PILOT PLANT SCALE-UP TECHNIQUE

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❖ INTRODUCTION

Pilot plant scale up techniques involves reproducible manufacture of an experimental formulation on high speed production equipment, in a cost effective manner. It is a part of pharmaceutical industry, where the same process is used during research and development (R&D) of dosage form.

They are applied to different output volume usually greater than that obtain during R&D. It is used for commercial manufacturing.

Plant- It is place were the 5M's like money, material, man, method & machine are brought together for manufacturing of the products.

Pilot Plant- It is a part of pharmaceutical industry where a lab scale fortune is transferred into a viable product by development of liable & practical procedure of manufacture.

❖ GENERAL CONSIDERATION

1. Reporting Responsibility

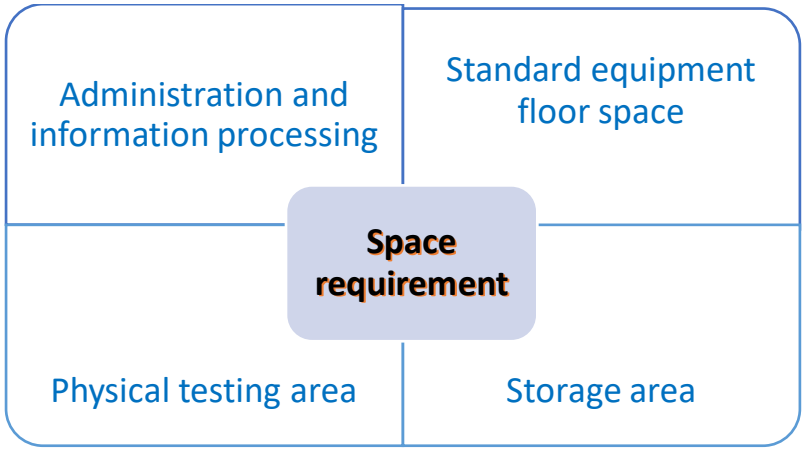
- R & D group with separate staffing.
- The formulator who developed the product can take into the production and can provide

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.

3. Space requirement



4. Review of the formula

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

5. Raw Materials

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

6. Equipment

The most economical and the simplest and efficient equipment, which are capable of producing product within the proposed specifications are used.

7. Production rates

The immediate as well as the future market trends/requirements are considered while determining the production rates.

8. Process Evaluation Parameters

- Order of mixing of components.

- Mixing speed
- Mixing time
- Rate of addition of granulating agents, solvent, solution of drug etc.
- Heating and cooling rates.
- Filter size (liquids)
- Screen size (solids)
- Drying temperature and drying time

