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Foam Granulation an Advanced Technique of Granulation

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A B S T R A C T

Granulation process is the most widely used technique for manufacturing materials for tablet in pharmaceutical industry. The methods, which include the granule formation, are microencapsulation, multi particulate system for modified release mechanism etc. Foam granulation technique involves addition of liquid binders in aqueous foam base. During foam granulation binders in aqueous form are added. More preferable over spray(wet) granulation. FGT is advantageous over wet granulation technique considering some factors like less water required for granulation, uniform distribution of binder, no over wetting of granules and no spray nozzle is required and most importantly suitable for water sensitive drugs. But Analysis of the foam allows small particles to adhere to larger particles in the early stages of granulation, and then get more completely agglomerated through the entire operation.

Keywords: Granulation, Spray, Foam, nozzle, binder and agglomeration.

A R T I C L E I N F O

CONTENTS

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1. Introduction

Granulation: Granulation has been impacted over the years as an important an operation that is by any where minute dusty particles be clustered keen on bigger entities called granules Out of all the existing techniques in performing granulation in the pharmaceutical industry, including: enhancing flow ability, mixing properties, and granules appearance for the purpose of enhancing physico chemical properties of fine powder. In the manufacture of oral solid dosage forms high-shear wet granulation continues to be an important process. Usually, an aqueous solution of a binder is sprayed on the powder during mixing in a granulator [1]. Granulation process is the most widely

used technique for manufacturing materials for tablet in pharmaceutical industry. The methods which include the granule formation are microencapsulation, multi particulate system for modified release mechanism etc.

Preparation of granules has different reasons as follows.

- To improve compression characteristics of blending.
- To enhance bulk density parameter of drug.
- To improve flow property and to maintain dose uniformity.
- To facilitate volumetric dispensing.
- To control the rate of drug release
- To improve the appearance of product [2].

Ideal characteristics of granules

a. Spherical shape of granules
b. Particle size distribution with fines to fill void spaces between granules
c. Acceptable moisture content [1-2 %]
d. Good flow Properties
e. Better compressibility
f. Bearable hardness [3]

Reasons for granulation

- For the prevention of splitting of constituents in the powder mix
- For improving the flow related properties of the mix
- To improve the constriction characters of the mix
- Facilitates cake formation and adhesion of hygroscopic materials present in the mix as the granules absorbs moisture and still hold the flow-property because of their size
- Usually granules occupy less volume per unit weight and more dense than the powder mix, hence more convenient for storage and transportation [4].

2. Foam Granulation

During foam granulation binders in aqueous form are added. More preferable over spray (wet) granulation. Foam granulation technique involves addition of liquid binders in aqueous foam base [5].

Quality of Foam

Certain features of the polymer like concentration, molecular weight, and substitution-type impart greater flexibility to the nature of liquid phase and quality of foam (FQ), and monitor stability of foam. Stability of foam is highly process dependent. Viscous solutions with viscosity 100 to 300 cp generally produce elastic foams that are stable to high yield stress. These viscous foams, which are tediously produced, often possess lowest FQ, and do not spread easily. Low viscosity having viscosity of 3- 100 cp very conveniently foamed and can result high viscosity foams with low consistency [6].

Advantages:

- Spray nozzle is not used
- To improve strength of the process
- Limited water is consumed for granulation
- Time saving in drying
- Applicable for water sensitive formulation [8].
- Carry out consistent distribution of binder. .
- Cost effective, fast and reproducible process.
- Requires less binder than Spray Granulation.
- Flexibil for adopting continuous (or) batch process
- Uniform binder distribution
- No over wetting
- Requires less amount of the water and binder for granulation [9]
- Easy to formulate immediate release and controlled-release products [10].

Figure 1: Foam Image [7]

Applications:

- For granulating water sensitive formulations,
- For designing immediate Release (IR) and Controlled Release (CR) formulations [11].
- Less water utilization for granulation, which facilitate less drying time.
- Overcomes the problems of wet granulation
- Distribution of a very low concentration drug level i.e. milligram (or) micro gram per tablet in a powder bed.

Foamed Binder Technology (FBT)

FBT helps in achieving better-wet granulation, which uses METHOCEL polymers and improves distribution of binder in the formulation mix. It helps in reducing water requirements, improves reproducibility and helps in eliminating spray nozzles and their many variables in granulation processing equipment [12].

Working:

It gives advantage in increasing the liquid surface area and volume of polymeric binder foams to improve the distribution of the water or binder system throughout the powder bed.

