

MATERIALS MANAGEMENT IN PHARMACEUTICAL INDUSTRY - A REVIEW

Madhumita Roy*, Dr Padmini Sharma and Atika Gaikawad

Department of Quality Assurance Techniques, Padm. Dr. D. Y. Patil College of Pharmacy,
Akurdi, Pune, Maharashtra. India.

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***Correspondence for
Author**

Madhumita Roy

Department of Quality
Assurance Techniques,
Padm. Dr. D. Y. Patil
College of Pharmacy,
Akurdi, Pune,
Maharashtra. India.

ABSTRACT

The pharmaceutical manufacturing operations are to produce finished pharmaceutical products from active, inactive raw materials and various packaging materials. The quality of finished products produced solely depends upon the quality inputs and hence materials management becomes a very important activity in pharmaceutical manufacturing operation. The total material management activity starts right from selection of vendors for raw material and packaging material to dispatch of finished products to its destination. All incoming materials should be quarantined immediately after received or processing, until they are released for use or distribution.

KEYWORDS: Material management, raw material, packaging material, finished product, rejected products.

INTRODUCTION^[3]

Materials Management is simply the process by which an organization is supplied with the goods and services that it needs to achieve its objectives of buying, storage and movement of materials. Materials Management is related to planning, procuring, storing and providing the appropriate material of right quality, right quantity at right place in right time so as to co-ordinate and schedule the production activity in an integrative way for an industrial undertaking. Most industries buy materials, transport them in to the plant, change the materials in to parts, assemble parts in to finished products, sell and transport the product to the customer. All these activities of purchase of materials, flow of materials, manufacture them in to the product, supply and sell the product at the market requires various types of materials to manage and control their storage, flow and supply at various places. It is only

possible by efficient materials management. The materials requirements planning, purchasing, inventory planning, storage, inventory control, materials supply, transportation and materials handling are the activities of materials management. They will be discussed in details in various chapters to follow.

About 20-25 years ago, there was no cut-throat competition in the market to sell the various consumer items manufactured by different industrial undertakings and the availability of materials to manufacture these items was not scarce. Therefore, materials management was not thought to be so important and its separate identity in the organization was not felt. But today it has become an important management activity to streamline production. Actually before the production begins it is necessary to ensure availability of all the types of materials needed for production and its supply at the various production centers. Planning, purchasing and scheduling are the main functions of materials management. It aims at improved productivity. It is used to reduce the cost, which increases profitability and streamlines the production. Apart from management of material cost and its supply it helps in its proper utilization, transportation, storage, handling and distribution.

The market research and forecasting both for sales of company's product and purchasing of various materials required for producing the product are needed at the planning stage. Purchasing, procurement of materials, transportation, storage, inventory control, quality control and inspection of materials and goods supplied at various production centers before production are also managed as routine work. Materials handling, packaging, warehouse planning, accounting, scrap, surplus and obsolete materials disposal, finished goods safety and care are the activities managed by the materials management department. Selection of personnel for marketing, purchasing, inventory control, stores management and materials handling and their training and placement is also to be seen by the materials management department. This indicates that it is very essential to have a materials management department in any organization to support the management in the production activities. It also helps in the marketing, sales promotion and control of all the types of materials for its quantity, quality and cost.

OBJECTIVES OF MATERIALS MANAGEMENT^[3]

The basic objectives of management in an organization are.



Fig.no.-1: In order to fulfill these basic objectives of management the objectives of materials management should be set in such a way that they should totally help to meet ultimate goals.

The functions of materials management are discussed below.

In order to fulfill the objectives of materials management as stated above to meet the basic objectives and goals, the functions of the materials management are also categorized as primary and secondary function.

The objectives of materials management can be categorized in two ways as follows.