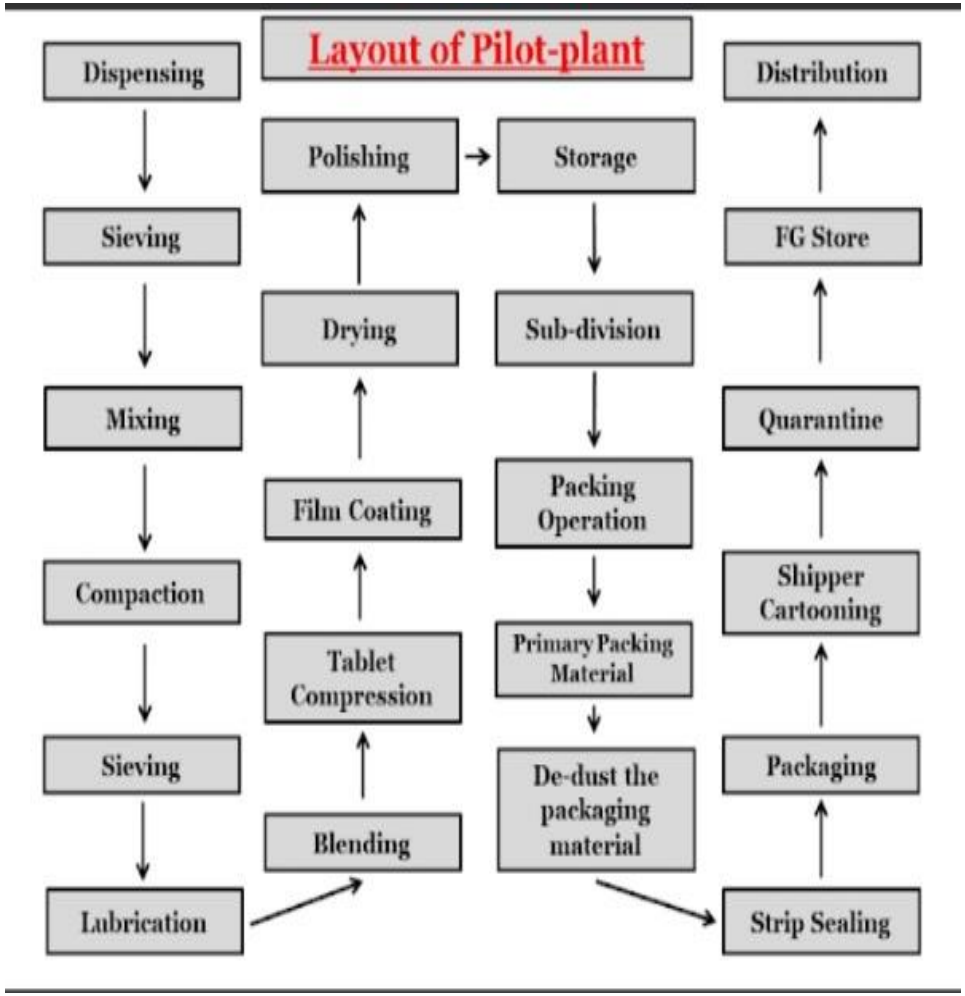
9. Master manufacturing procedures

Various specification like addition rate, mixing time, mixing speed, heating , cooling rates, temperature, storing of the finished product samples, etc. should be mentioned in the batch record direction.

10. Product stability and uniformity

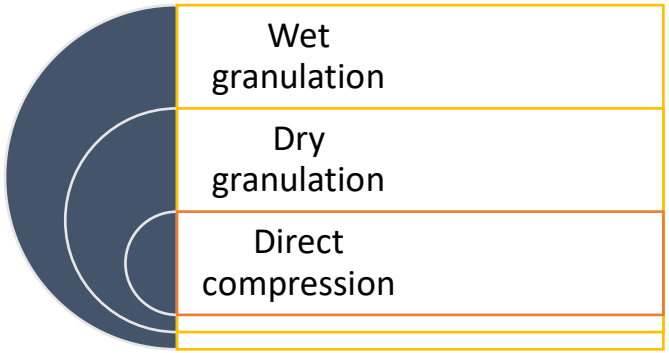
Stability studies should be carried out in finished packages as well.