Figure 2: Foamed binder

Binders used in foam granulation:

Foam generation apparatus is used incorporating air into a conventional water-soluble polymeric excipients binders. In

this technology hypromellose polymers are used as they are good film formers and create stable foams. Surfactants (e.g., sodium laurel sulfate) may also be used as excipients to generate foam.

- Hydroxy propyl cellulose
- Ethyl cellulose
- Polyethylene oxide
- Methyl cellulose
- Sodium carboxy methyl cellulose (sodium CMC)
- Hydroxyl propyl methyl cellulose (HPMC)

3. Process involved in foam granulation

Table 1: Process Involved in Foam Granulation with the Equipments Required**:**

Type of Process	Equipment Required
Dry Mixing	Blender or Rapid Mixer Granulator
Foam Preparation of Binder	Foam Generator
Foam Granulation	High Shear Mixer Granulator or Rapid Mixer Granulator
Drying	Tray Dryer or Fluid Bed Dryer
Milling	Multimill
Sifting	Vibratory or Mechanical Sifter
Pre-Lubrication	Double cone or Conta bin or Octagonal Blender
Lubrication	Double cone or Conta bin or Octagonal Blender

Foam granulation procedure:

Measured quantities of drug, diluent and disintegrates were taken and placed into a high shear mixer granulator. These powders were mixed previously for some timebased on the requirement with the help of impeller. High quality foam of binder solution (most commonly Hydroxypropyl cellulose) was generated with the help of a foam generator. Foam was applied using a rigid plastic pipe from foam generator into the RMG with variable speeds of impeller or chopper (at low or high speed depending upon the nature of the materials [11]. A conventional foam generation apparatus is used to incorporate air into a water-soluble Polymeric excipients binder. The foam generator can be connected directly to high-shear or low-shear fluid bed granulation equipment for continuous processing [9].

Figure 3: Foam formed through a foam generator

Figure 5: Initial foam charge

Figure 6: After 1 minute of mixing

Figure 7: After 2 minutes of mixing

Foam addition by simple batch process

Unlike spray addition methods, foamed binders may be added to the granulate as a single quantity. The foam very quickly and efficiently distributes through the powder bed during normal granulator operation. Figure 2 shows an example of the process of foam added through a top port in a lab-scale high shear granulator. After one minute of mixing, the foam get distributes well into the granulate mix, and fully distributes through the granulate after just two minutes of mixing [12].

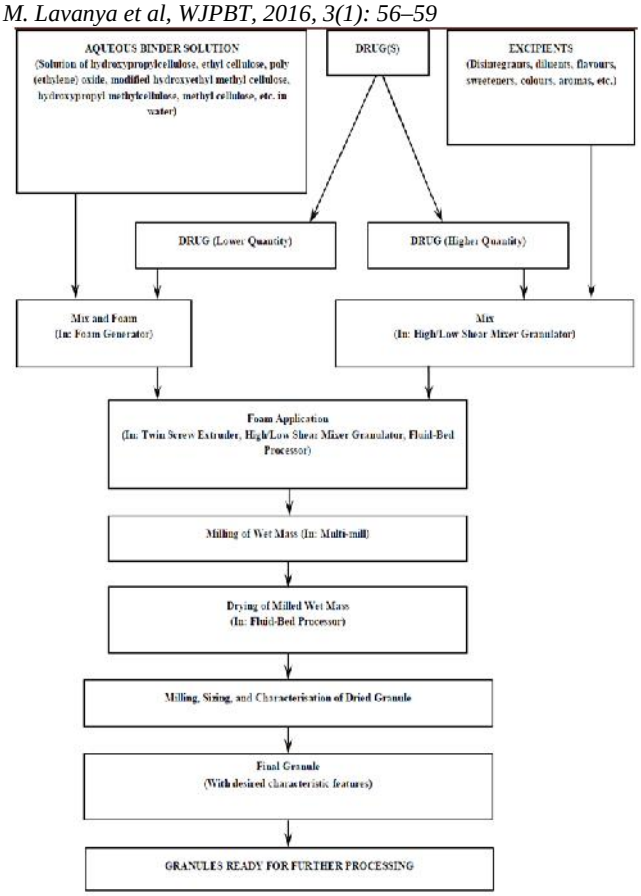

Figure 8: Flow Chart of Foam Binder Granulation Process

4. Conclusion

FGT is advantageous over wet granulation technique considering some factors like less water required for granulation, uniform distribution of binder, no over wetting of granules and no spray nozzle is required and most importantly suitable for water sensitive drugs. But Analysis of the foam allows small particles to adhere to larger particles in the early stages of granulation, and then get more completely agglomerated through the entire operation..

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