

Co-Processed Excipients- A Review

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Abstract: Here is no single-component excipient satisfies all the essential execution to permit a active pharmaceutical component to be formulated into a selected dosage form. Co-processed excipient has received substantially more consideration in the definition improvement of different dosage form, uncommonly for tablet preparation by direct compression strategy. The main aim of this review is to talk about the rise of co-processed excipients as a present and future pattern of excipient innovation in pharmaceutical manufacturing. Co-processed excipients is a novel idea of consolidating at least two excipients designed to physical mixing without significant chemical change. These co-processed excipients have high functionalize compared to individual excipients such as better compressibility, flow property. All the developed excipients are enlisted for their beneficial and multifunctional characteristics. Further it gives opportunity for use of single multifunctional excipient rather than multiple excipients.

Keywords: co-processed excipients, multifunctional excipients, spray drying

I. Introduction

The International Pharmaceutical Excipients Council (IPEC) defines excipient as substances save for the API that are befittingly evaluated for safety and are by design enclosed in a very drug delivery system. In the beyond 10 y, the focus of each academia and pharmaceutical enterprise has been shifted from growing new energetic pharmaceutical element (API) to components technology.[1,2] Pharmaceutical excipients have played a primary role in that shift. Pharmaceutical excipients are defined as the substances aside from the API which has been appropriately evaluated for protection and are intentionally included in a drug shipping system. The International Pharmaceutical Excipients Council (2009) defines excipients as the materials which found in a finished pharmaceutical dosage form other than the active drug substance. Excipient may be classified into four categories typically: single entity excipient, a bodily combination of a couple of excipients, new chemical entity excipient and co-processed excipient. It is generally agreed by means of the system scientist that there may be no unmarried-component excipient fulfills all the needful overall performance to allow an active pharmaceutical element to be formulated into a specific dosage shape. On the alternative hand, growing a new chemical entity excipient requires a big sum of investment.[1]

To counter this issue, method scientist has delivered a novel idea of co-processing that's combining of two or more excipients that possess vast benefits that can't be achieved the usage of a bodily admixture of the same aggregate of excipients. A co-processed excipient is a aggregate of or extra compendial or non-compendial excipients designed to alter their physical homes in a way not viable by means of simple physical mixing, and without substantial chemical change. By formulating few excipients into a unmarried composite cloth with specialized manufacturing method results in an development in functionality of the quit product This has grow to be a newer fashion in components development. [2,3]

Co-processed excipient has acquired much extra attention within the formula development of various dosage forms inclusive of a tablet, capsule, powder, cream, ointment, and others. It isn't the same as the bodily combination. Physical mixture is simply a easy admixture combining few excipients by using short duration shear processing. However, inside the case of co-processed excipients, they possess performance advantages that can not be achieved

using a bodily admixture of the same combination of excipients. Combination of cost-effective excipient with others of optimal quantity of a functional cloth will produce an included product with superior capability than the easy mixture of components.[5,6]

Oral delivery remains the most popular route of administration, it is because of convenient route of administration. The most common methods to manufacture tablets are wet granulation, dry granulation and direct compression. Direct compression was reported as most preferred method due to ease of production absence of heat and moisture in process.

1.2 Types of Excipients:

1. Single excipient
2. Mixture of multiple excipients
3. New chemical entity
4. Co-processed excipients.

1.2.1 Single excipients

Single excipients can be defined as excipients containing one component which is primary component called as excipient.

1.2.2 Mixtures of multiple excipients

Simple physical mixture or blends of two excipients by means of low to medium share process where the individual component are mixed together without significant chemical change.[7]

1.2.3 New chemical entities

It can be defined as the excipients which are chemically modified to form new excipients. These are generally not listed in FDA inactive ingredient database (IID). These are not fully qualified by existing safety database with respect to currently proposed level of exposure or route of administration.[8]

1.2.4 Co-processed excipients

A co-processed excipients is a combination of two or more compendial or non-compendial excipients designed to physically modify their properties. Many different co-processing methods may be used as spray drying, milling, melt extrusion, granulation.[9]

The co-processing excipients leads to formation of excipients granulates with superior of physical mixture of component or with individual components. The main aim of co-processing is to obtain product with added value related to the ratio of functionality.