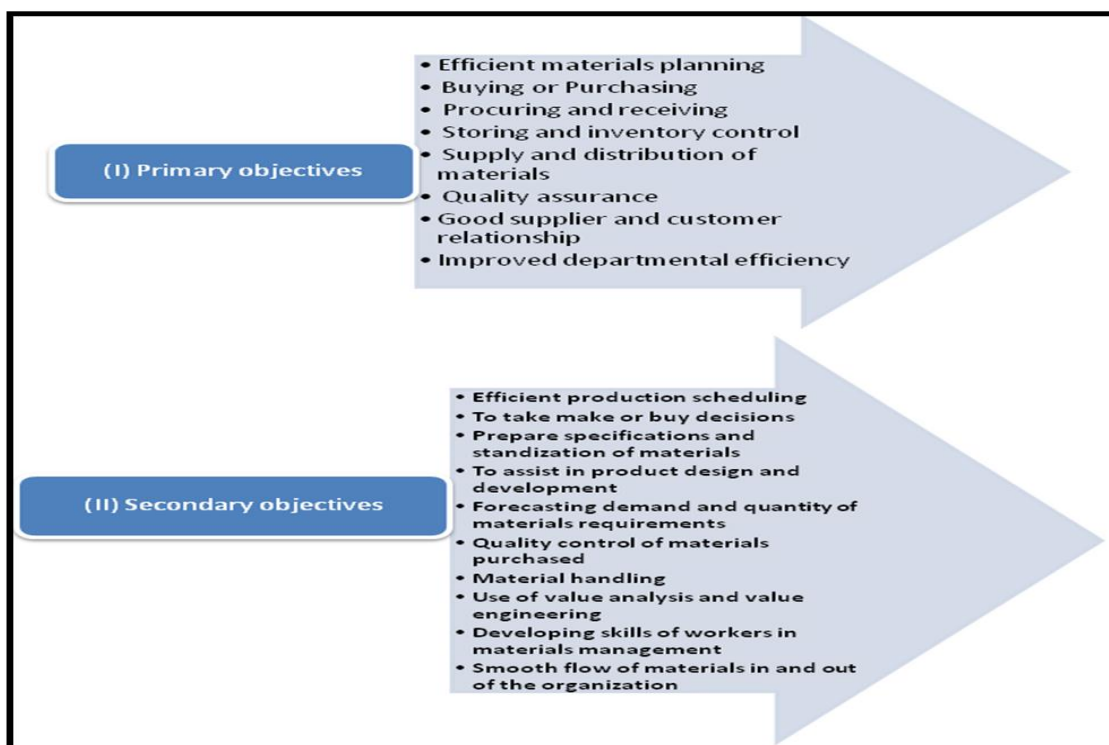


Fig.no.-2: To fulfill all these objectives, it is necessary to establish harmony and good co-ordination between all the employees of material management department and this

department should have good co-ordination with the other departments of the organization to serve all production centers.

FUNCTIONS OF MATERIALS MANAGEMENT^[3]

In order to fulfill the objectives of materials management as stated above to meet the basic objectives and goals, the functions of the materials management are also categorized as primary and secondary function.

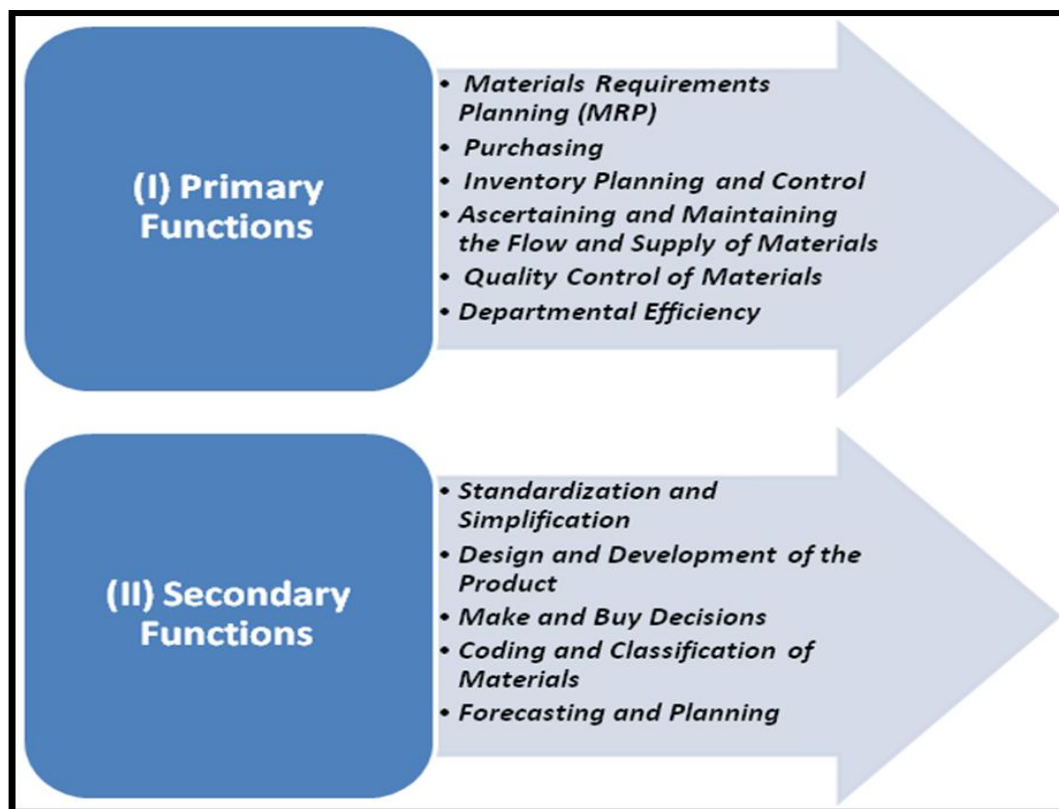


Fig.no.-3: In case of fluctuating demands, there can be uncertainties in supply as well. This can be overcome by maintaining the proper quantity in inventory of short supply materials at proper time. The different techniques available to use correct forecasting have to be utilized by materials manager to plan the procurement, purchase, supply, managing the outside and inside transport and storing of the materials to maintain the supply chain lines at every production facility to meet the changes in production quantity and schedule of production to meet the fluctuating demand of sales of products manufactured by the organization. To fulfill the objectives and functions of materials management and control the activities of this department, they are thoroughly studied and analyzed.

The topics for this study and analysis are given as follows.