Layout of pilot plant



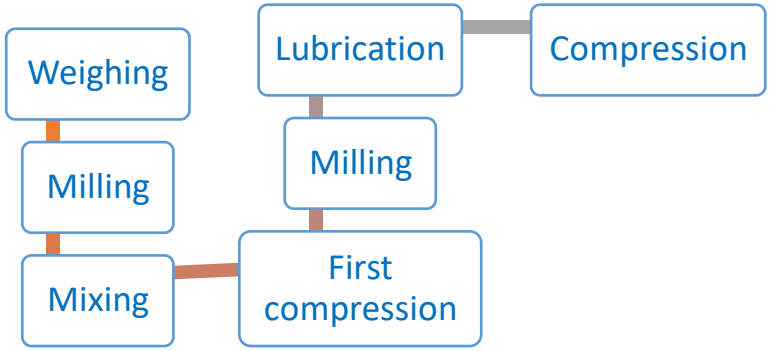
❖ SCALE UP FOR SOLID DOSAGE FORM

PILOT PLANT SCALE UP TECHNIQUES FOR TABLET

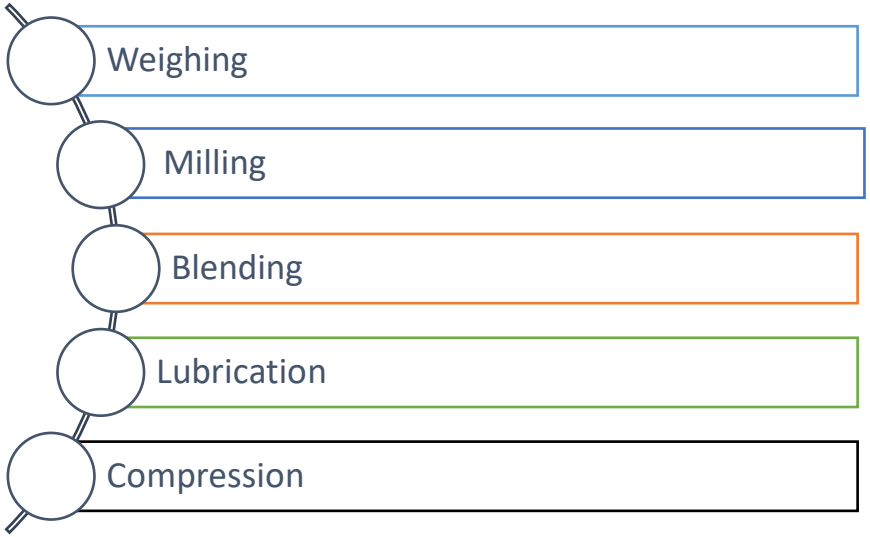


1. Wet granulation

2. Dry granulation



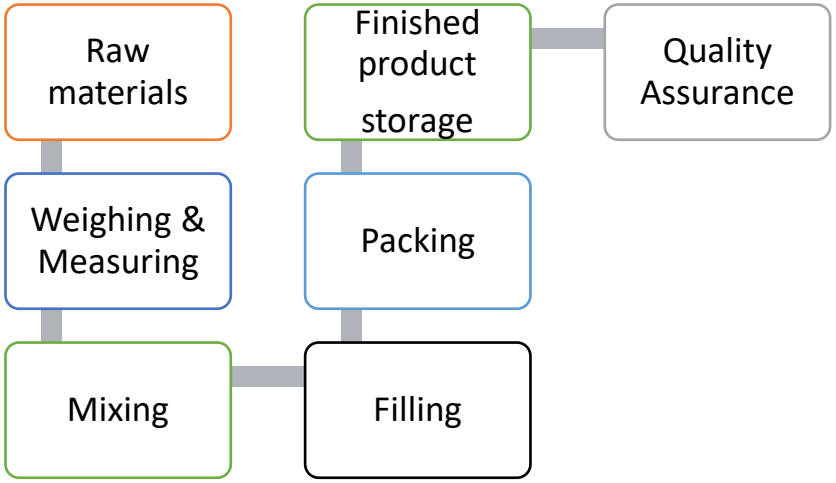
3. Direct compression



PILOT PLANT SCALE UP FOR CAPSULE

- Steps in capsule production=
  1. Mixing of ingredients
  2. Granulation and lubrication
  3. Making of capsule
  4. Filling of capsule
  5. Uniformity testing
  6. Packing and labeling

