

Excipients in current and emerging scenario

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A PART from active ingredients, the inactive excipients play a vital role in the development of formulations. Excipients are substances other than the pharmaceutical active drugs or prodrugs included in the manufacturing process or the finished pharmaceutical product dosages formation.

Excipients are defined in numerous ways. It includes the inert substances that are used as diluents for the drugs. The major problem with this definition is that the excipients have proved to be anything but inert that possess the ability to react with the other set of ingredients in the formulation, causing hypersensitive reactions in the patients. These range from mild rashes to potentially life-threatening reactions.

Excipients play the central role in the drug development procedure. Forming a stable dosage is crucial as a terrible choice of an excipient can lead to severe intoxications, as experienced in 2-3% of the cases in the 1960s record. Different brands have developed the same drug that contains additional excipients, especially preservatives and colourants. The list provided by the consumer excipients includes all the necessary information related to the safety of the individual excipients found in the drug.

Brief on the excipients

The word Excipient has been derived from the Latin word excipere that means 'to except'. It is explained in different ways, like 'other than'. The pharmaceutical excipients are everything other than active pharmaceutical ingredients. It is ideally inert that makes respon-

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sive reactions if not used correctly.

What are excipients doing in the field of medicines?

In today's world, medicines are available in numerous dosages, including capsules, oral liquids, topical creams, gels, transdermal patches, tablets, implants, eye products, nasal products, and inhalers suppositories. Pharma-

ceutical excipients are a part of pharmaceutical dosages that do not form their direct therapeutic actions. It aids in manufacturing the procedure to simply protect, support and enhance the stability or the biodiversity and even patients' acceptability.

It often assists in product identification and enhances the overall safety or function of the product during storage or use. There are thousands of diverse excipients that are used in medicine and makeup. As per estimates made by the industry experts, on average, 90% of each product contains excipients. They simply represent the market value of \$3 billion to \$4billion, accounting for 0.5% of the total pharma market.

Which are the common excipients that are used in the tablets?

Excipients are used in the list of purposes defined in the international pharmacopoeias in the long run. Numerous excipients are used for more than one purpose. It simply reduces

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Protect tablets from environment

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the number of excipients that are needed and minimises the chances of interaction between them. The use of tablets is widely used in dosages. The manufacturers can be in a most complex process. The considerable ingenuity and the formation of the products with stable dosage are required for storage, transport, handling. Yet, it will release the active pharmaceutical ingredients that are necessary once ingested. Numerous excipients are used in the following ways:

1: Excipient- Diluents

Function: Provide bulk and enable accurate dosing of potent ingredients

Example: Sugar compounds, e.g. lactose, dextrin, glucose, sucrose, sorbitol Inorganic compounds, e.g. silicates, calcium and magnesium salts, sodium or potassium chloride

2: Excipient- Binders, compression aids, granulating agents

Function: Bind the tablet ingredients together, giving form and mechanical strength

Example: Mainly natural or synthetic polymers, e.g. starches, sugars, sugar alcohols and cellulose derivatives

3: Excipient- Disintegrants

Function: Aid dispersion of the tablet in the gastrointestinal tract, releasing the active ingredient and increasing the surface area for dissolution

Example: Compounds that swell or dissolve in water, e.g. starch, cellulose derivatives and alginates, croscopolidone

4: Excipient- Glidants

Function: Improve the flow of powders during tablet manufacturing by reducing friction and adhesion between particles. They are also

used as anti-caking agents.

Example: Colloidal anhydrous silicon and other silica compounds

5: Excipient- Lubricants

Function: Similar action to glidants. The properties of glidants and lubricants differ; some compounds, such as starch and talc, have both activities. They often slow the disintegration and dissolution.

Example: Stearic acid and its salts (e.g. magnesium stearate)

6: Excipient- Tablet coatings and films

Function: Protect tablets from the environment (air, light and moisture), increase the mechanical strength, mask taste and smell, aid swallowing, assist in product identification. It can be used to modify the release of the active ingredient. It sometimes contains flavours and colourings.

Example: Sugar (sucrose) is replaced by film coating by using natural or synthetic polymers. Polymers are insoluble in acid, e.g. cellulose acetate phthalate, used for enteric coatings to delay the release of the active ingredient.

7: Excipient- Colouring agents

Function: Improve acceptability to patients, aid identification & prevent counterfeiting. Increase the stability of light-sensitive drugs.

Example: Mainly synthetic dyes and natural colours. Compounds that are themselves natural pigments of food may also be used.

Examples of substances that can be used as excipients or active pharmaceutical ingredients (API)

Product- Glycerol

Role as excipient- plasticiser, cosolvent, hu-

mectant, sweetening agent, preservative, wetting agent

Role as API- laxative

Product- Ascorbic acid, a-tocopherol

Role as excipient-antioxidant

Role as API-vitamin

Product- Castor oil

Role as excipient-oleaginous vehicle, solvent, plasticiser

Role as API-laxative

Product- Benzalkonium chloride

Role as excipient-antimicrobial preservative, solubilising agent, wetting agent, permeation enhancer

Role as API-spermicide, disinfectant

Product- Boric acid

Role as an excipient-preservative, buffering agent

Role as API-disinfectant (ophthalmology gynaecology)

Product- Ethanol

Role as excipient-(co)solvent, preservative

Role as API-disinfectant

Product- Macrogols (polyethylene glycols)

Role as excipient-ointment/suppository base, tablet lubricant/binder, (co)solvent, plasticiser

Role as API- laxative

Functions of the Excipients

The intended function of the excipient guarantees the physicochemical and biopharmaceutical properties of the pharmaceutical preparation. Few excipients have multifunctional formulations. The hypromellose, cellulose derivatives are often used as a coating agent, emulsifying agents and viscosity increasing agents. As the excipients are part of the medicine formulation, the compendial requirements to test the functionality and control the properties often influence the suitability and dosage of the prepared end products of medicine.

To conclude, the medicine contains ingredients other than the active drugs that are chiefly an essential part of the manufacturing, stability and functionality. Excipients are a crucial and integral part of the pharma industry – the potential cause of medicinal usage. Surveys indicated that excipients are formulated replacements that will stay with the medical science forever, positively affecting correct dosage and verifications. Find appropriate information that will help to ensure safe outcomes for the patient in the long run. ○

(The author is a leading pharma consultant)