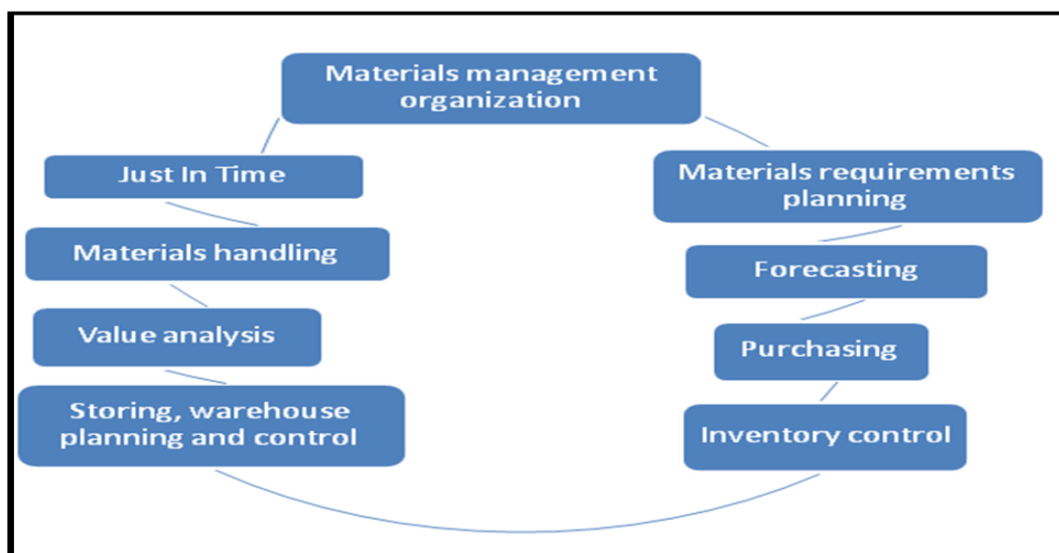


Fig.no.-4:

The main functions of materials management are summarized as follows.

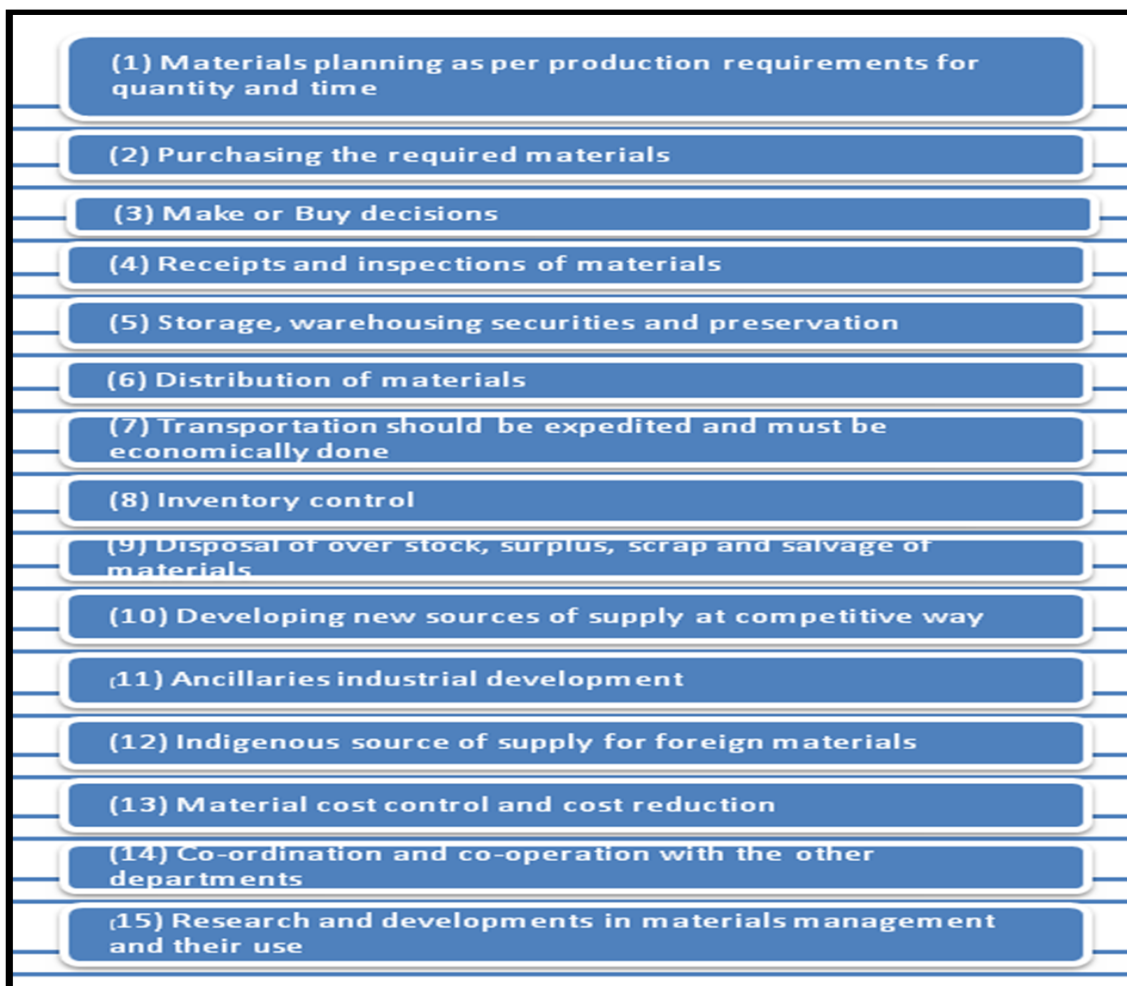


Fig.no.-5

SCOPE OF MATERIALS MANAGEMENT^[3]

Referring to the various functions of materials management stated above the materials management co-ordinates various departments of manufacturing concern. Since the cost involved in manufacturing has maximum investment in the materials. It is about 55% to 65% of the sales value as has been investigated by the Directorate of Industrial Statistics during 1954-57 in India. As soon as materials are purchased and brought by the organization, its value goes on increasing as the other costs as required for ordering the materials, carrying the materials in inventory, its maintenance and handling charges must be assigned to the cost of materials before it enters in to a product or transformed in to some other form. In order to economize all the costs of materials management company has to adopt definite method of deciding the quantity of materials to be ordered, quantity to be stored as inventory and work in process inventory. In order to reduce the material cost and all other costs stated above, there has to be some efficient and effective materials management techniques, which must be dynamic to adjust with changing demand and production.

