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NATURAL PHARMACEUTICAL EXCIPIENTS, AN OVERVIEW

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ABSTRACT

Pharmaceutical excipients are the inert materials which provide additional desirable characteristics to the dosage form. Although these additives are termed as inert but they have a great influence on stability, bioavailability and the process by which the dosage forms are prepared. Natural excipients are those excipients which have got natural origin. Natural excipients may be derived either from .

1. plant for example Acacia, Starch, Pectin.
2. Animals for example Gelatin, Egg yolk, wool fat
3. Minerals for example Bentonite, Veegum.

In comparison to synthetic excipients, natural excipients are nontoxic, less expensive, compatible & freely available. Natural gums can also be modified & thus can compete with the synthetic biodegradable excipients available in the market.

Key Words: Excipients, Bentonite, Natural gums, Acacia.

INTRODUCTION

Drugs play a crucial role in saving lives, restoring health and preventing diseases and epidemics but they need to be safe, efficacious, of good quality, & should be used rationally. Their product, import/export, storage, supply & distribution should be a subject to government control through prescribed norms & standards & an effective regulatory system.

In order to prepare a drug substance into final dosage form pharmaceutical ingredients are required. These ingredients fall into two basic groups.

(a) The active ingredient or the medicament or the therapeutic moiety.
(b) The excipients or the additives or the adjuvants.

All non-drug components of a formula are known as excipients., These are inert substances used to given the finished dosage form a suitable form and consistency.
Ideal quality of pharmaceutical excipients.

- They must be non-toxic & acceptable to the regulatory agencies in all countries where the Product is to be marketed.
- They must be commercially available in an acceptable grade in all countries were the product is to manufactured.
- They must be physiological inert.
- Their cost must be acceptably Low.
- They must be physically & chemically stable by themselves & in combination with the drug & other dosage components.
- They must be free of any unacceptable microbiologic load.
- They must be color – compatible (so as to not product any off – color appearance)
- They must have no deleterious effect on the bioavailability of the drug(s) in the product.
- They must not in any group of population for example sucrose in diabetic patients & sodium in hypertensive patients.

Natural excipients:- Excipients which have got a natural origin are called as natural excipients. Based on their origin natural excipients are broadly classified into three categories:

1. Plant origin excipients : They have got plant origin. Examples include Acacia, Starch, Pectin.
2. Animal origin excipients : They have got Animal origin. Examples include Gelatin, Egg yolk, wool fat
3. Mineral origin excipients : They have got mineral origin examples include bentonite, veegum etc.

On the basic of the function, which excipients play in the finished dosage form, they may be classified as follows :

1. Diluent : These are also known as basis. They are added to table formulations to increase the bulk of the table when the drug dose is inadequate to produce the bulk. Natural diluents include

(i) Starch : Starch consists of polysaccharide granules obtained from the grains of maize (zea mays), rice (oryza gativa) or weat (triticum aestiuum), belonging to family Graminea or from the tubers of potato (solanum tuberosum), family solanaceae. It is used as a tablet diluent. The USP grade of starch posses a high typical moisture content of between 11% and 14% . Specially dried type of starch that have a standard moisture level of 2% to 4% are available. Various directly compressible starches are now available commercially for example Sta-Rx 1500, which is free-flowing directly compressible starch and it may used as diluent, binder and/or disintegrating agent. Sta-Rx 1500 contains about 10% moisture & has got self lubricating properties. Two hydrolyzed starches Emdex and celutab which are basically 90-92% dextrose & directly compressible. These materials contain about 8% - 10% moisture.

(ii) Bentonite : Bentonite is a native clay basically it is colloidal hydrated aluminum silicate. It is insoluble in water, swells to approximately twele films its volume upon addition water. It is use as a diluent for wet granulation.

2. Binders & Adhesive (Granulators) : These are materials used to hold powders together to form granules or promote cohesive compacts for ultimately holding the compressed tablet together after comperession & during handling & shipping.

(i) Starch Paste : It is one of the most commonly used granulating agent. It is used in the concentration range of 5-15%. It is prepared by dispersing starch into water, which is then heated for some prescribed time. During the heating, the starch undergoes hydrolysis to dextrin & to glucose. A property made paste is translucent rather than clear and produce cohesive tablets that readily disintegrates when properly formulated.

(ii) Gelatin : Gelatin is a natural protein and is sometimes used in combination with acacia. It is a more consistent material to prepare in solution form and forms tables equally as hard as ace or trangacanth. Gelatin is also used in capsules. Where the basic empty capsule shells are made from a mixture of gelatin, sugar & water are clear, colorless, essentially tasteless. Gelatin, USP is a product obtained by the partial hydrolysis of collagen obtained from the

skin, white connective tissue, & bound of animals. It is found commercially in the form of a fine power, a coarse power shreds, flakes or sheets.

(iii) Natural gums : Natural gums which are used as granulating agents or binders are :
(a) Acacia : Gum acacia/Gum arabic is the dried gummy exudation obtained from the stem & branches of Acacia arabica belonging to family leguminosae. It is a odourless, light brown in colour and its taste is mucilaginous. It is soluble in water & insoluble in alcohol. In the form of solution ranging from 10-25% concentration alone or in combination with tragacanth it can be used as a binder.

(b) Tragacanth : It is the dried gummy exudation obtained by incision from stems & branches of Astragulus gummifer belonging to family leguminosea. It is odoulers, tastes muciligenous. The flakes are white or pale yollwish – white. Mucilage of tragacanth (10% - 25%) is used as a binding agent in the tablets.

