

## EQUIPMENTS & RAW MATERIALS

### Definition of Equipment

- Equipment may be defined as any piece of plant, machinery, instrument etc, which is used for carrying out a specific activity or operation e.g. mixer, dryer, HPLC etc,
- Equipment can be a single piece or it may consists of a set of integrated pieces to perform a common activity e.g. water purification plant.

### EQUIPMENT SELECTION

While selecting the equipment, following points should be considered:

#### i. Design

The design of the equipment should meet user requirements, for which the equipment is selected. For this purpose User Requirement Specification (URS) should be prepared. URS will

vary from equipment to equipment but this should at least answer the following questions'.

1. Which kind of operation we are going to perform using this equipment?
2. What capacity it should have in terms of holding and in terms of output?
3. Which materials we are going to use in this equipment and do they have any interaction with the material of construction?
4. How this equipment will be cleaned?
5. Whether we are going to face any problem in validating the cleaning operation?
6. Do we have trained operators to operate this equipment?
7. 'What will be the starting and stopping time for the equipment?
8. Whether maintenance of this equipment causes any contamination to the product being handled?
9. What is the level of technology used?

Based on such information the user requirement specification is made and sent to the supplier who prepares the design qualification of design specification.

#### ii. Size

Size of the equipment is decided based on the volumes of materials, which we are going to handle. Batch sizes are also directly related to the size of the processing equipment.

In case of size of equipment following things should be considered:

1. Physical dimensions of the machinery (length x height x width).
2. Size of the room in which the machine is going to be installed and the path in the plant through, which it will be transported.
3. Holding and output capacity of the equipment.

4. Minimum-and maximum volume of materials we are going to handle and whether the equipment is able to process those minimum and maximum volumes.

### **iii. Location**

Decision of locating the equipment in the plant depends upon the logical process movement

Following are the factors which influence the location of the equipment:

- a) Utility services required.
- b ) Potential danger of contamination and mix-ups.
- c) Material handling and movement.
- d ) Movement for processing and cleaning
- e) Men movement for repair and maintenance.

### **iv. Construction**

Following four main factors should be considered:

- a) Ease of cleaning the equipment and surrounding area.
- b ) Ease of operation of the equipment.
- c) Ease of maintenance of the equipment.
- d ) The material of construction (MOC)

## **DOCUMENTS REQUIRED WITH EQUIPMENT**

- (i) Machine/Equipment manuals/SOP.
- (ii) Machine/Equipment layout drawing, showing the position of the equipment in the rooms.
- (iii) Equipment validation reports.

## **PURCHASE SPECIFICATIONS FOR EQUIPMENTS**

While purchasing equipment following parameters/ specifications should be considered:

- A. Operating criteria are adequate for the process- size, speed and effectiveness.  
Availability of spares and servicing (Spare parts should be easily available).
- B. Ease of maintenance and cleaning.
- C. Environmental issues (Equipments disseminating dust may cause contamination to other products being manufactured and Equipment producing noise)
- D. Construction material (material used for construction of equipment should be non reactive with A.P.I, Raw materials and products being manufactured).
- E. Availability of process controls (e.g. Automatic weight adjustment on tablet press and temperature records on oven).
- F. Cost of equipment.
- G. Availability of SOP, design and maintenance manuals from supplier with equipments those are important for operating, handling, validation and qualification.

(**Note** : New Equipments should not be used for commercial production until it is qualified and validated for the process).

## **MAINTENANCE OF EQUIPMENTS**

- a) Equipments shall be maintained at appropriate intervals to prevent the malfunction that can affect the process used for manufacturing.
- b) Written procedures shall be established and followed for the maintenance of equipments used for manufacturing and the procedures shall include:
  - i. Maintenance schedule (Frequency of maintenance, calibration, validation).
  - ii. Assignment of responsibility for maintenance of equipment.
  - iii. A description of method/procedures used for maintenance.
  - iv. Protection of equipment.
  - v. Inspection of equipment before use.
- c) All the records related to equipment maintenance shall be kept for further use.

## **DEFINITION OF RAW MATERIAL**

"It is defined as the starting material used in manufacturing of finished product".

## **PURCHASE SPECIFICATIONS FOR RAW MATERIALS**

Regarding purchasing of raw materials following points should be considered:

- a) Cost of raw material.
- b) Identity, purity and quality of raw material.
- c) Vendor selection: Materials should be purchased and sourced only from approved suppliers and manufacturers. Choice of vendor should be primarily based on quality consideration and Supplier/Manufacturer of the material should have his name listed in companies approved vendors list.
- d) All raw materials should be checked for following things:
  - i. Name of the manufacturer/ supplier.
  - ii. Name of the product/material.
  - iii. Batch numbers.
  - iv. Date of manufacture and date of expiry.
  - v. Quantity received and number of containers or packages.
  - vi. Condition of containers and materials.
- e) Storage conditions: (Appropriate special storage conditions e.g. store at low temperature, low humidity away from direct light etc. or sterile material etc.) should be clearly mentioned.
- f) Labels on raw materials should bear the following information :
  - i. The name and code number of the product.
  - ii. The batch number given by the supplier/ manufacturer.

- iii. Storage conditions.
- iv. Melting/ Boiling point.
- v. Molecular weight.
- vi. Expiry date of the product
- vii. Handling hazards associated with raw material.
- viii. Precautions/Safety measures.
- g) Instructions for sampling.
- h) Frequency of re-examination of stored raw material.

## **MAINTENANCE OF STORE FOR RAW MATERIALS**

### **STORAGE AREA**

- A. There should be a sufficient area/ Capacity for the storage of raw materials.
- B. The area used for storage of raw materials should be clean, dry and maintained within acceptable limits of environmental conditions.
- C. There should be a well equipped and appropriately designed reception area for receipt of raw materials.
- D. There should be a Separate area for sampling.
- E. There should be separate areas for storage of rejected, recalled or returned material.
- F. There should be a separate Safe and secure area for storage of narcotics, psychotropic, hormones, steroids, highly active, dangerous and risky material to avoid hazards and contamination of other products.
- G. There should be a separate area for in-process materials, bulk products and finished products.
- H. There should be separate areas for retained samples.

### **STORAGE CONDITIONS**

The raw materials in the store should be stored according to its storage conditions required: For example:

- A. For general product: Room temperature should be 30°C and Relative humidity should be 60%.
- B. Products requiring storage in air conditioning (Temperature should be 25± 2°C & Relative
- C. humidity should be 45 to 55%)
- D. Products requiring Low temperature storage (Temperature should be 2 to 8°C)
- E. Separate area for sterile product storage in AC under sterile conditions.
- F. Light sensitive material in amber color container.

### **LABELLING OF MATERIAL IN STORAGE AREA**

- A. Designated name of product and code
- B. Batch no. given by supplier
- C. Storage conditions
- D. Handling procedure
- E. HAZards and risks associated with it.
- F. Precaution to be taken.
- G. Safety Measures
- H. Expiry date or date beyond which retesting is necessary.