



Dry Granulation

Lab 3

Industrial pharmacy

۲۰۲۵-۲۰۲۴

Fifth stage

Dry granulation

Granulation, the process of particle enlargement by agglomeration technique, is one of the most significant unit operations in the production of pharmaceutical dosage forms, mostly tablets and capsules.

Granulation process transforms fine powders into free-flowing, dust-free granules that are easy to compress.

It sometimes, serves as an intermediate product in the manufacture of tablets or capsules.

Also, it works to prevent segregation as well as to improve compaction characteristics of the mix.





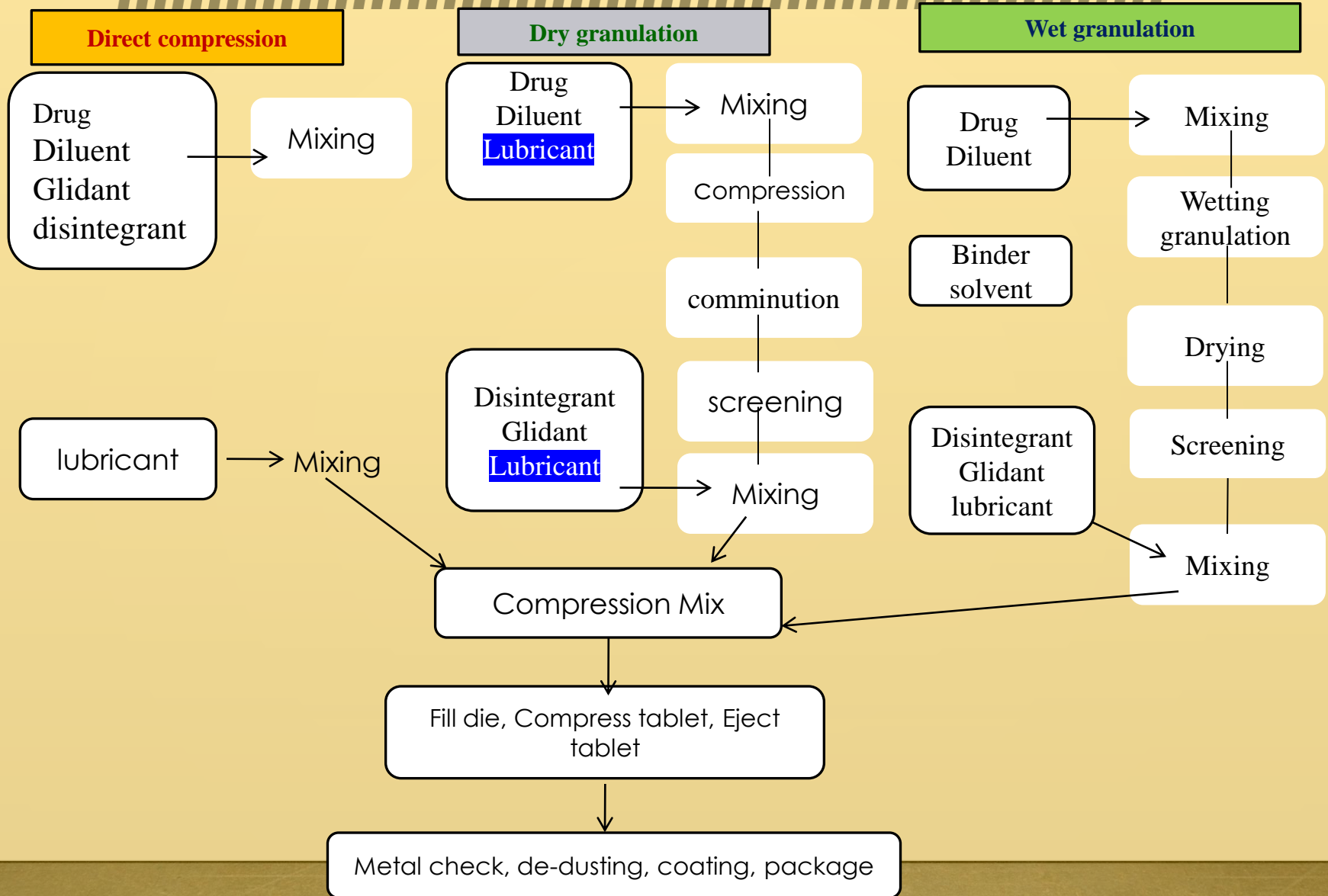
Secondary reasons for granulation

Reduce the hazard associated with the generation of **toxic dust** which may arise when handling powder.

