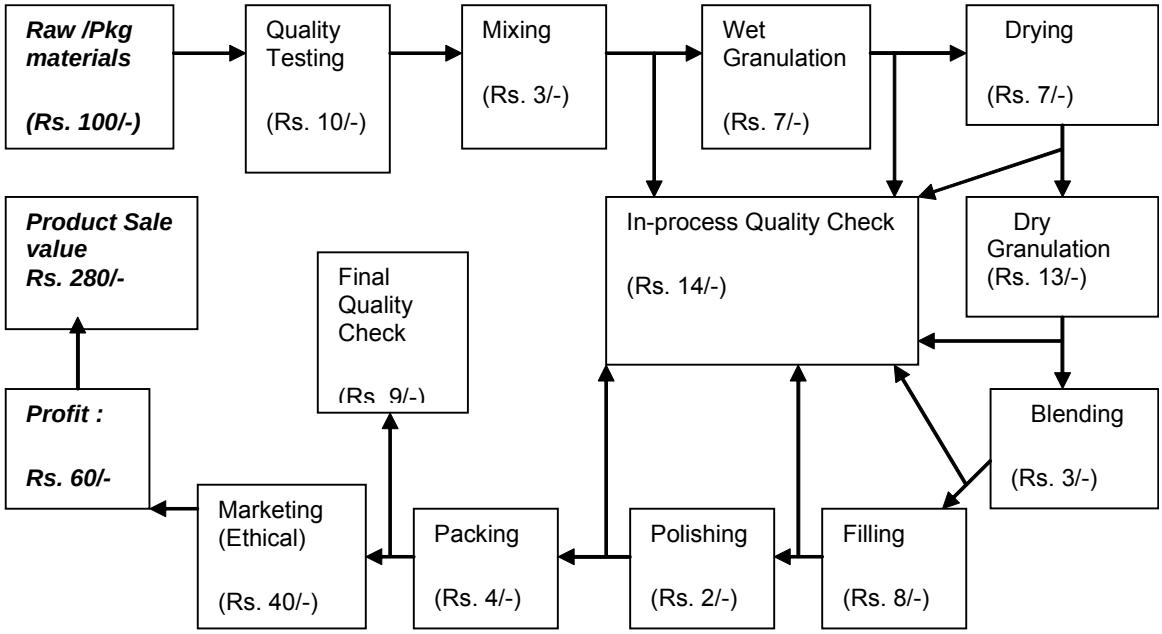


Fig. 8 Value chain for a formulation unit (capsules) implementing GMP/ GLP compliances

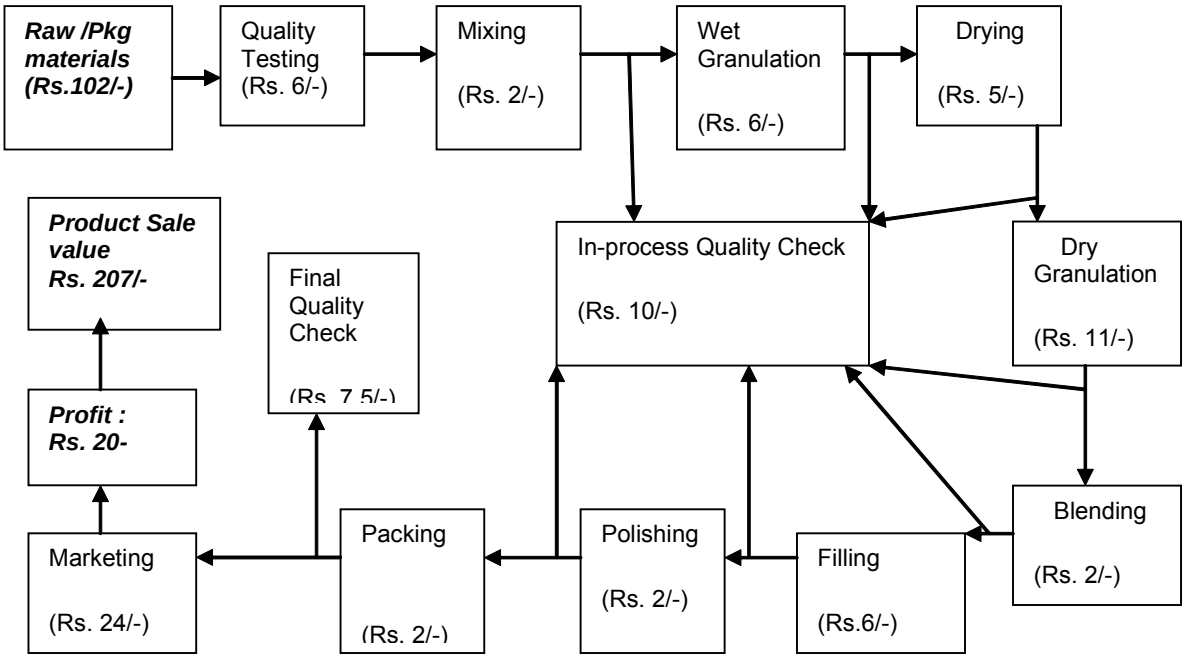


Fig. 9 Value chain for a formulation unit not implementing GMP and GLP compliances
(Assumption: cost of raw and packing material for manufacturing a product is assumed as Rs. 100/- and Rs. 102/- respectively for GMP complied and non-complied units)

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.

A. The cost of processing is low in the units which do not comply GMP/GLP norms work with obsolete technology to produce inferior quality of medicines at low profit margin by giving more benefit to traders for push sell.

B. The implementation of GMP and GLP norms has a definite impact on the processing cost including quality checks and the firms have an advantage to increase profit margin and sell it for a higher price with ethical promotion.

2. Analysis of Techno-Commercial aspect

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 interest 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 scarcely available in Odisha.

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 and other special excipients 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.

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) Manufacturing

- Own Product Manufacturing

Most of the SME pharma units have their own licensed products and distribution channel to market the products. The capacity utilization in manufacturing own products is almost 50% in most of the units.

- 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.

D) Quality Testing Facilities

Pharmaceutical manufacturers have to upgrade their quality testing facilities on a regular basis based on current regulatory requirements of GLP. 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.

E) Manpower & Employment

As technology and regulations are continuously upgrading, the employable manpower availability for pharma SMEs in Odisha 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.

F) Information and Communication Technology (ICT)

The firms are doing e-commerce in a limited way, where as small 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 is less in majority of the manufacturing firms and still manually maintain documents. 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.

Besides all the above aspects, safety, environmental issues and energy management are also vital for the drugs and pharmaceutical units, on which awareness campaign has to be initiated at government level for entrepreneurs.

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.

Conclusion

All the pharmaceutical units under study are following good manufacturing practices (GMP), as prescribed in Schedule M of Drugs and Cosmetics rules, 1940. The SME units which follow GMP norms procure raw materials from open market sometimes at a higher price.

All the GMP complied firms follow prescribed test methods to test the quality of its raw materials whereas for certain tests they depend on outside testing laboratory. This provides some extra cost for GMP certified units and saving for non-GMP firms.

However the firm that follows the GMP standards is able to sell its product through profitable mode, whereas the firm that does not follow the standards needs to depend on local traders to market its 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 GMP norms is higher on production cost, the final profit realization is higher compared to a non-compliant firm**.** The former 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.

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