GOALS OF MATERIAL MANAGEMENT^[2]

As was mentioned previously, the role of the materials manager is strictly economical within an organization. This section will describe some of the aspects that the materials manager should keep in mind to handle all activities related to materials appropriately. Cavinato (1994) states that the objectives of a material management system should include lowest final cost, optimum quality, assurance of supply, and lowest administrative costs. The materials manager should obtain the materials needed at the lowest cost possible. By buying products at the lowest possible costs, operating costs can be reduced and profits can be increased. Proper handling and storage of materials can reduce the total cost of materials; therefore the materials manager should ensure that materials are handled properly and stored in the most adequate places. Quality is a very important aspect that the materials manager has to keep in mind. When specifications require a high quality product, quality could become the most important objective. Suppliers play an important role in any organization. Many companies rely greatly in outside suppliers for the materials needed for production. Good relations with suppliers might be decisive for a company to be in business. Companies that have good relations with suppliers could be more successful in attracting customers than companies that have bad relations with suppliers. When a company has good relations with its suppliers it could benefit from cost reductions, cooperative environment from the employees of the supplier, and willingness to help with materials ordered and orders pending. When a

company has bad relation with their suppliers it might be possible that it experiences late deliveries or wrong materials delivered. This will have an impact in the total cost of the product, possibly increasing the total costs, and delaying the completion of the final product. Materials acquisition from the procurement time until it is received in the field can have a significant impact on the schedule of a construction project. Based on the studies presented, it is clear that effective management of materials can minimize the impact that lack of materials or improper management of materials could have in the overall schedule and cost of the project. The materials manager should assure that effective and economical transportation are used to transport materials to the site.

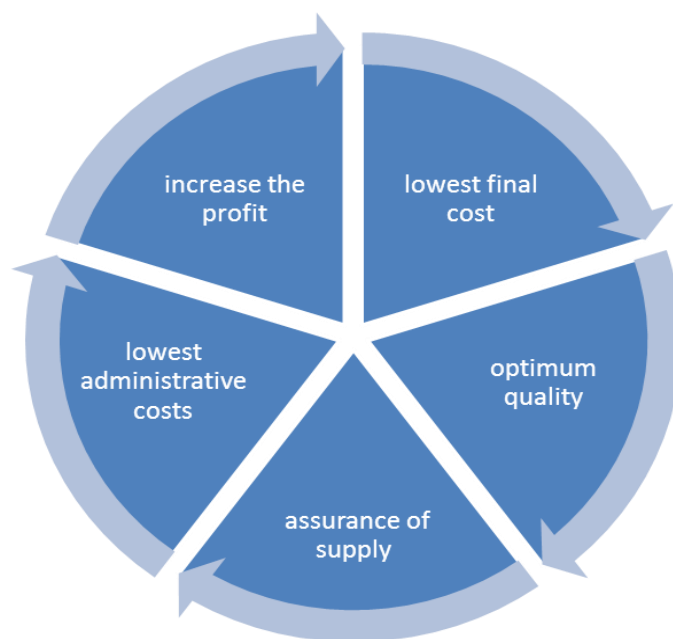


Fig.no.-6

BENEFITS OF MATERIAL MANAGEMENT^[2]

An effective material management system can bring many benefits for a company. Previous studies by the Construction Industry Institute (CII) concluded that labor productivity could be improved by six percent and can produce 4-6% in additional savings (Bernold and Treseler, 1991). Among these benefits are.

