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Fluidized Hot Melt Granulation: Promising Technique for Dissolution Enhancement

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Abstract

Fluidized Hot-melt granulation is an agglomeration process; granules are obtained by melting binders that are heated to near or above their melting point. FHMG is an innovative technique involving meltable binder to agglomerate fluidized dry powders. Fluidized Hot-melt granulation techniques have received enhancing attention due to the significant advantages compared to the other granulation methods. Fluidized hot melt granulation (FHMG) is recommended as promising technique. FHMG is simple and rapid granulation technique that enables a scientist to manipulate drug release rate depending on the properties and concentration of the meltable binder. It provides a sophisticated robust process for poorly soluble drug of oral dosage form. Proper selection & optimization of formulation, equipment & process related variable in Fluidized hot melt granulation can lead to successful scale up of Fluid-bed processing technology from the small scale to large scale production successfully.

Keywords: Fluidized hot melt granulation; Fluidized bed granulation; Fluidized bed process; Meltable binder

Abbreviation

FHMG**:** Fluidized Hot Melt Granulation

Introduction

Granulation is the act or process of forming or crystallizing into grains. Granules have a size range between 0.2 and 4.0 mm depending on their use. After granulation, the granules have to be mixed with other excipients prior to tablet compression or capsule filling. Granulation method classified into two types: Wet granulation and Dry granulation. Novel granulation technologies are such as a Pneumatic Dry Granulation, Freeze granulation Technology, Foamed Binder Technologies, Hot Melt Granulation Technology, Steam Granulation, Moisture Activated Dry Granulation, Extrusion & spheronization and Thermal Adhesion Granulation Process.

Drugs of Biopharmaceutical Classification System (BCS) class II are characterized by high membrane permeability, slow dissolution rate (due to low aqueous solubility) [1-3]. The solubility or dissolution rate of a drug in this category is a major factor in determining the rate and amount of its absorption.

Salt formation, solubilization and particle size reduction have commonly used to enhance dissolution rate of the drug, but there are particular limits with these techniques. The bioavailability enhancement may not always be achieved. Formulation approach that significantly enhances the absorption of drugs, to enhance bioavailability of poorly water soluble drugs is hot melt granulation technique.

The fluid bed granulation process is a combination of three steps: dry mixing, spray agglomeration and drying to desired granule size [4].

The Fluidized hot melt granulation technique is a process by which pharmaceutical powders are efficiently agglomerated by the use of a low melting point binder which is added to the other components of the powder. At molten state, the binder acts as a granulating liquid. Liquids containing melts binder are sprayed into a fluidized bed system. Due to the high heat exchange the aqueous or organic solvents evaporate immediately, and the solids form small particles as starter cores. These are sprayed with other liquids which in turn, after evaporation, form a hard coating around the starter core (Figure 1 and 2). On top spray method is a zone of liquid drops, and spraying is the act of breaking up a liquid into a multitude of these droplets.

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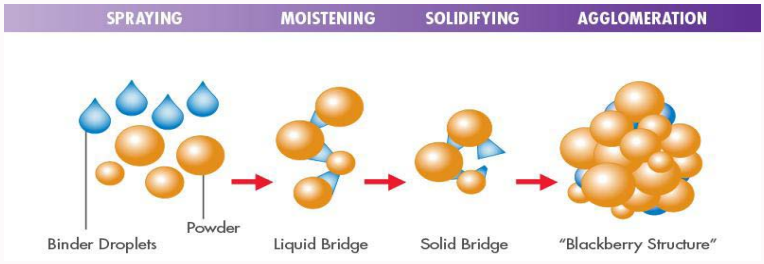

Figure 1: Principle of Fluidized bed process.

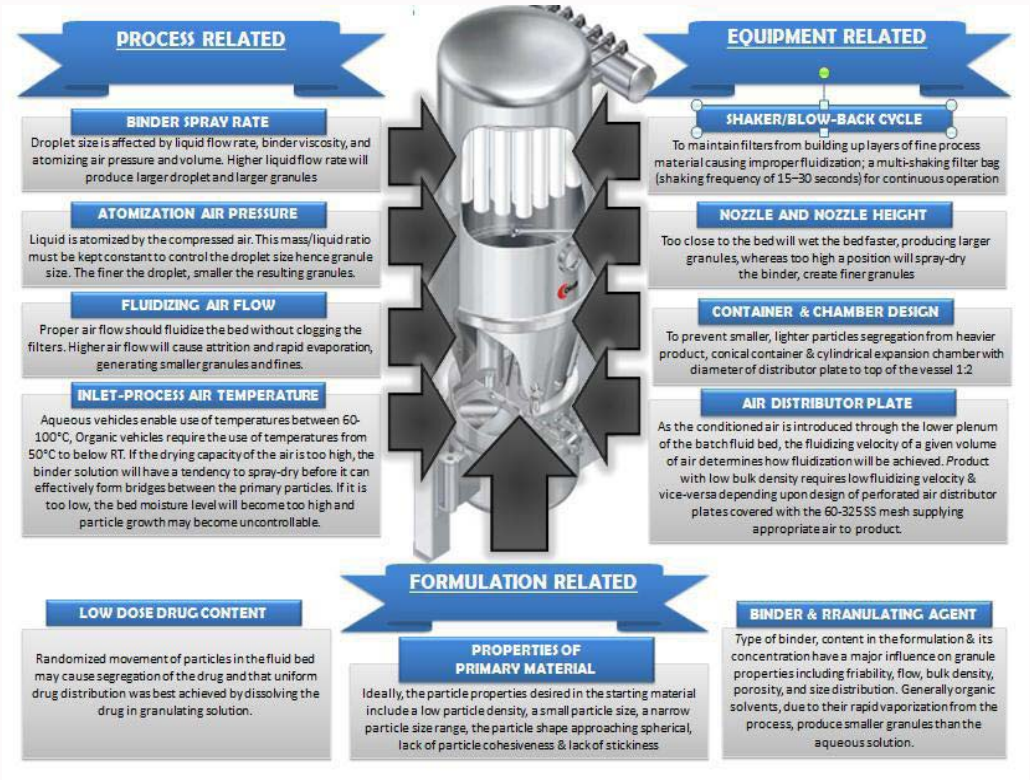

Figure 2: Factors affecting FBP Development.

1. The enhanced dissolution rate of drugs from this technique is based on four different Mechanisms [2]:Wetting of the drug is improved by direct contact of the drug with the hydrophilic or hydrophobic binder.

2. The saturation concentration around small particles is higher than around large particles.

3. The Particle surface area is increased.

4. The drug has more energy in the amorphous state than in the crystalline state, the saturation concentration is increased.

Requirements of Hot Melt Granulation

Amount of meltable binder is 10%-30% w/w with respect to that of fine solid particles isused. A Meltable binder suitable for melt a granulation has a melting point typically within the range of 60-80°C. Hydrophilic Meltable binders are used for prepare immediate-release dosage forms while the hydrophobic Meltable binders are preferred for prolonged-release formulations [5,6]. The melting point of other fine solid particles should be atleast 20°C more than that of the maximum processing temperature.

Conclusion

The fluidized hot melt granulation technique can be used to enhance the dissolution rate of the poorly soluble drugs.

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