❖ PILOT PLANT SCALE UP TECHNIQUES FOR LIQUID ORALS



❖ PILOT PLANT SCALE UP TECHNIQUES FOR SEMI-SOLID DOSAGE FORM

Trituration method

- Ex. Ointments creams pastes

Fusion method

- Ex. Ointments creams paste

Chemical reaction method

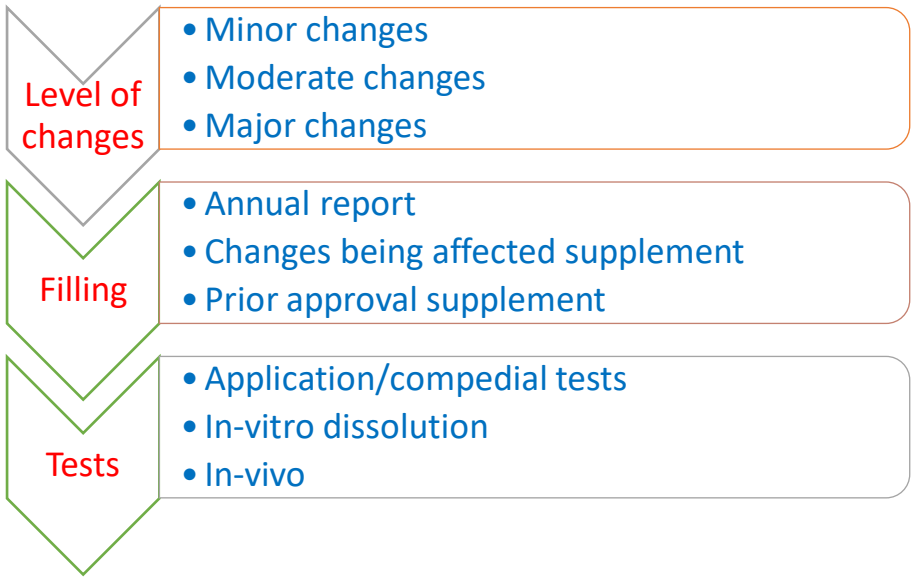
- Ex. Ointments creams

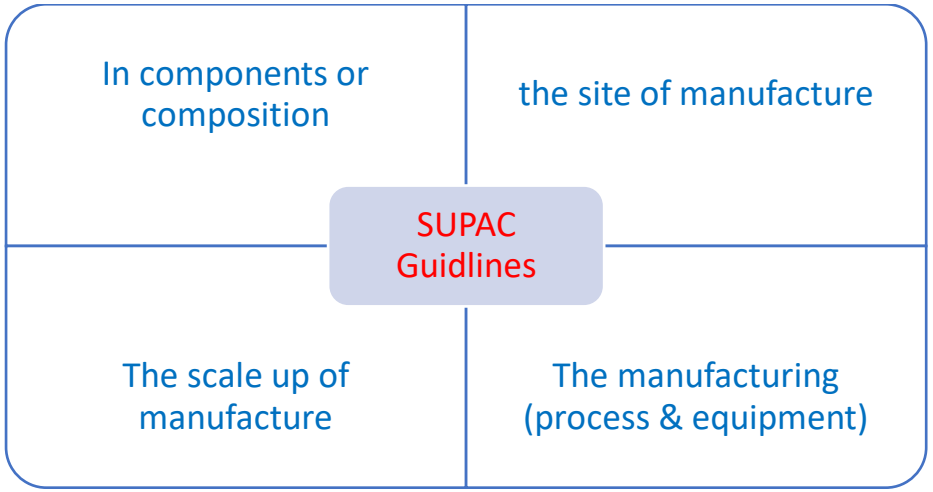
Emulsification method

- Ex. Ointment creams

❖ SUPAC GUIDANCES

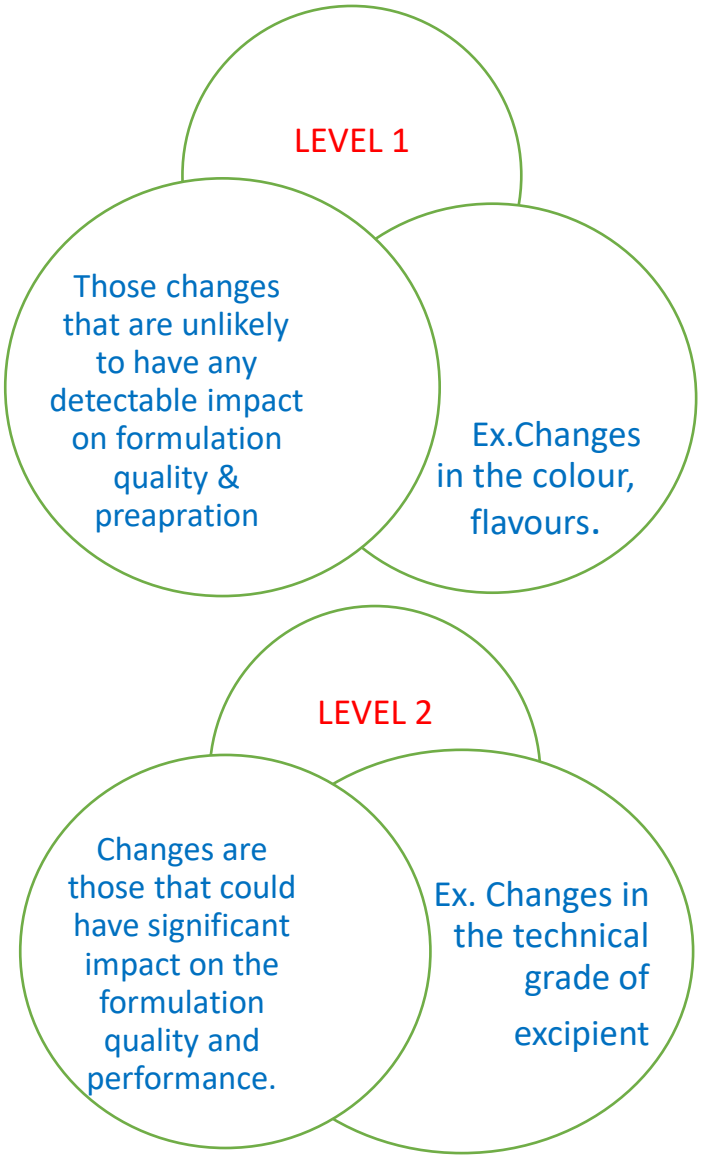
Supac is the scale-up & the post approval change like in the formulation of the drug, batch size process.