3. Disintegrants : These are the substance that facilitate break up or disintegration of a tablet when it comes in contact with water in GIT. Disintegrants act by three mechanisms

- By swelling (Busters) for example Starch
- By improving penetration of aqueous liquids (Wetting agents) for example clays
- By liberation of gas from an effervescent base for example citric acid
- Naturely occurring disintegrants include

(i) Starch : Starch USP & various starch derivatives are the most common disintegrating agent. They also have the lowest cost. Starch is typically used in a concentration range of 5% to 20% of tablet weight. Some modified starches are

- Primogel
- Explotab

Various pregelatinized starched are also employed as disintegrants, usually in a 5% concentration.

(ii) Guar Gum : Guar gum is the powder of the endosperm of the seeds of cyamopsis tetragonolobus belonging to family leguminosae. It is colourless or pale yellowish-white coloured powder with characterisitic odour & gummy taste. Its 1% mucilage is similar in viscosity as that of mucilage of acacia & 3% mucilage is similar to mucilage of trangacanth.

It has 5 to 8 times thickening power than starch. It is used as a protective colloid a binding agent & a disintegrating agent

(iii)Gellan Gum : It is a exocellular heteropolysaceharide produced by fermentation. It has got high gel strength, high clarity, excellent film forming capacity. It is used as a disintegrant for tablets & capsules.

(iv)Clays : Clays such as vecgum Hv and bentonite have been used as disintegrants at about a 10% lavel. Such use of these materials is limited unless the tablets are coloured, since the clays produce an off-which appearance. The clays are typically less effective as disintegrants than some of the newer modified polymers & starches, which can increase in volume in the presence of water by 200% to 500%.

4. Lubricants, Glidants and Antiadherants : Lubricants are intended to reduce the friction during tablet ejection between the walls of the tables and the walls of the die cavity in which the tablet is formed. Glidants are intended to promote flow of the tablet granulations as powder materials by reducing friction between the particles. Antiadherents are indended to reduce sticking or adhesion or any of the tablet granules or power to the face of the punches or to the die wall. Examples of natural Lubricants/Glidants/Antiadherants are :

(i) Vegetable oil : Vegetable oils are used as internal lubricants that is they are mixed with the dry powder prior to moistening with granulating fluid (Self Lubricating). Among vegetable based fatty acid Lubricants Tristar 149 is widely used Lubricants. It is a fine white powder composed of 90% palmitic & stearic acid. Vegetable based food grade and contains based food grade and contains no metal residue. It is used in wet granulation, dry granulation and in direct compression in the form of Lubricants. It is good for chewable tablets, makes hard shiny tablets with out impending dissolution. Less sensitive to overblending than the metal stearates not reactive with acid.

(ii) Starch : Starch has been reported to possess some Lubricants properties being a natural Lubricants it does not damage or the finished dosage form.

5. Colors, Flavors & Sweetness : Colors are used in dosage forms as they serve the following three purposes:

(i) Disguising of off-color drug

(ii) Product identification

(iii)Production of a more elegant product

Flavors are usually limited to chewable tablets & liquid dosage forms sweetness tablets & some liquid dosage forms. Natural colors flavors/sweetness which are used in pharmaceutical dosage forms included.

1. Natural colors for example

(i) cochineal, carotene, chlorophyll, curcumin

(ii) Saffron / Kesar : It consist of dried stigms & upper parts of style of plant known as crocus sativus belonging to family Iridaceae. It has got strong, characteristic & aromatic odour. It is used as a coloring (food dye) & flavoring agent.

(iii)Directly compressible dried honey : It is golden yellow, granular, free-flowing power that maintains the flavor enhancing, taste masking of undesirable flavors.

Examples of Natural flavors include clove, eucalyptus, lemon, mint, orange, winter green, jasmine, lavender, rose ets.

Match between Taste & Flavors

Taste	Flavor / Flavors
Alkaline	Mint, Vanilla
Acid (some)	Lemon, Orange, Onion, Liquorice, Raspberry, cherry, strawberry
Bitter	Anise, mint, fennel, cherry
Metallic	Grape, Lemon
Salty	Citrus flavors, Raspbery, melon.
Sweet	Vanilla, Honey

Match between Flavors & Colours

Flavor	Colour
Cherry, Raspbery, Apple, Rose	Pink to red
Honey, Walnut	Brown
Lemon, Orange, Cherry	Yellow to Orange
Banana, Mint	Green

Spearmient, Jasmine	White to Offwhite
Grape, Liquorice	Violet to Purple
Mixed fruit, Plum, Blue Berry	Blue

Naturally occurring Sweetening agent include Glycerrhizin, Neohesperidin, Honey etc.

In short there are a very large number of natural excipients which can be used in pharmaceutical dosage forms. Such type of excipients are easily available, less expensive, non-toxic, bio-compatible. On the other hand synthetic/semi-synthetic/chemical excipients may not be compatible with the active ingredient & hence lead to undesirable effects for example Lactose with amino drug (milliard reaction) calcium with tetracycline (complex formation), Sodium Saccharine (Artificial Sweetner) has been found to be carcinogenic.

CONCLUSION

All said above about natural excipients it seems that they are much better then Synthetic/Semi-synthetic excipients in terms of cost, compatibility, inertness, availability etc Although much work has been done in the field of "Natural Excipients", yet, further Steps need to be taken in order to achieve more promising results in the said field.

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