# Methods of Granules Preparation

- MOIST GRANULATION METHOD
- DRY GRANULATION METHOD
- GRANULES BY PRELIMINARY COMPRESSION

#### MOIST GRANULATION METHOD

- ✓ API + excipients such as diluents, binding agents, disintegrating agents with q.s. moistened granulating agent.
- Make a coherent mass.
- ✓ Pass through sieve no. 8 or 10.
- ✓ Dried at 60°C.
- ✓ Then dried granules passed through sieves.
- ✓ Then add lubricating agent, any volatile subst. & mixed well.
- Ready for compression.

# DRY GRANULATION

- Dry granulation process are generally use for those drugs having crystalline properties or for having present in granules & having it's own binding property.
- Those drugs are passed through sieve no.20 or any other specified sieve.
- Then mix with additional excipients such as diluents & lubricants.
- Ready for compression.
- e.g. Aspirin tablets, sodium bromide tablets etc.

#### **GRANULES BY PRELIMINARY COMPRESSION**

- This method is also called as "SLUGGING METHOD".
- This method is used for those drugs which are unstable in presence of moisture.
- In this method firstly dry powder is compressed into large tablets or slugs.
- Then those tablets or slugs broken into small pieces & passed through a specified sieve to obtained a suitable size granules.
- Then mixed with a suitable lubricating, disintegrating & granulating agents.
- Ready for compression.

# EXCIPIENTS USED IN FORMULATION OF TABLETS

- 1. Diluents
- 2. Granulating agents
- 3. Binding agents
- 4. Disintegrating agents
- 5. Lubricants
- 6. Adsorbents
- 7.Colouring agents, Flavouring agents and Sweetening agents.

## **DILUENTS:**

- The diluents is needed in the formulation of tablets, when the quantity of medicament in each tablet is very small & it is not possible to make a good tablet.
- E.g. Lactose, Sucrose, Sodium chloride, Dextrose, Starch, Mannitol, Sorbitol, Calcium sulphate dihydrate, dibasic calcium phosphate dihydrate.
- **GRANULATING AGENTS**: Those agents converts the fine powder into granules .
- By providing proper moisture to convert fine powder to damp mass.
- E.g. Water, Alcohol, Mucilage of starch, Mucilage of acacia, Mucilage of tragacanth, Gelatin solution, Isopropyl alcohol, Acetone etc.

#### **BINDING AGENTS:**

- These agents provides good strength to the granules, in order to keep the tablet intact after compression.
- Concentration of binding agents depends upon the type of tablet i.e. In lozenges & implants tablets have very high conc. of binding agents.
- Whereas in other cases where the tablets has to disintegrate quickly in that conc. of binding agent used in lower proportion.
- Binding agents used along with granulating agents.
- E.g. Acacia powder, Tragacanth, Gelatin, Sucrose, Methyl cellulose.

#### DISINTEGRATING AGENT:

- Disintegration agents gives ensured to disintegrate of the tablets into smaller particles when swallowed.
- These agents are used in the formulation of oral or sublingual tablets.
- Those agents divided into two parts, one part is mixed with other excipients before granulation & other part is mixed with the dry granules before compression.
- They act in three ways :
- By swelling: in contact with water or moisture e.g. maize starch, potato starch, methyl cellulose & bentonite.
- By producing effervescence : e.g. sodium bicarbonate, citric acid & tartaric acid.
- They melt at body temperature: e.g. cocabutter.

- LUBRICANTS: They provide to improve appearance, flow properties & use to prevent the sticking of the materials to the dies & punches.
- Means they play three roles Viz.. Lubricant, Glidants & anti-adhesive agents.
- E.g Talc, Magnesium stearate, calcium stearate, sodium chloride, Boric acid, Starch, Liquid paraffin, Stearate acid etc.
- ADSORBING AGENTS: These substances are used to adsorb volatile oil, liq.extract & tinctures etc. which are included in the formulation of tablets.
- E.g. Magnesium carbonate, Kaolin & Starch

### • COLOURS, FLAVOUR & SWEETNING AGENTS:

- Colours produce elegance effect on tablet.
- Certified F.D & C dyes are used. They mixed with granulating agents or mixed with other ingredients before granulation.
- Flavours are used mainly in Lozenges, effervescent & in chewable tablets.
- Falvouring agents is dissolved in organic solvents & then sprayed on the granules.
- Sweetening agents use to improve the taste of tablets.
- Now a days artificial sweetening agents are used e.g. Saccharin & Cyclamates.
- Commonly used sweetening agents are Sucrose, Lactose, Mannitol.