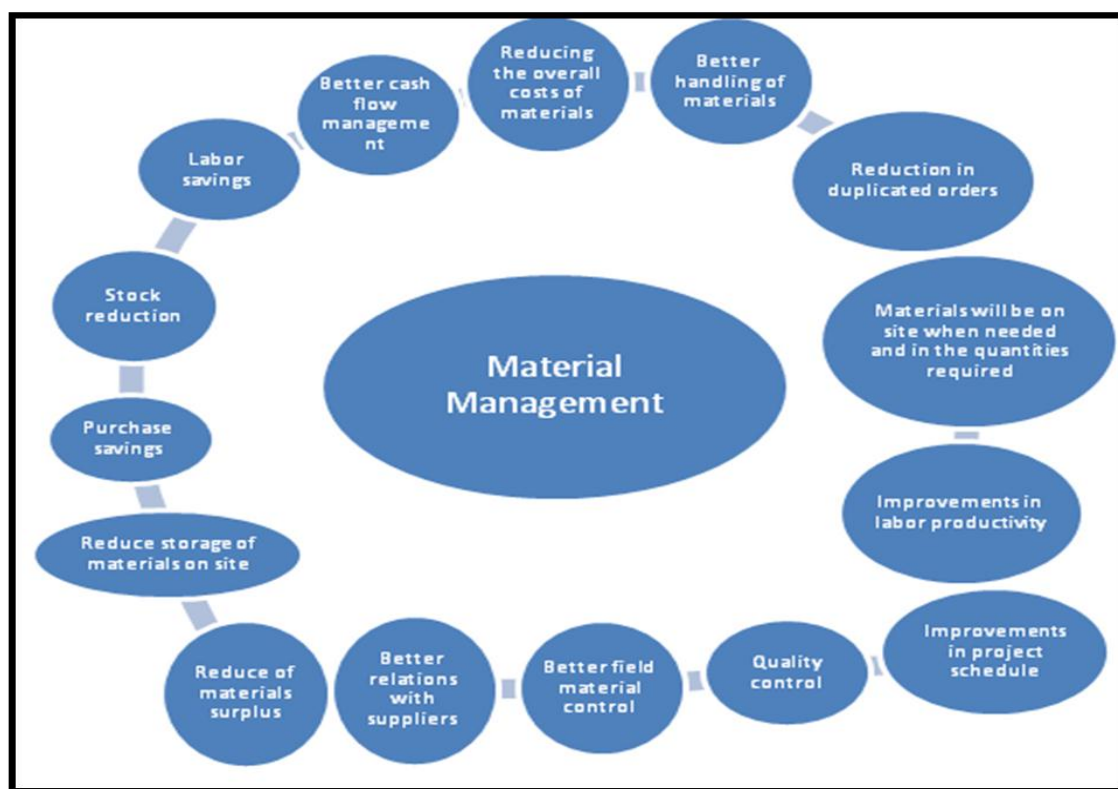


Fig.no.-7

This chapter provided an introduction to material management and the benefits that could be realized by having an effective material management system. The basic knowledge needed to understand the basis of the research and why it is important to undertake this research work was presented. The next chapter will present the current state of knowledge in material management, particularly for the small scale Electrical Contracting industry. In addition, areas related to material management that are particularly important for this research work, such as cultural change and knowledge management, are also described.

QUALITY ASSURANCE STANDARDS OF MATERIAL MANAGEMENT^[4]

Quality assurance, or QA for short, refers to planned and systematic production processes that provide confidence in a product's suitability for its intended purpose. It is a set of activities intended to ensure that products (goods and/or services) satisfy customer requirements in a systematic, reliable fashion. QA cannot absolutely guarantee the production of quality products, unfortunately, but makes this more likely. Two key principles characterize QA: "fit for purpose" (the product should be suitable for the intended purpose) and "right first time" (mistakes should be eliminated). QA includes regulation of the quality of raw materials, assemblies, products and components; services related to production; and

management, production and inspection processes. It is important to realize also that quality is determined by the intended users, clients or customers, not by society in general: it is not the same as 'expensive' or 'high quality'. Even lowly bottom-of-the-range goods can be considered quality items if they meet a market need.

1) Quality assurance versus quality control

Whereas quality control emphasizes testing and blocking the release of defective products, quality assurance is about improving and stabilizing production and associated processes to avoid or at least minimize issues that led to the defects in the first place. However, QA does not necessarily eliminate the need for QC: some product parameters are so critical that testing is still necessary just in case QA fails.

2) Failure testing

A valuable process to perform on a whole consumer product is failure testing, the operation of a product until it fails, often under stresses such as increasing vibration, temperature and humidity. This exposes many unanticipated weaknesses in a product, and the data is used to drive engineering and manufacturing process improvement. Often quite simple changes can dramatically improve product service, such as changing to mould-resistant paint or adding lock-washer placement to the training for new assembly personnel.

3) Statistical control

Many organizations use statistical process control to bring the organization to SIX Sigma levels of quality, in other words, so that the likelihood of an unexpected failure is confined to six standard deviation on the normal distribution. This probability is less than one-million. Items controlled often include clerical tasks such as order-entry as well as conventional manufacturing tasks. Traditional statistical process controls in manufacturing operations usually proceed by randomly sampling and testing a fraction of the output. Variances in critical tolerances are continuously tracked and where necessary corrected before bad parts are produced.

4) Total quality control

Deep analysis of QA practices and premises used about them is the most necessary inspection control of all in cases where, despite statistical quality control techniques or quality improvement implemented, sales decrease. The major problem which leads to a decrease in sales was that the specification did not include the most important factor, "What the specifications have to state in order to satisfy the customer requirements?". The major

characteristics, ignored during the search to improve manufacture and overall business performance were:

- ☐ Reliability
- ☐ Maintainability
- ☐ Safety
- ☐ Strength

5)Standards

The final component of materials management is standards compliance. There are standards that are followed in supply chain management that are critical to a supply chain's function. For example, a supply chain that uses just-in time or lean replenishment requires absolute perfection in the shipping of parts and material from purchasing agent to warehouse to place of destination. Systems reliant on vendor-managed inventories must have up-to-date computerized inventories and robust ordering systems for outlying vendors to place orders on. Materials management typically insures that the warehousing and shipping of such components as are needed follows the standards required to avoid problems. This component of materials management is the fastest changing part, due to recent innovations in SCM and in logistics in general, including outsourced management of warehousing, mobile computing, and real-time logistical inventories.

PURCHASING:^[1]

Regarding purchasing of pharmaceutical materials following points should be considered.

