Co-Processed Excipients-A Step Towards Better Drug Product Performance

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ABSTRACT

Objective: The aim of the study to focus on the significance of co-processed excipients in drug delivery and product performance.

Keywords: Co-processed, extrusion, spray-drying, freeze-thawing.

INTRODUCTION

Co-processed excipients are produced by mixing two or more existing excipients to get modified properties. The excipients or pharmaceutical adjuvants are defined by the International Pharmaceutical Council (IPEC) as "These are the substances which are properly assessed for safety and added to the drug delivery system on purpose." Excipients serve many functions in any formulation. For instance, they help in manufacturing of the drug delivery system, promote and increase stability, bioavailability and patient compliance, aid in recognition of the product, boost other characteristics which contribute in final safety, efficacy as well as delivery of drug product throughout storage and usage. The functionality of excipients can be enhanced by a newer technique that is called as co-processing whereby useful features are maintained and newer ones are added.[1]

A co-processed excipient is defined as" It is the mixing of two or more than two pharmacopoeial or non-pharmacopoeial excipients in such a way that their characteristics are altered physically, which is not attainable with physical mixing and without undergoing remarkable chemical modification. Various techniques, including unit operations are employed for preparation of coprocessed excipients such as granulation, melt extrusion, spray drying and fluid-bed coating etc. The techniques for preparation are selected based on many factors including the type of material utilized, their physical form (dry powder or liquid) as well as the particular characteristics required. Similarly, the proportions of combining excipients may differ based on required characteristics.[2]

These processed excipients have enhanced functionalities as compared to individual excipients. These functionalities include improved flow property, compressibility, low lubricant sensitivity and better dilution potential. [3]

Table 1. Commercially available co-processed excipients. [4]

S.No.	Co-processed excipients	Individual excipients	Offered advantages
1	Ludipress	Lactose monohydrate, Kollidone K30 and Kollidone CL	Better flowability
2	Prosolv 90	Avicel 102 and Aerosil	Enhanced powder blend and

			tablet characteristics, but not flow property
3	Cellactase	Cellulose and lactose	Enhanced mechanical properties, better mouth feel
4	Avicel CE-15	Microcrystallie cellulose, guar gum	Improved palatability, reduced grittiness
5	MicroceLac 100	Microcrystalline cellulose and lactose	Improved flowability and binding
6	Co-processed crospovidone-sodium starch glycolate	Crospovidone and sodium starch glycolate	Rapid disintegration and dissolution
7	Pharmatose DCL 40	Anhydrous lactose, lactitol	Higher compression property, lower lubricant sensitivity
8	Starlac	Lactose, maize starch	Good flow, use in fast dissolving tablets
9	Formaxx	Calcium carbonate and sorbitol	Taste masking, improve compressibility and content uniformity
10	Advantose FS-95	Starch and fructose	Fast disintegration

These co-processed excipients prevent the unwanted effects of individual excipients and also provide cost-effectiveness. There are many techniques by which these combination excipients can be prepared like roller compaction, wet granulation, hot-melt extrusion, spray-drying, freezethawing etc. With the advancements in tablet formulation techniques, demand for multifunctional excipients has been increased. [5]

In a research study, co-processed microcrystalline cellulose-Eudragit E excipient was developed and Infrared spectra of this co-processed excipient was contrasted with the respective excipients i.e. microcrystalline cellulose and Eudragit E.The spectra of co-processed excipient revealed that no chemical reaction took place as the peaks of individual excipients were recorded.Furthermore, X-ray powder diffraction showed that no change occurred in the crystal structure of microcrystalline cellulose.[5]

METHODOLOGY

In current study perform comparative evaluation of drug performance to describe the purpose of the study and shows the importance of co-processed excipients for the betterment of the product performance and transforming development of health care products for consumer concern.

RESULT/ CONCLUSION

Co-processed excipients successfully employed in directly compressible tabletting thereby causing less time consumption as well as cost reduction. Current study Showed more promising results as compare to other regular exicipients which required more number of excipients and strength of excipients to fulfill the desirable requirements.

Most commonly these excipients have useful application in directly compressible tablet formulations, but they can also be successfully employed in orally disintegrating tablets, dispersible tablets and controlled release formulations due to their enhanced functionality, hence resulting in improved performance of these formulations. These excipients overcome the undesirable characteristics of individual excipients and present many advantages such as better flow ability, compressibility, better dilution potential, low lubricant sensitivity and many others.

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