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Tablets Manufacturing Methods and Granulation Techniques

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Review Article

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ABSTRACT

From past hundred years tablet manufacturers have developed materials and processes that can produce compressed tablets containing a precise amount of an active pharmaceutical ingredient (API) at high speed and at relatively low cost. Granulation may be defined as a size enlargement process which converts small particles into physically stronger & larger agglomerates.

INTRODUCTION

Granulation method can be broadly classified into two types: Wet granulation and Dry granulation.

Wet Granulation

The most widely used process of agglomeration [1-7] in pharmaceutical industry is wet granulation. Wet granulation process simply involves wet massing [8-15] of the powder blend with a granulating liquid, wet sizing and drying. Important steps involved in the wet granulation

i) Mixing of the drug(s) and excipients.
ii) Preparation of binder solution.
iii) Mixing of binder solution with powder mixture to form wet mass [16-18].
iv) Drying of moist granules.
v) Mixing of screened granules with disintegrant, glidant, and lubricant.

Advantages

a) Permits mechanical handling of powders without loss of mix quality.
b) Improves the flow of powders by increasing particle size and sphericity [19-23].
c) Increases and improves the uniformity of powder density.

Limitation of wet granulation

i) The greatest disadvantage of wet granulation [24-28] is its cost. It is an expensive process because of labor, time, equipment, energy and space requirements.
ii) Loss of material during various stages of processing.

Dry Granulation

In dry granulation process the powder mixture is compressed without the use of heat and solvent. It is the least desirable of all methods of granulation [29-33]. The two basic procedures are to form a compact of material by compression and then to mill the compact to obtain a granules. Two methods are used for dry granulation [34-37]. The more widely used method is slugging, where the powder is recompressed and the resulting tablet or slug are milled to yield the granules [38-42]. The other method is to recompress the powder with pressure rolls using a machine such as Chilosonator.

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ROLLER COMPACTION

The compaction of powder by means of pressure roll can also be accomplished by a machine called chilsonator. Unlike tablet machine, the chilsonator [42-48] turns out a compacted mass in a steady continuous flow. The powder is fed down between the rollers from the hopper which contains a spiral auger to feed the powder into the compaction zone. Like slugs, the aggregates are screened or milled for production into granules [49-56].
Use: Use in the production of directly compressible excipients, the compaction of drugs and drug formulations, the granulation of inorganic materials, the granulation of dry herbal material [57-62] and the production of immediate/sustained release formulations.

ADVANCEMENT IN GRANULATIONS

Steam Granulation

It is modification of wet granulation. Here steam is used as a binder instead of water. Its several benefits includes higher distribution uniformity, higher diffusion rate into powders, more favourable thermal balance [63-67] during drying step, steam granules are more spherical, have large surface area hence increased dissolution rate of the drug from granules, processing time [68-72] is shorter therefore more number of tablets are produced per batch, compared to the use of organic solvent water vapour is environmentally friendly, no health hazards to operators, no restriction by ICH on traces left in the granules, freshly distilled steam is sterile and therefore the total count can be kept under control, lowers dissolution rate so can be used for preparation of taste masked granules without modifying availability of the drug [73-80].

Melt Granulation / Thermoplastic Granulation

Here granulation is achieved by the addition of moldable binder [81-84]. That is binder is in solid state at room temperature but melts in the temperature range of 50 – 80˚C. Melted binder then acts like a binding liquid. There is no need of drying phase since dried granules are obtained by cooling it to room temperature [85-90].

Foam Granulation

Here liquid binders are added as aqueous foam. It has several benefits over spray(wet) granulation such as it requires less binder than Spray Granulation, requires less water to wet granulate [91-92], rate of addition of foam is greater than rate of addition of sprayed liquids, no detrimental effects on granulate, tablet, or *in vitro* drug dissolution properties, no plugging problems since use of spray nozzles is eliminated, no over wetting, useful for granulating water sensitive formulations, reduces drying time, uniform distribution of binder throughout the powder bed, reduce manufacturing time [93-94], less binder required for Immediate Release (IR) and Controlled Release (CR) formulations.

CONCLUSION

Direct Compressible Excipients, which can be used universally with any of the APIs, can lead to a revolution in tablet manufacturing techniques by way of low cost and efficient tablet manufacturing [95-98]. These economic advantages will be beneficial for both manufacturing and consumer, we can also go for certain synthetic but inert materials, and by using them we can produce tablets using ingredients than otherwise could not possibly be compressed to a tablet. This indicates that dry granulation produces granules [99-100] with good flow properties and that by direct compression are fair in grading.

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