- I. All materials should be purchased against an approved and adequate specification which defines not only the grade and quality of the materials, but also the nature of the packaging and container to be used. The quality material, should clearly specify the physical, chemical and microbiological specifications as specified in pharmacopoeal specification or in house specifications. The quality parameters should also specify characteristics like, bulk density, particle size amorphous or crystalline nature of the material, specificity of isomers etc.
- II. Materials should be purchased and sourced only from approved suppliers and manufacturers. Choice of vendor should be primarily based on quality considerations and when these are met other commercial consideration should play their role, like, price, delivery period. Consistency in quality, delivery and price should be given importance.
- III. R.M. and P.M. should only be purchased by buyers who are trained and who possess sufficient technical knowledge. Materials managers who has sufficient exposure on

R.M./P.M. for pharmaceuticals should be appropriate persons for this ; alternatively industrial pharmacists with training in materials management can do a much better job.

RAW MATERIALS

➤ *General Controls*

Written procedures should be established describing the purchase, receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of raw materials. Such procedures should be followed. Raw materials should be handled and stored in a manner to prevent contamination and cross-contamination. Bagged and boxed raw materials should be stored off the floor and suitably spaced to permit cleaning and inspection. Raw materials that are stored outdoors should be in suitable containers. Identifying labels should remain legible and containers should be appropriately cleaned before opening to prevent contamination. For solvents or reagents delivered in bulk vessels (e.g., tanker trucks), a procedural or physical system, such as valve locking or unique couplings, should be used to prevent accidental discharge of the solvent into the wrong storage tank. Each container or grouping of containers of raw materials should be assigned and identified with a distinctive code, lot, or receipt number. This code should be used in recording the disposition of each lot. A system should be in place to identify each lot's status. Large containers (e.g., tanks, silos) that are used for storing raw materials, including their attendant manifolds, filling and discharge lines, should be appropriately identified.

Following steps involve in raw material management:

Receipt, Sampling, Testing, and Approval of Raw Materials

Use and Re evaluation of Approved Raw Materials

Control of Recovered Solvents, Mother Liquors, and Second Crops

water process quality

Water used in the production of APIs should be routinely tested and, at a minimum, meet the standards for potable water, as stated in the United States Environmental Protection Agency's (EPA) National Primary Drinking Water Regulations (NPRDWR) or comparable standards of other authorities such as the European Union, Japan, or the World Health Organization. The potable water supply, regardless of source, should be assessed for chemicals that may affect the API process. Information should be periodically sought from local authorities concerning potential contamination by pesticides or other hazardous chemicals. Water of suitable quality, with tighter chemical and microbiological quality specifications, should be used during certain process steps (e.g., cell cultures, final crystallization and isolation) and during early process steps if impurities that affect API quality are present in the water and cannot be removed in later steps. For example, if water is used for a final wash of a filter cake, or if the API is crystallized from an aqueous system, the water should be suitably treated (e.g., deionization, ultrafiltration, reverse osmosis, or distillation) and routinely tested to ensure compliance with appropriate chemical and microbiological specifications. If used for final rinses during equipment cleaning, the water should be of the same quality as that used in the manufacturing process. Water used in the final isolation and purification steps of nonsterile APIs intended for use in the preparation of parenteral products should be tested and controlled for bioburden and endotoxins. Where water is treated to achieve an established quality, the treatment process and associated distribution systems should be qualified, validated, maintained, and tested following established procedures to ensure water of the desired quality.

PACKAGING MATERIALS^[5-18]

Packing: Packing consists of enclosing an individual item, or several items, in a container, usually for shipment or delivery. This operation is mostly done by hand and machine.

Pharmaceutical Packaging: Pharmaceutical packaging means the combination of components necessary to contain, preserve, protect & deliver a safe, efficacious drug product, such that at any time point before expiration date of the drug product, a safe & efficacious dosage form is available.

Types of Packaging Systems:^[5-18]

- **Primary package system:** Made up of those package components & sub-components that come into direct contact with the product, or those that may have a direct effect on the product shelf life.

- Secondary or tertiary package system: Includes cartons, corrugated shippers & pallets.

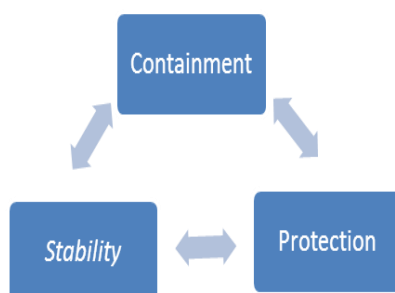
Packaging must meet the following Requirements: [ideal requirements]^[5-18]

- Protect the preparation from environmental conditions.
- Non-reactive with the product and so does not alter the identity of the product
- Does not impart tastes or odours to the product
- Nontoxic
- FDA approved
- Protect the dosage form from damage or breakage
- Meet tamper-resistance requirements, wherever applicable.
- Adaptable to commonly employed high-speed packaging equipment's.

Possible Interactions between primary packaging materials and the included pharmaceutical product^[5-18]

- ☐ The release of chemicals from components of the packaging materials
- ☐ The release of visible and/or sub visible particles
- ☐ The absorption or adsorption of pharmaceutical components by the packaging materials
- ☐ Chemical reactions between pharmaceutical product & the packaging materials
- ☐ The degradation of packaging components in contact with the pharmaceutical products
- ☐ The influence of the manufacturing process (e.g. sterilization) on the container.

Functions of packaging:



There are numerous possibilities of interactions between (primary) packaging materials and pharmaceutical products, such as:

- the release of chemicals from components of the packaging materials;
- the release of visible and/or subvisible particles;
- the absorption or adsorption of pharmaceutical components by the packaging materials;

- chemical reactions between the pharmaceutical product and the packaging materials;
- the degradation of packaging components in contact with the pharmaceutical products;
- the influence of the manufacturing process (e.g. sterilization) on the container.