1.3 Advantages of Co-Processed Excipients

1. Better dilution potential

It is the ability of excipients to retain its compressibility even when diluted with another excipients. Co-processed excipient with high dilution potential is desirable so that the compressibility of mixture of powder can be maintained even after dilution.[11]

2. Reduced lubricant sensitivity

The presence of a large degree of brittle character in a co-processed excipient provides low lubricant sensitivity because it prevents the formation of a coherent lubricant network by forming newly exposed surfaces upon compression, thus breaking up the lubricant network. Generally, hydrophobic lubricant provides a negative impact on the compression.

3. Improved compressibility

Compressibility is an important factor of consideration in tablet development. Majority of the co-processed excipients overcome this limitation.[12]

4. Improved flow properties

Good flowability is desired especially in case of high speed rotary tablet machine. The co-processing excipient play an important role in improving flow property by controlled optimal particle size and particle distribution.

5. Stability

The ingredients used should be inert and do not interact with other excipient or API. It should be physically and chemically stable.

1.4 Need of Co-Processed Excipients

It has capability to change the solubility, stability and permeability. To address the problems like flowability, compressibility hence co-process excipient will be appropriate to overcome these problems. The development and improvement in the formulation process enhance in production at low rate. The role of co-processing comes into the picture by interacting two or more excipients at the sub-particle level, aimed at providing a synergy of functionality improvements, as well as masking the undesirable properties of the individual excipients.[15]

1.5 General Steps In Developing Co-Processed Excipients

a. Identification of the group of excipients to be co-processed

Recognition of the excipient group to be co-processed by carefully study. The material characteristics functionality required.

b. Assessing the particle size

Evaluate the particle size required for co-processing. This is mostly important when one of component is processed in dispersed phase post processing, particle size of latter depends on its initial particle size.

c. Selecting a suitable technique to co-process various excipient

There are many methods which can be used for co-processing such as wet granulation, melt granulation, freeze drying, spray drying, hot melt extrusion.

d. Optimizing the process and the proportion of each excipient

In which selecting the appropriate process i.e selecting appropriate drying process such as spray or flash drying .[17]

1.6 Limitation of Co-Processing

During developing the co-processed excipient the user has no freedom to alternate ratio of excipient.

Though co-processed excipient has list of benefits there are few drawbacks the co-processed excipients are available as premixed at a fixed ratio of individual constituents.

For this reason, a co-processed adjuvant is not accepted by pharmaceutical industry unless it exhibit significant advantages.

1.7 Methods of Co-Processing

- Spray drying
- Solvent evaporation
- Crystallization
- Melt extrusion

1.7.1 Spray Drying

In this technique, the fluid state material can be converted into solid dried particle.

The fluid state can be suspension, dispersion, emulsion or solution. After conversion it can be granules, powders.

After giving warm drying by evaporating droplets to form powders.

1.7.2 Solvent Evaporation

In which the excipient is dissolved in volatile solvent, a core excipient material to be microencapsulated is dissolved with agitation.

The mixture is then heated to evaporated the liquid vehicle temperature.

1.7.3 Crystallization

The process of formation of solid crystals precipitating from solution. For crystallization solution must be supersaturated that after evaporating solvent we can get easily crystals.

1.7.4 Hot Melt Extrusion

It is the process of formation of pellets. In which excipients are melted and then apply pressure through die and solidify into various shapes. Solvent is not required in the process as molten polymer can work as binder.

1.8 Marketed Products

There are many marketed products of co-processed excipients available. The marketed products are presented in table 1.

Table 1: Products of co-processed excipients which are available in the market

Trade Name	Excipients	Added Advantages
Cellactose	cellulose and Lactose	Good mouth feel, High compressibility
Starlac	Lactose and maize starch	Rapid disintegration, Acceptable crushing force
Pearlitol SD	Granulated Mannitol	For chewable tablet, good mouth feel
Ludipress	Lactose Kallidon 30, Kallidon CL	Low hygroscopic ,Good flow
Dipac	sucrose , dextrin	Good flow, directly compressible grade
Ludiflash	Mannitol, crospovidone and polyvinyl acetate	Suitable for high speed tableting.
Xylitab	Xylitol, sodium carboxy methyl cellulose	directly compressible, good flow
Effersoda	Sodium bicarbonate and sodium carbonate	Improve the stability of effervescent product
Finlac DC	Directly compressible lactitol	Good mouth feel, Fast disintegration

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