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A COMPREHENSIVE REVIEW ON PELLITIZATION TECHNIQUE

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Abstract:

Pelletization is a process for producing spherical beads or pellets with mean diameters ranging from 0.5 to 2.0 mm. These pellets can be coated and employed in controlled-release dose forms in the future. The usage of pelletization and pellets improves the flowability, appearance, and mixing properties, avoiding excessive dust and decreasing segregation and in general, eliminating unwanted properties and improving the physical or chemical properties of fine powders. Extrusion spheronisation , rotogranulation , solution, suspension or powder layering, spray-drying or spray-congealing are some of the procedures used to make pellets. The purpose of this study is to go over some general elements of pellets and pelletization, as well as several typical procedures utilised in the pharmaceutical sector.(1-7)

Key words: Pellatization, pellets

1. Introduction:

Pelletization is defined as an agglomeration (size-enlargment) process that produces small, free-fl owing, roughly spherical units known as pellets from fine powders (7).

Granules, pellets, agglomerates, and spheroids are the terms used to describe the units produced during granulation, which is also known as pelletization, agglomeration, or spheronization (8).

The phrases "granulation" and "pelletization" are occasionally used interchangeably, with no evident distinction. In general, if a size-enlargement process produces agglomerates with a size distribution of 0.1 to 2.0 mm and a high porosity (approximately 20-50%), the process is referred to as "granulation," and the resulting agglomerates are referred to as "granulate." (9)

"Pelletization" is a size-enlargement process that involves the production of agglomerates with a relatively limited size range, typically with mean sizes ranging from 0.5 to 2.0 mm, known as "pellets." Pellets are free-flowing and have a low porosity (about 10%). (9)

2. Methods of pellitization:

Pelletization methods used in the pharmaceutical sector can be classified based on a variety of characteristics, such as the type of equipment used, the intensity of the mechanical forces involved, or the processes utilised to produce pellets. (10-12)

2.1 Extrusion / Spheronisation:

Extrusion / spheronisation is a multistage technique for producing uniformly sized pellets from wet granulates (extrudates).

The approach consists of the following major steps

- dry mixing of the constituents to produce homogeneous powder dispersions
- Wet massing is the process of combining powders to generate a sufficiently deformable mass.
- An extrusion stage, in which the wet mass is formed into cylindrical segments of uniform diameter;
- spheronisation stage, in which the small cylinders are rolled into solid spheres (spheroids);
- drying of the spheroids to achieve the desired final moisture content;
- screening (optional), to achieve the desired narrow size distribution.(6)

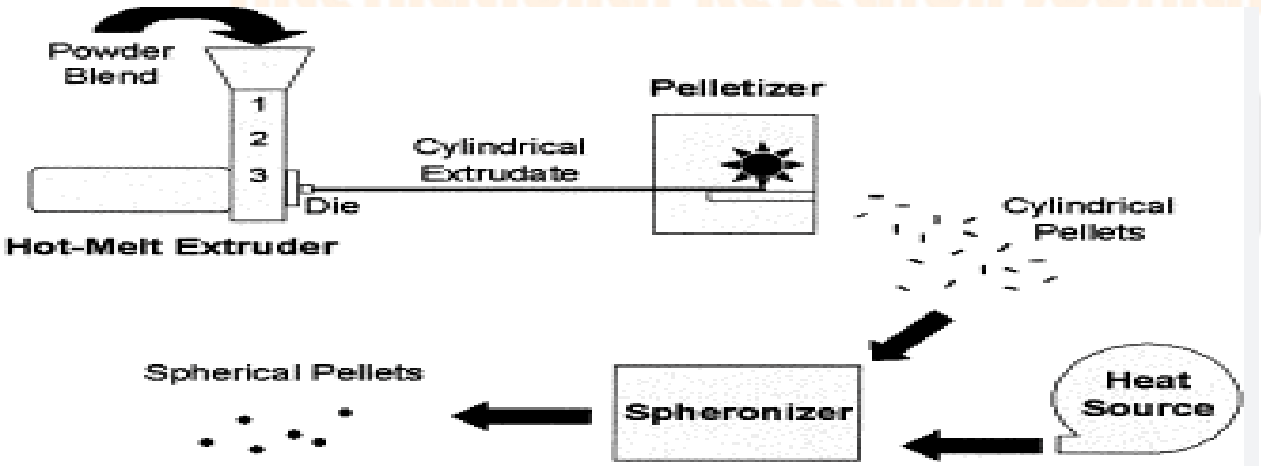

Figure1: production of spherical by hot melt extruder.

2.2 Fluid-bed granulator:

In a fluid-bed granulator, the process is carried out continuously.

It entails spraying a granulation solution onto the suspended particles, which are subsequently rapidly dried in the hot air stream.

The fluid-bed granulation procedure consists of the following steps (2):

- preblending of the formulation powder, including the active ingredients, fillers, and disintegrants, in a flow of air.
- granulation of the mixture by spraying a suitable liquid binder onto the fluidized (suspended) powder bed.

Fluid-bed granulation has various advantages over traditional wet granulation, including the fact that it is automated and executed in a single unit, saving money, transfer losses, and time. On the other hand, the process necessitates significant effort in both the initial formulation and the scale-up from development to manufacturing.