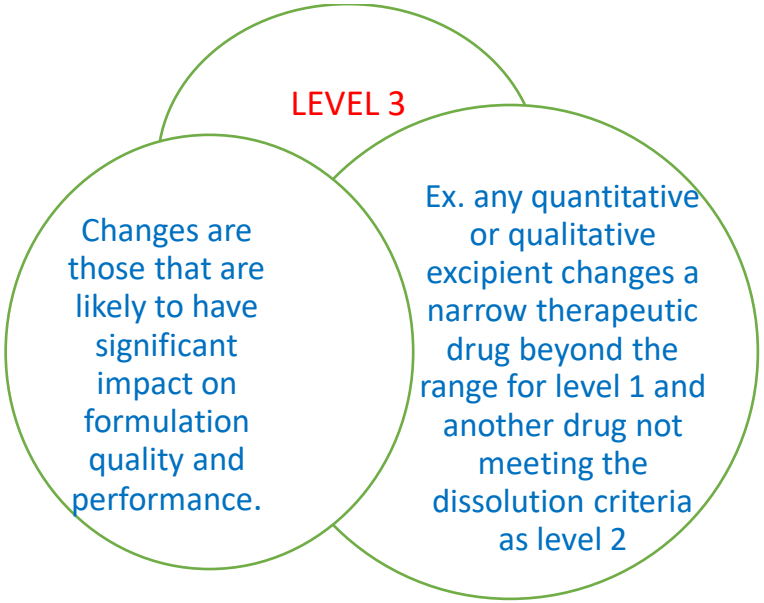




SUPAC-IR	SUPAC-MR	SUPAC-SS
• Focus on the change in amount of exipients in the drug product. • Not focus on change in the amount of the drug substance.	• Components and composition of non- release controlling excipient and release controlling excipient. • Changes in components or composition that have the effect of adding a new excipient or detecting an excipient are defined at level 3.	• Focus non-sterile semisolid dosage form including creams, ointment, gels and lotions.

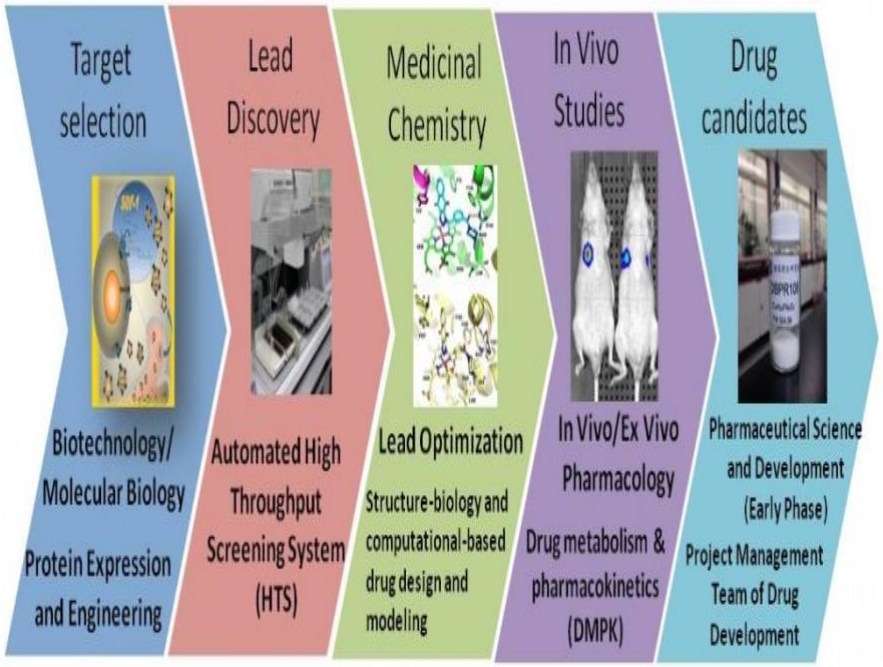
❖ Level of changes





PLATFORM TECHNOLOGY

The platform technology may be generally defined as a common, method, equipment, procedure or work practice that may be applied a cross multiple product under development manufacture.



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