

IMPROVEMENT OF TABLETING PERFORMANCE BY CO-PROCESSED EXCIPIENTS


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ABSTRACT

The objective of co-processed excipients is to improve the functionality of the formulation. In early the introduction of spray dried lactose and avicel had changed the tablet manufacturing process and opened avenues of direct compression tableting. In co-processing of excipients two or more excipients are interact at the sub-particle level. It overcomes the drawback of individual excipients. Due to increasing high industrial output demand and new drug development, new excipients with purpose satisfying characteristics are the need of the hour. Generally, it increase the properties like flow ability, compressibility, disintegration potential. Mostly, combination of plastic and brittle materials is used for co-processing which is used to reduce the tendency of capping and lamination resulting in optimum tablet performance. However, with the increasing number of new drug entities with various properties, there is challenge to manufacturer to search for new excipients to achieve the desired properties.

Key words: Particle engineering, Compressibility, Tableting, Excipient

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INTRODUCTION

Tablets are the most acceptable dosage form by patients, as they can easily administer and ensure good patient compliance. Compared with the oral liquid dosage form, it has easy preparation, ease of administration, accurate dosage and most stable, temper proof compared to capsules and in terms of safety it is better than parenteral dosage forms makes it a popular and versatile dosage form and can be manufactured comparatively at low cost.¹ Recently, Scientist in the pharmaceutical sector has realized that single component excipients do not provide the results necessary for the proper formulation or production of specific drug. In response to this shortcomings, scientists in the pharmaceutical field are dependent on increasing number of combination excipients such as co processed excipients.^{2,3}

Excipient co-processing is a new method for preparation of tablet formulations, where only physical modifications of excipients are carried out without changing their chemical properties. The aim of this technique is to improve the flow properties of the tools used compared to those with a physical mixture of individuals.⁴

Requirements of co-processed excipients^{5,6}

- The popularity of the direct compression process is increasing, and in search of ideal filler-binder that can replace two or more excipients.
- It speeds up the work of tablet machines that need additives to ensure excellent compressibility and small weight changes, despite the short residence time.
- No excipients to meet the needs of a particular patient, for example diabetes, hypertension and lactose and sorbitol sensitivity.
- The ability to control the solubility, permeability or stability of drug molecules.

Advantages of co-processed excipients^{7,8}

- Absence of chemical changes
- Enhanced flow characteristics
- Enhance compressibility
- Increase Dilution capability
- Fill weight variation
- Reduced lubricant sensitivity

Preparation of co-processed excipients

- Roller compaction method
- Wet granulation method
- Hot melt extrusion (HME) method
- Spray drying method
- Solvent evaporation method
- Co-precipitation method
- Dispersion with high shear mixer method

Roller compaction

In the roller compaction process, powder mixes first pass a feeding zone, where the greater part of the adjustment happens. The thick powders at that point experience a compaction zone, where expanding force is being applied by two counter-turning rolls. As the pressure goes up further into the compaction zone, the particles twist, section, and bond to form ribbons.⁹

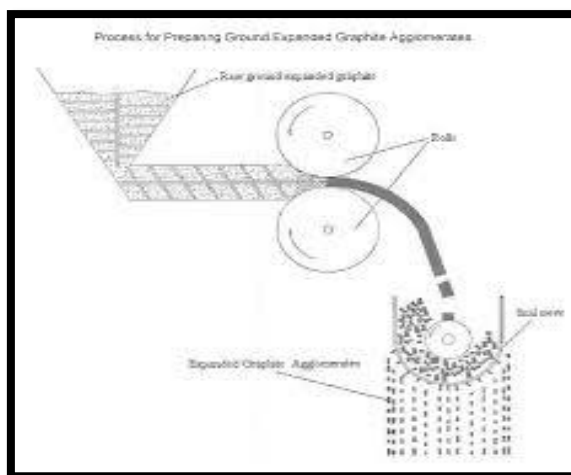


Figure no. 1- Roller compaction

Hot melt extrusion

Hot melt extrusion is another thermal processing technique that has attracted interest as a novel approach for the development of polymeric immediate, sustained release or transdermal/transmucosal delivery system. This process is broadly utilized in exchanging and

softening of polymer inside a barrel by a rotating screw. The polymer soften is then pressurized through the die into assortment of shapes. Extrusion can be additionally prepared into tablets or granules.¹⁰

Spray drying

This technique allows the conversion of feed from a liquid state to the shape of dry particles by spraying feed in a hot drying environment. This is a continuous process for drying in particle processing. Feed can be a solution, suspension, dispersion or emulsion. The dried product can be in the form of powder, granules or agglomerates, depending on the physical and chemical properties of the feed mixture, dryer design and desired final powder properties.^{11, 12}

The spray drying process basically consists of five steps:

- I Concentration: feed stock are usually concentrated before being put into a spray dryer.
- II Atomization: The sprinkling step provides optimal evaporation conditions for dry products that have the desired properties.
- III. Contact with air droplets: In the room, the atomised liquid is brought into contact with hot gas, where 95% of the water contained in the droplets is evaporated for a few seconds.
- IV. Droplet Drying: Moisture is evaporated in two stages: During the first stage there is sufficient moisture in the droplets to replace liquid evaporated on the surface, and evaporation is relatively constant. The second stage begins when there is not enough moisture left to maintain the saturation condition on the surface of the droplets, forming a dry shell on the surface. Evaporation then depends on the diffusion of water vapour through the shell, whose thickness increases.
- V. Separation: Cyclones, bag filters and electrostatic deposits can be used for the final separation step. Wet scrubbers are often used to clean and cool the air so they can escape to the atmosphere.¹³

List of co-processed excipients^{14, 15}

Co-processed excipients	Trade name	Manufacturer	Advantages
Lactose, povidone, crosspovidone	Ludipress	BASF Pharma	Low degree of hygroscopicity, Good flowability, Tablet hardness independent of machine speed, lubricant, binder and best disintegrant.
Lactose monohydrate, Cellulose	Cellactose	Meggle Excipients and technology	Highly compressible, improved tablet hardness and adherence capacity, good content uniformity due to low segregation tendency of the active ingredient.
MCC, Silicon dioxide	Prosolv	JRS Pharma	Good flow, Reduced sensitivity to wet granulation, Better hardness of tablet, Excellent compactibility, High intrinsic flow, Enhanced lubrication efficiency, Improved blending properties, Superior binding properties, Increased capacity.
MCC, Guar gum	Avicel CE-15	FMC health and nutrition	Less grittiness, Reduced tooth packing, Improved over all palatability.
Calcium carbonate, Sorbitol	ForMaxx calcium carbonate 70	Milliporesigma	Controlled particle size distribution
MCC, Lactose	Microcelac	Meggle excipients and technology	Capable of formulating high dose, diluent/binder in oral dosage formulation, good flowability and compactibility
β -lactose, lacticol	Pharmatose 150M	DFE Pharma	High compressibility

Lactose, Maize starch	StarLac	Roquette	Good flow, fast disintegrant and diluent
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Table no.: 1 list of co-processed excipients

CONCLUSION

Excipients are not any more considered as inert ingredients of a formulation, however have a very much characterized role. Advancements in particle engineering have given wide roads to planning excipients with predefined usefulness necessities. Co-processed excipients are an after effect of this burdensome development just, where in two excipients are co-processed to furnish items with made strides usefulness by holding their ideal and keeping away from the ominous properties. The achievement of these excipients relies upon their quality, safety, and usefulness. The primary obstruction in the achievement of co-processed excipients is the exclusion of their monographs in official pharmacopoeias, which discourages their utilization by pharmaceutical producers.

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