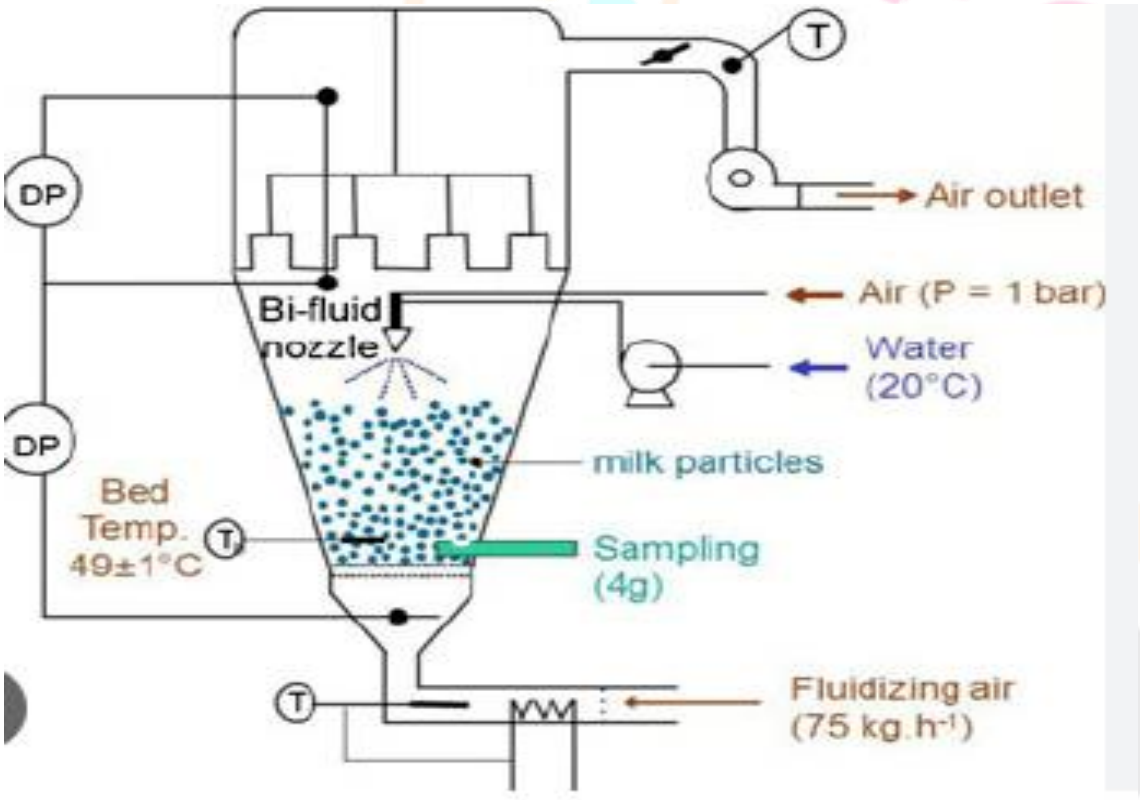

Figure 2: Fluid bed granulator

2.3 Rota granulation:

One of the most recent technologies for producing spheroids is rotogranulation. Centrifugal granulator, rotary fluidized-bed granulator, rotary fluidized bed, rotary processor, or rotor granulator are all words used to describe the single-unit spheronizing device.

The centrifugal force is proportional to the rotation speed of the disc, but the vertical distance travelled by the particles is determined by the air velocity and volume.

The combined action of the three forces causes the material to move in a spiral, twisted, rope-like manner (7).

2.4 Solution and suspension layering :

Layering a drug suspension or solution on a seed material (often a coarse crystal or nonpareil) can result in pellets with uniform size distribution and generally very good surface shape (13).

These qualities are especially desired when pellets are coated to achieve controlled release. This type of equipment consists of specifically modified standard coating pans (perforated pans) and various configurations of fluid-bed equipment (13).

2.5 Spray drying:

Another procedure with limited application in the creation of pharmaceutical pelletized products based on globulation is spray-drying. Spray-drying involves spraying a medication solution or suspension, with or without excipients, into a heated air stream, resulting in dry and highly spherical particles.

Though the technology is appropriate for the manufacture of controlled-release pellets, it is most commonly used to improve dissolving rates and thus bioavailability of poorly soluble medicines.

2.6 Spray-concealing:

Spray-concealing (spray-chilling) is a comparable process to spray-drying.

Spray-concealing refers to the process of allowing a medication to melt, disperse, or dissolve in hot melts of gums, waxes, fatty acids, or other melting solids.

The dispersion is then sprayed into a stream of air and other gases that is cooler than the melting point of the formulation components. Spherical congealed pellets are created under the right processing conditions.

The resultant material can be used for the production of prolonged-release dosage forms (2, 8).

3. FACTOR INVOLVING PELLETIZATION TECHNIQUE :(14-16)

- The amount of moisture
- elasticity properties
- solubility of drugs in granulating fluid
- Extrusion screen
- Components of Granulating Fluid
- Physical Features of Initial Material
- Rate of the Spheronizer Drying Technique and Drying Temperature.

4. Application: (17)

- Taste masking
- Immediate release
- Sustained release
- Chemically incompatible products
- Changing the dose without reformulating

5. Conclusion:

Pelletization has gained popularity in recent decades, owing to the possibility of using pellets in the production of modified-release solid oral dosage forms. There are various pelletization processes available today, the most common of which is extrusion/spheronization. Pellets are predicted to continue to play an important role in the design and fabrication of solid dosage forms due to their good technological, pharmacokinetic, and biopharmaceutic features, as well as the flexibility of the manufacturing processes involved.

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