Dry and wet G ranulation

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Granulation

- Is the process in which powder particles are made to adhere to form larger, multiparticle entities called granules.
- Pharmaceutical granules have size range between 0.2-4mm.
- **Classification of Granulation Technologies:**
- 1. Conventional methods.
- (i) Dry granulation.
- (ii) Wet granulation.
- (a) High-shear wet granulation.
- (b) Low-shear wet granulation
- 2. Novel/advanced methods include:
- Moisture activated dry granulation, Thermal adhesion granulation, Pneumatic dry granulation, Melt/thermoplastic, granulation,Fluidized bed granulation, Extrusion-spheronization granulation, Spray drying granulation, Freeze granulation, Foam binder granulation, Steam granulation.

Why do we use granulation??

- increases flowability.
- increase compressibility.
- Improve content uniformity of the powders.
- Inhibit the separation of blend components.
- Reduce the amount of fine particles.
- This process helps to achieve improved yields with less tablet manufacturing defects.

Dry granulation

- Granules with no liquid solution added
- Done by: slugging

DISPENSING

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SIFTING

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SLUGGING

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COMPRESSED SLUGS

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SCREENING

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GRANULES FORMATION

Roller compactor

DISPENSING

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pass through high pressure rollers

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collect flakes

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milling of granules

Examples of excipients used in dry granulation

- Binder:

Alginic acid, PVP, HPMC and methyl cellulose.

- Filler:

Magnesium stearate, lactose, sucrose, cellulose and calcium carbonate.

- **Advantages**:
- Very less equipment and space needed.
- Saving time.
- Elimination of costly and time consuming dry steps .

- **Disadvantage**:
- Requires specialized heavy duty tablet press,
- Does not permit uniform colour distribution,
- Tends to create more dust with respect to wet granulation, and
- Increases the potentiality of cross contamination.

Wet granulation :

- Most widely used technique
- Include: low and high shear

DISPENSING

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SIFTING

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MIXING

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PREPARATION OF GRANULATING FLUID

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GRANULATION

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SCREENING OF WET MASS

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DRYING OF GRANULES

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MILLING OF DRIED GRANULES

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BLENDING WITH THE LUBRICANT

Examples of excipients used in wet granulation

- Solvent:

Water , ethanol , isopropanol and methylene chloride .

- Binder:

Starch ,pregelatinized, gelatin, sodium algenate, PVP, HPMC and sugars.

- Fillers:

Glycerin, manitol, lactose and starch, microcrystalline cellulose .

- **Advantage**:
- Less dust produced
- Keep the blend without creation any incompatibilities.
- Better content uniformity.
- Better color distribution.

- **Disadvantage**:
- Over wetting will cause lump formation.
- High power consumption
- Expensive and time consuming
- Difficulties in validation

- Low shear: about 100 rpm
- High shear: 500 or 1000 rpm

	Particle size distribution	**porosity**	**friability**
Low shear	Wide size distribution and fine particles	More porous	More friable
High shear	Narrow size distribution	Less porous the granules	Less friable

Best choice..

Drug properties	Wet granulation	Dry granulation
Thermolabile	✗	✓
Moisture sensetive	✗	✓
Poorly water soluble	✓	✓
Thermostable	✓	✓
Low melting point	✗	✓
Water soluble carier	✗	✓
Compressibility	✓	✗
Coloration	✓	✗

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