Storage. Packaging materials should be stored in accordance with GMP for storage areas. The characteristics of the active pharmaceutical ingredients will determine whether different packaging will be needed. For example, the packaging requirements of medicinal products kept at temperatures between 2 and 8°C may differ from those of products intended for tropical countries or light sensitive products. If the contents are sterile, sterility must be maintained, including that of any unused remaining product. The shelf-life and utilization period are always determined in relation to storage conditions and the stability of the active pharmaceutical ingredient. Normal storage conditions are defined as “storage in dry, well ventilated premises at temperatures of 15–25°C or, depending on climatic conditions, up to 30 °C. Extraneous odours, other indications of contamination, and intense light have to be excluded”.

INTERMEDIATE AND BULK PRODUCTS^[1]

In pharmaceutical industry normally main or central warehouse is responsible for management of raw, packaging and finished products. However intermediate and bulk product storage is the responsibility of the production department. Intermediate or bulk product may be defined as the material, which has started processing but not yet got converted into the finished saleable product e.g.

- Granulated materials ready for compression.
- Compressed tablets for coating or packaging.
- Filtered or unfiltered liquids for oral or injectable etc.

These products should be kept under appropriate storage conditions of temp, relative humidity, class of air etc. Intermediate or bulk products purchased as such should be handled on receipt as though they were raw materials.

FINISHED PRODUCTS^[1]

Finished products are products which are in the marketable pack. These products should be held in quarantine until their final release, after which they should be stored as usable stock under conditions established by the manufacturer. Each batch of the finished product should be tested as per laid down testing procedure against its specifications and then only released

for distribution or sale. Products failing to meet the established specifications or any other relevant quality criteria should be rejected. Reprocessing may be performed, if feasible, but the reprocessed product should meet all specifications and other quality criteria prior to its acceptance and release.

REJECTION AND RE-USE OF MATERIALS^[1]

Rejection

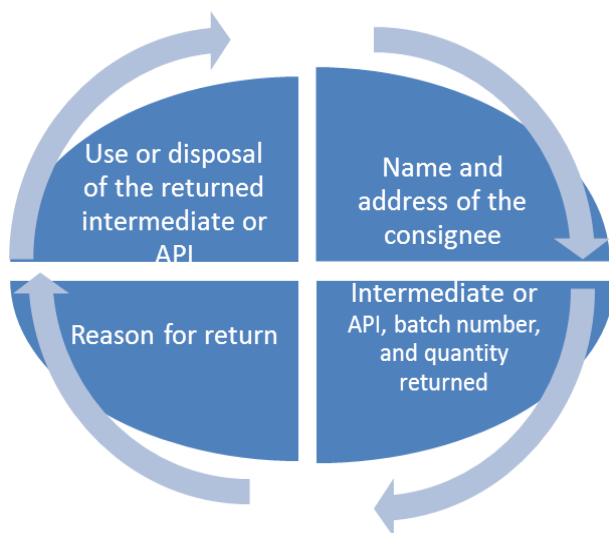
Intermediates and APIs failing to meet established specifications should be identified as such and quarantined. These intermediates or APIs can be reprocessed or reworked as described below. The final disposition of rejected materials should be recorded.

Reprocessing

- Introducing an intermediate or API, including one that does not conform to standards or specifications, back into the process and reprocessing by repeating a crystallization step or other appropriate chemical or physical manipulation steps (e.g., distillation, filtration, chromatography, milling) that are part of the established manufacturing process is generally considered acceptable. However, if such reprocessing is used for a majority of batches, such reprocessing should be included as part of the standard manufacturing process.
- Continuation of a process step after an in-process control test has shown that the step is incomplete is considered to be part of the normal process. This is not considered to be reprocessing.
- Introducing unreacted material back into a process and repeating a chemical reaction is considered to be reprocessing unless it is part of the established process. Such reprocessing should be preceded by careful evaluation to ensure that the quality of the intermediate or API is not adversely impacted due to the potential formation of by products and over-reacted materials.
- solvents meet appropriate standards before reuse or co-mingling with other approved materials.
- Fresh and recovered solvents and reagents can be combined if adequate testing has shown their suitability for all manufacturing processes in which they may be used.
- The use of recovered solvents, mother liquors, and other recovered materials should be adequately documented.

Returns materials

- Returned intermediates or APIs should be identified as such and quarantined.
- If the conditions under which returned intermediates or APIs have been stored or shipped before or during their return or the condition of their containers casts doubt on their quality, the returned intermediates or APIs should be reprocessed, reworked, or destroyed, as appropriate.
- Records of returned intermediates or APIs should be maintained. For each return,

Documentation should include**COMPLAINTS AND RECALLS^[1]**

- All quality related complaints, whether received orally or in writing, should be recorded and investigated according to a written procedure.
- Complaint records should include.
 - Name and address of complainant;
 - Name (and, where appropriate, title) and phone number of person submitting the complaint;
 - Complaint nature (including name and batch number of the API);
 - Date complaint is received;
 - Action initially taken (including dates and identity of person taking the action);
 - Any follow-up action taken;
 - Response provided to the originator of complaint (including date response sent); and
 - Final decision on intermediate or API batch or lot.