Reduce the hazard associated with the storage of powder that is slightly hygroscopic and may adhere to form a **cake**.

More convenient for storage and shipment as it is denser than powder and occupies less volume per unit weight.

Unit operations in tablet manufacturing





Methods of dry granulation

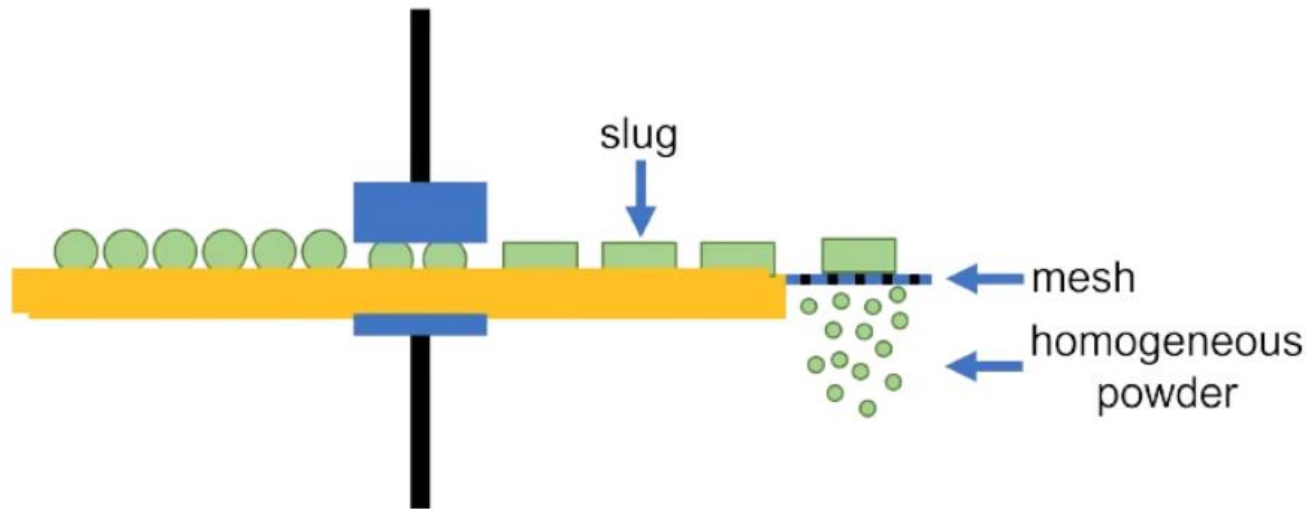
**A. Slugging technique
(double compression)**

**B. Roller compaction
technique**



A- Slugging technique:

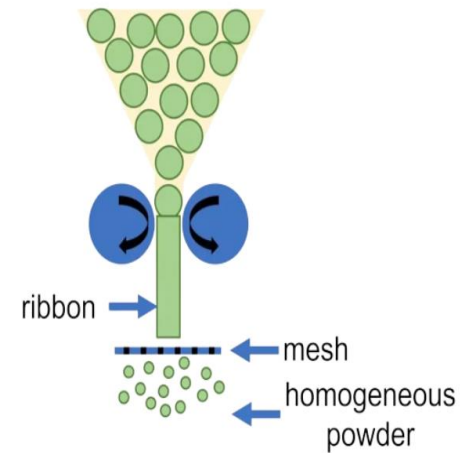
It is also known as precompression or double compression. This cost-effective dry granulation method also works well for raw materials that are sensitive to heat and moisture.



1. Prepare the formula, then milling.
 2. Weigh all the substances and $\frac{1}{2}$ amount of lubricant. (Because it is needed during slugging by tablet machine to eject the slug from die).
 3. Mix well by mixer and compress into large tab. (slug) using large punch and die
 4. Grinding slug by dry granulator or homogenizer to convert slug into granules.
 6. Weigh granules and divide by weight of single tablet to get real no. of tablets
- (Real no. of tablets = total weight of granules before 2nd lubrication/wt. single tab. Before 2nd lubrication)**
7. Second compression after addition of calculated amount of lubricant, mix and compress by normal machine.



Roller compactor



- The roller compaction method transports the powder blend to a pair of counter-rotating rollers.
- This can be done using either gravity or by feed system.
- As the powder runs into the gap between the rollers, the gap diameter gets smaller.

