

PILOT PLANT SCALE UP TECHNIQUE FOR TABLETS

**DR. SHASHI KIRAN MISRA
SCHOOL OF PHARMACEUTICAL SCIENCES**

INTRODUCTION :-

1- General consideration regarding solid dosage for pilot plant staff members:-

a) They should have sufficient knowledge regarding new formulation.

b) They should scale large number of products in efficient way.

2- The design and construction of pilot plant for solid preparation should be:-

a) Feasible

b) Cost effective

c) Easy to maintain and clean

3- If possible the construction unit should be start on the ground floor that make easy delivery and shipment.

4- All the preparations should be protected from any kind of microbial attack(contamination) or microbial load:-

a) Fluorescent lighting features should be on ceiling.

b) Their should be floor drain facility to make simplified cleaning.

c) The construction area should be humidity control by dehumidifiers, air conditions.

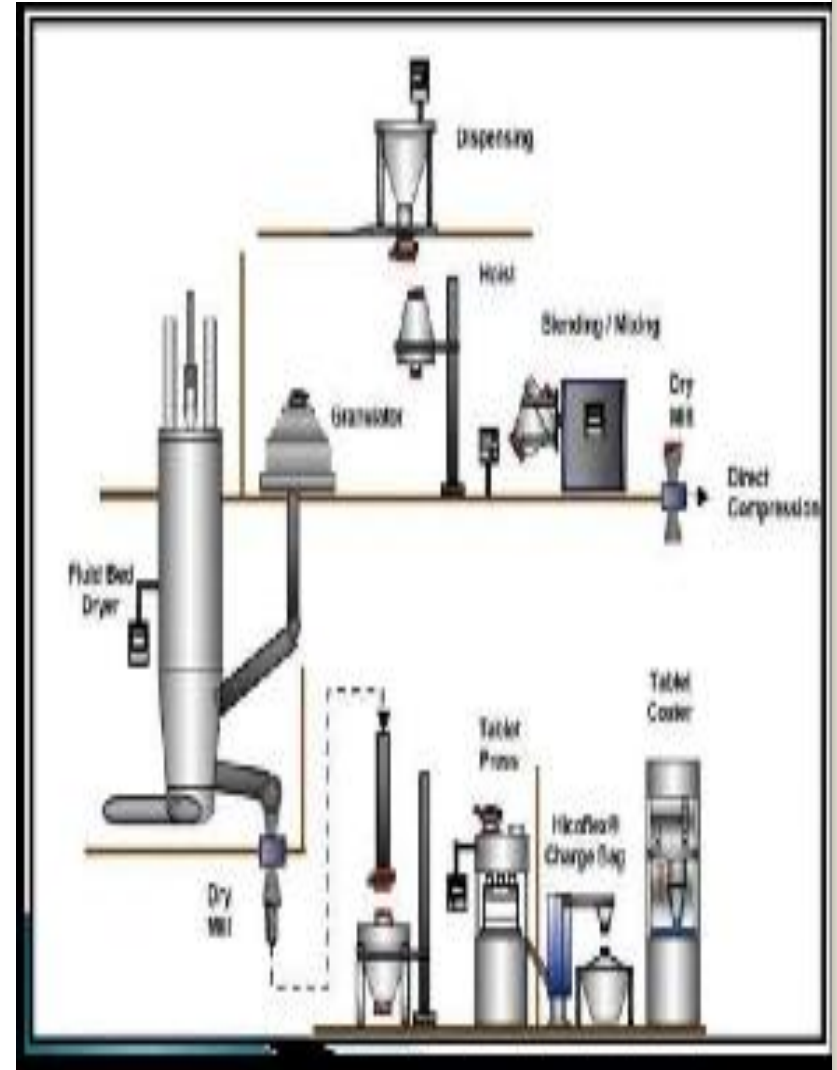
d) High density concrete floor should be installed.

e) Their should be enamel painting overs the wall of the construction area.



STAGES OF PRODUCTION OF TABLET

- 1- Material handling
- 2- Dry blending
- 3- Granulation
- 4- Drying
- 5- Reduction of particle size
- 6- Special granulation technique-
 - a) Wet granulation
 - b) Direct compression
 - c) Slugging (Dry granulation)



1- MATERIAL HANDLING:-

- In intermediate or large scale operations handling of materials are often necessary to prevent cross contamination with other materials.
- More sophisticated methods of handling material such as vacuum loading system , metering pumps, screw feed system etc. are used.

2- DRY BLENDING

- The blending of fine and coarse (different size) particles to breaks down the agglomerates of fine and proper mixing.
- Inadequate blending at any stage result in discrete portion of the batch being either high or low in potency.
- Steps should be taken to ensure all the ingredients are free from lumps and agglomerates.

