Raw Material Management in Pharma Industry

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ABSTRACT: This article deals with the raw Material Management in Pharma Industry starting from Purchase of raw materials till Approval / rejection of raw materials. Here the raw materials can be Active pharmaceutical ingredients, Excipients, packaging and Labelling materials. Water is frequently employed as a raw material, component, and solvent. So, water treatment, storage and handling is also being discussed. A lot of specifications need to be followed for the raw materials in order to maintain quality in the final product. So, utmost importance is required for the raw Material Management in Pharma Industry.

Key words: Raw Material Management, Active pharmaceutical ingredients and Pharma Industry

INTRODUCTION
Pharmaceutical manufacturers i.e., sponsors and contract service organisations must handle a complicated network of raw material and extending from gathering the pharma raw materials to getting in hand the ready product for the supply (1) Since pharmaceutical industries are growing globally, & for it to fundamentally separate from other industry types it needs to be accurate & meticulous in each step, related to
• Purchase of raw materials
• Receiving of raw materials & packing materials
• Handling of raw materials & packing materials
• Storage of materials
• Sampling of materials
• Testing of samples
• Approval / rejection of raw materials (2)

CATEGORIZATION OF RAW MATERIALS
Generally, pharmaceutical Raw materials can be categorized into following three categories. Raw materials are in the form of
● Active pharmaceutical ingredients
● Excipients
● Packing materials (3)

1. Pharmaceutical raw materials of API’S
API is one of the main reasons for the drug action / pharmacological. Activity mainly used in combination of other ingredients to diagnose, cure, mitigate, & treat the disease. API’S must maintain the accuracy & precision & its strength is measured using certain standards. FDA approves a drug into market after its clinical trials. (4)

2. Pharmaceutical raw materials of excipient
Excipients are also called as inactive ingredients or which does not have any (pharmaceutical activity) pharmaceutical act But may influence in the bioavailability of the API’S & are in the form of solvents / carriers. E.g., Sorbitol (60mg) affect the bioavailability of risperidone. (5)

3. Pharmaceutical raw materials used for packaging
Packing of pharmaceutical products also a vital role & should be done perfectly & precisely. The material used in packing includes e.g. Aluminum foils: which have malleability, low cost, O2 barrier & light reflectivity. (6)
Typical packaging systems includes plastic, glass, polymers etc., as the new drug delivery system are developing their ideal packing ideas are also increased a lot. (7)

Water the main raw material
In many pharmaceutical and life sciences activities, water is a crucial component. Water is frequently employed as a raw material, component, and solvent. Water quality monitoring during the processes of production, storage, and distribution is also important. (8)

Handling of water
• Testing for conductivity test, Toc and microbial contamination:
  - Conductivity testing shows that a high ion count lowers water quality and can be a sign of a processing problem. The amount of dissolved salts (ions) in the sample affects its conductivity.
  - Total organic compound (TOC) analysis determines whether the sample’s carbon content is kept below the legal limit of 500 parts per billion (ppb). A high reading is a solid sign that the sample is contaminated.
  - With the use of bio burden testing, which counts the microorganisms in a water sample, it is possible to ensure that bacterial loads are within acceptable USP limits. (9)
**Treatment of water:**
Pharmaceutical water is mostly produced by well-proven methods like ion exchange, distillation and membrane applications such as reverse osmoses, ultrafiltration and electrode ionization. Physical or chemical methods ensure disinfection and sanitation. Commonly used is the combination of ultraviolet light and ozone treatment.

**Disposal of water:**
Handling of waste Regulations set forth by the Environmental Pollution Control Board must be followed while disposing of sewage and wastewater. All bio-medical waste must be disposed of in accordance with the Bio-Medical Waste Regulations, 1996. It is necessary to keep records. It is necessary to make provisions for the appropriate storage of waste materials. (10)

**RAW MATERIAL MANAGEMENT**
- **PURCHASE SPECIFICATION**
  Definition: Written guidelines that precisely define the operational, physical, or chemical characteristics, as well as the quality and quantity of a particular item to be acquired.

**Mode of purchasing:**
By inspection, by sample, by description of brand

**Steps involved in purchase procedure:**
1. For whom should it be bought
2. Regarding cost effectiveness, safety, quality, and price, which medicine should be bought
3. From whom should the drug be bought
4. At what price should it be bought
5. How should it be paid (11)

**RECORDS OF RAW MATERIALS**
It includes intermediates, API labeling and packaging materials. Records should be maintained including:
1. The name of the manufacturer, identity, and quantity of each shipment of each batch of raw materials, intermediates, or labeling and packaging materials for APIs; the name of the supplier; the supplier's control number(s), if known, or other identification number; the number allocated on receipt; and the date of receipt.
2. The results of any test or examination performed and the conclusions derived from this records tracing the use of materials.
3. Documentation of the examination and review of API labeling and packaging material for conformity with established specifications.
4. The final decision regarding rejected raw materials, intermediates, or API labeling and packaging materials.
Master (approved) labels should be maintained for comparison to issued labels (12)

**HANDLING OF RAW MATERIALS**
Material handling is concerned with moving raw material, work in process and finished goods into the plant within the plant and out of the plant to warehouse, distribution network or directly to the customers. (13)

**STORAGE OF RAW MATERIAL**
Issues that can arise when handling bulk dry / powder materials
- Handling multi-ton volumes of raw materials, like buffers, salts, and stabilising chemicals, must be done as quickly as feasible in the pharmaceutical production process as it delays production.
- With solid raw materials, handling issues can arise if the substance has a propensity to harden or cake together, making it challenging to weigh exactly, dispense out of the primary container, and flow through processing apparatus. This decreases the effectiveness of manufacturing and may cause process halts and quality abnormalities.
- To fix these issues, operators usually manually break up solidified materials using hammers or other tools, but this takes time and frequently puts workers at danger of damage.
- Considering the exposure of workers. Specialized equipment is needed to regulate dust formation Long-term exposure to their dust, such sodium chloride, are not thought to be harmful, can still seriously endanger the health of the users. (14)

**SAMPLING OF MATERIALS**
Raw material identity and verification in the pharmaceutical industry as per guidelines
Crucial step in the pharmaceutical industry is inspecting incoming raw materials to make sure the correct raw material has been received and that it complies with quality requirements. If specifications are not met, it will not only help to protect safety but also to assure the highest quality of the finished product, minimize wasted time, material costs, and shipment delays.

**Sampling strategy**
The next stage in examining incoming raw materials is inspecting packages for damage and appropriate labelling. In order to avoid (cross-) contamination and operator exposure, incoming raw materials are often transported to a sampling booth (safe sampling area) after being visually inspected. Once inside the sampling booth, the bag or container is opened, and a sample is taken. When leaving the sampling booth, the containers or bags must be thoroughly and securely closed to prevent contamination, concerns with shelf life, and instability.

The pharmaceutical industry frequently uses two sampling techniques with the aim of identifying raw ingredients, namely:
1. During sampling, N samples are obtained for every container.
2. Sampling N containers, plus one extra, where N is the total number of containers in the lot. (15)
CONCLUSION:
Raw Material Management in Pharma Industry starts from Purchase of raw materials till Approval / rejection of raw materials. Here the raw materials can be Active pharmaceutical ingredients, Excipients, packaging and Labelling materials. A lot of specifications need to be followed for the raw materials in order to maintain quality in the final product. So, utmost importance is required for the raw Material Management in Pharma Industry.

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