To increase the bulk density and homogeneity, the gap between the rollers is controlled and that the powder blend is compacted by the given force.

SO, the powder feeding, the applied compaction pressure, and the gap diameters are the most important factors in the roller compaction process

Advantages of dry granulation

The process only requires a roller compactor, mill, sieve, feeder, and discharging equipment. So, it generally takes up much less space than other processing methods.



No need for drying so it is not time consuming.



Used for moisture sensitive materials such as ?.



The disintegration time is improved because the binder used in powder form, so the adhesive effect is less so fast disintegration.



No migration of colors (mottling) that may occur in wet granulation because of presence of moisture.

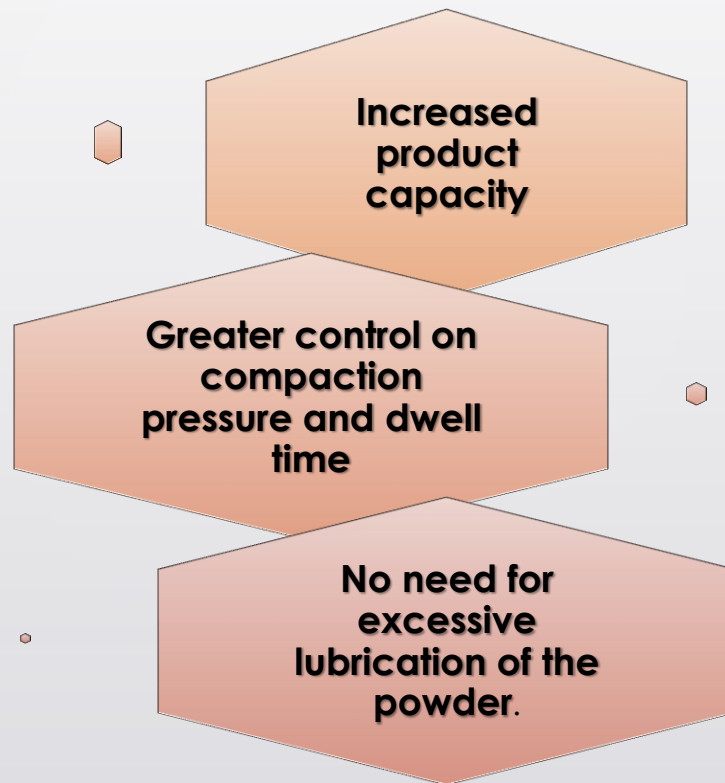


Disadvantages of dry granulation

1. slugging required specialized heavy duty machine
2. it creates a significant amount of dust, which may lead to cross-contamination.
3. generation of charges of static electricity and lead to reduce flowability (multiple screening that will reduce p.s.).
4. decreases the dissolution of insoluble drugs (lipophilic drug) in spite of reducing particle size. here, sticking of particles that may affect flowability.



Advantage of roller compactor over slugging





Preparation of sodium phenobarbital tab. by using dry granulation

- **Organoleptic properties** (crystalline powder)
- **Solubility** (freely soluble in water 1:3)
- **Stability** (phenobarbitone is not affected by heat or moisture, but sod. phenobarbital decompose by heat and moisture so it's hygroscopic by absorbing CO_2 from atmosphere to convert to phenobarbitone).



Formula

Sod. Phenobarbitone	15 mg	(active ingredient)
Lactose	5 mg	(diluent)
Emcompress	20 mg	(diluent)
Starch	20 mg	(disintegrant)
Acacia	10 mg	(binder)
Mg. Stearate	5 mg	(lubricant)
Prepare 30 tablets.		

Calculations:-

Total weight of each tablet= $15+5+20+20+10+5= 75$ mg

Since, half amount of lubricant should be added in the 1st mixing step;

So,

$$5\text{mg}/2= 2.5 \text{ mg of Mg. stearate/tablet}$$

1. $2.5 * 30 = 75$ mg of Mg. Stearate should be added in the 1st lubrication

2. $75-2.5= 72.5$ mg of single tablet before 2nd lubrication

Suppose, the wt of granules mixture before 2nd lubrication are 2040 mg

3. (Real no. of tablets = total weight of granules before 2nd lubrication/wt. single tab. Before 2nd lubrication)

$$= 2040\text{mg}/72.5\text{mg}$$

$$= 28.2 \text{ tablets}$$

So; $2.5*28.2= 70.5$ mg of Mg. Stearate added in the 2nd lubrication



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