CONSIDERATIONS :-

- a) Time of blending
- b) Blender loading
- c) Size of blender

PROBLEMS OF IMPROPER BLENDING:-

- a) No content uniformity
- b) Flow problem throughout equipment
- c) Non-reproducible compression

EQUIPMENT USED :-

- a) V blender
- b) Ribbon blender
- c) Double cone blender
- d) Slant cone blender
- e) Bine blender

3- GRANULATION

Small particles are gathered into larger permanent masses in which the original particles can still be identified.

Types of granulation:-

a) **Wet method-**

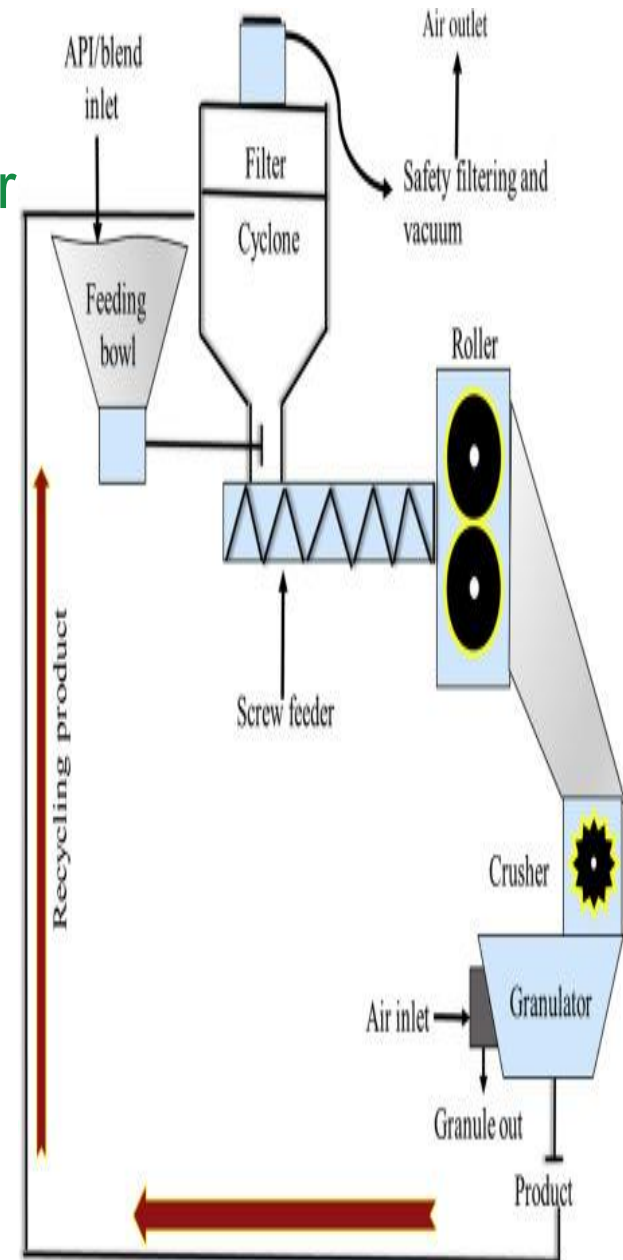
- :- Sigma blade mixer
- :- heavy duty planetary mixer

b) **Dry method:-**

- :- Roller compaction mill
- :- Shear mill

c) **Fluidized granulation:-**

- :- Fluidized bed granulator



4- DRYING

- To remove or/reduction in the moisture(excessive)
- Considerations:-
 - a) Air flow
 - b) Air temperatures
 - c) The depth of the granulations on the trays
- Equipment:-
 - a) Tray dryer
 - b) Fluidized bed dryer

5- REDUCTION IN PARTICLE SIZE

- It affects flow ability, compressibility, uniformity of tablet weight, content uniformity, tablet hardness and tablet color uniformity.

EXCIPIENTS USED IN TABLET:-

- Diluents/Filler
- Binders and adhesive
- Lactose USP
- Hydrolysed starch
- Manitol
- Sorbitol
- Acacia
- Gelatin
- Starch paste
- Tragacanth
- Cellulose
- Glucose/Sorbitol

- **Disintegrants**

- Starch, • Clays (Bentonite),
- Alginate,
- Primo gel

- **Lubricant**

- Stearic acid and derivatives
- Poly ethylene glycol
- Talc , • Waxes

- **Glidant and Flow**

- Silica derivatives
- Corn starch
- Talc

- **Colours**

- FD and C yellow no. 6
- D and C red no. 28
- PD and C blue no. 1