- Records of complaints should be retained in order to evaluate trends, product-related frequencies, and severity with a view to taking additional, and if appropriate, immediate corrective action.
- There should be a written procedure that defines the circumstances under which a recall of an intermediate or API should be considered.
- The recall procedure should designate who should be involved in evaluating the information, how a recall should be initiated, who should be informed about the recall, and how the recalled material should be treated.
- In the event of a serious or potentially life-threatening situation, local, national, and/or international authorities should be informed and their advice sought.

REAGENTS AND CULTURE MEDIA^[1]

Following points should be considered regarding management of reagents and culture media:

- I. All reagents and culture media should be recorded upon receipt or preparation.
- II. Reagents made up in the laboratories should be prepared according to written procedures and appropriately labelled. Such labels should indicate following information viz.
 - a. Name of the reagent.
 - b. Nominal concentration (0.1N, 1N etc.)
 - c. Standardisation factor (1N = 0.996N etc.)
 - d. Shelf life (or use before date).
 - e. Date when re-standardisation is required.
 - f. The storage conditions.
 - g. Name/Signature and date of the person who has prepared and standardised the reagent.

A register be maintained giving details of the reagents made, standardised, restandardised and used and destroyed if any.

- III. Both positive and negative controls should be applied to verify suitability of the culture media. The size of the inoculum used in positive controls should be appropriate to the sensitivity required.

WASTE MATERIALS^[1]

Pharmaceutical manufacturing operations generate lot of waste materials. These materials can be classified mainly in two categories.

- i. **Trash:** which do not have a resale value and may be disposed off by proper method depending upon the nature of the trash.
- ii. **Scrap:** which do have a resale value and may be sold to scrap dealers, after proper segregation.

Provisions should be made for proper and safe storage of waste materials awaiting disposal. Toxic substances and flammable materials should be stored in suitably enclosed cupboard, as required by national legislation.

Waste materials should not be allowed to accumulate. It should be collected in suitable containers for removal to collection points outside the buildings, and disposed off safely and in a sanitary manner at regular intervals.

Before disposal of these materials, they can be segregated in different categories.

- 1) Paper
- 2) Aluminium foils
- 3) Plastic
- 4) Glass
- 5) Metallic containers etc.

Safety of the materials to be disposed must be considered; particularly flammable solvent drums must be washed thoroughly before disposal since they pose a potential danger of fire or explosion.

REFERENCE STANDARDS^[1]

Reference standards may be available in the form of official reference standards. Reference standards prepared by the producer should be tested, released and then stored in the same way as official standards. They should be kept under the responsibility of a designated person in a secure area. Official reference standards should be used only for the purpose described in the appropriate monograph. Secondary or working standards may be established by the application of appropriate tests and checks at regular intervals to ensure standardisation. All in house reference standards should be based on official reference standards, when available. All such reference standards should be stored and used in a manner that will not adversely affect their quality.

MISCELLANEOUS MATERIALS^[1]

All those materials, which do not specifically fall under the category of R.M./P.M. Intermediates, bulk and finished pharmaceuticals may be considered under this category of miscellaneous materials. Such materials like, rodenticides, insecticides, fumigating agents and sanitising materials fall under this category, these materials should not be permitted to contaminate equipment, raw materials, packaging materials, in process materials or finished products.

CONCLUSION

From above the study it is concluded that all the materials and products should be stored under appropriate conditions, established by the manufacturer, and/or user. These should be stored in an orderly fashion to permit batch segregation and stock rotation by first in - first out (FIFO) and first expiry - first out (FEFO) rule. There shall be written procedures for all activities carried out related to materials handling like receipts, identification, storage, handling, sampling, testing, and approval or rejection of raw material/ packaging material.

REFERENCES

1. Potdar M.A., "Pharmaceutical Quality Assurance for student of pharmacy" Nirali Prakashan, 1, June 2006. Page no.- 4.1, 4.2, 4.5, 4.7, 4.8, 4.9.
2. Shodhganga.inflibnet.ac.in/bitstream/10603/3404/...../09-chapter/202pdf
3. [Www.newagepublisher.com/samplechapter/001386.pdf](http://www.newagepublisher.com/samplechapter/001386.pdf)
4. [Www.eiilmuniversity.ac.in/...../management/principlesofmaterialmanagement.pdf](http://www.eiilmuniversity.ac.in/...../management/principlesofmaterialmanagement.pdf)
5. Donald C. Liebe, Packaging of Pharmaceutical Dosage Form, *Modern Pharmaceutics* by Banker G.S., Marcel Dekker, 681-725.
6. Croce C.P., Fischer A. & Thomas R.L., Packaging material Science, *The theory & Practice of Industrial Pharmacy* by Leon Lachman, Third edition, 711-732
7. Plastic Packaging, *Remington: The Science and Practice of Pharmacy*, 19th edition, Volume II, p 1487. USP 24, NF 19, 2000. p 10.
8. <http://www.fda.gov>
9. <http://www.devicelink.com/pmpn/archive/98/08/002.html>
10. http://www.bombayharbor.com/Company11617/Shikha_International.html
11. <http://www.gosdar.com>
12. <http://www.sha.org/bottle/finishes.htm>
13. <http://www.indiamart.com>

14. <http://news.thomasnet.com/images/large/450/450948.jpg>
15. www.fda.gov/cder/guidance/index.htm
16. WHO Technical Report Series, No. 902, Annex 9, 2002
17. <http://www.mhra.gov.uk/home/idcplg>
18. <http://www.samedanltd.com/members/archives/archives1.asp>