PILOT PLANT
SCALE- UP TECHNIQUE Part-2

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A pilot plant can be used for

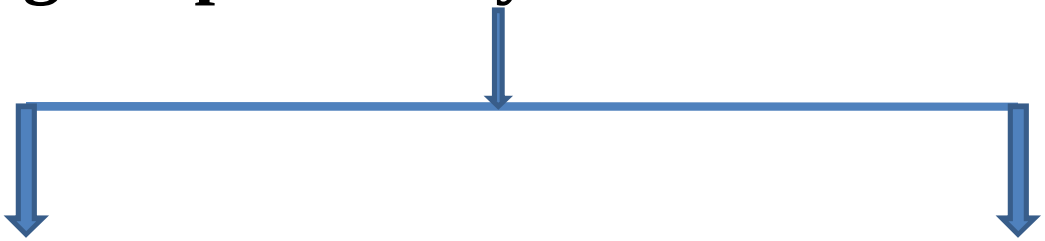
- Evaluating the results of laboratory studies and making product and process corrections and improvements.

- Producing small quantities of product for sensory, chemical, microbiological valuations, limited market testing or furnishing samples to potential customers, shelf-life and storage stability studies.

- Providing data that can be used in making a decision on whether or not to proceed to a full-scale production process; and in the case of a positive decision, designing and constructing a full-size plant or modifying an existing plant

General considerations

1. Reporting Responsibility



R & D group with separate staffing.

The formulator who developed the product can take into the production and can provide support even after transition into production has been completed.

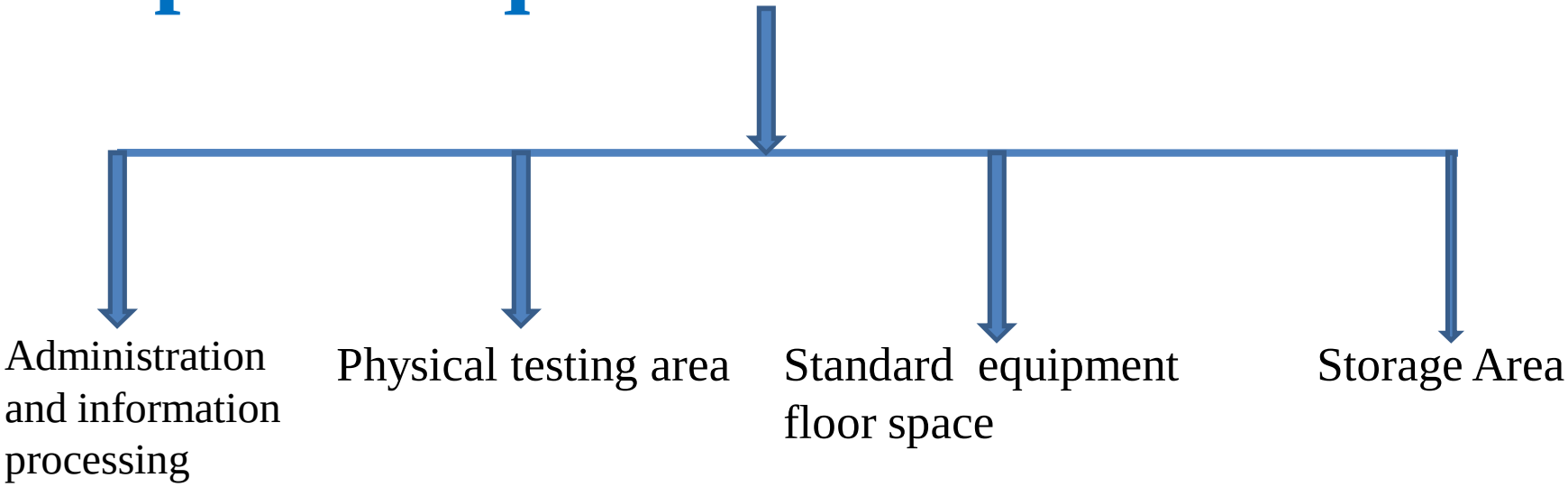
2. Personnel Requirement

- Scientists with experience in pilot plant operations as well as in actual production area are the most preferable.

- As they have to understand the intent of the formulator as well as understand the perspective of the production personnel.

- The group should have some personnel with engineering knowledge as well as scale up also involves engineering principles.

3. Space Requirements



Administration and information process:

- Adequate office and desk space should be provided for both scientist and technicians.

- The space should be adjacent to the working area.

Physical testing area:-

This area should provide permanent bench top space for routinely used physical-testing equipment.

Standard pilot-plant equipment floor space:-

- Discreet pilot plant space, where the equipment needed for manufacturing all types of dosage form is located.

- Intermediate – sized and full scale production equipment is essential in evaluating the effects of scale-up of research formulations and processes.

- Equipments used should be made portable where ever possible. So that after use it can be stored in the small store room.
- Space for cleaning of the equipment should be also provided.

Storage Area

➢It should have two areas divided as approved and unapproved area for active ingredient as well as excipients.

➢Different areas should provided for the storage of the in-process materials, finished bulk products from the pilot-plant & materials from the experimental scale-up batches made in the production.

➢Storage area for the packing material should also be provided.

Careful calculation of quantities and just-in-time inventory management allow for proper utilization of this consolidated lab supplies storage area.

4. Review of the formula:

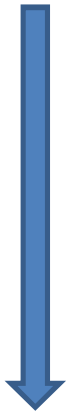
- A thorough review of the each aspect of formulation is important.

- The purpose of each ingredient and it's contribution to the final product manufactured on the small-scale laboratory equipment should be understood.

- Then the effect of scale-up using equipment that may subject the product to stresses of different types and degrees can more readily be predicted, or recognized.

5. Raw materials:-

One purpose/responsibility of the pilot-plant is the approval & validation of the active ingredient & excipients raw materials.



Why?

Raw materials used in the small scale production cannot necessarily be the representative for the large scale production.