Excipients

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1. What are excipients?
   Excipients are pharmaceutical additives, the inactive ingredients used to make up a medication.

2. Which are the included in excipients?
   Dyes, flavours, binders, emollients, fillers, lubricants, preservatives etc.

3. Give some examples for some pharmaceutical additives?
   Lactose, starch, talc, sucrose, gelatin, magnesium stearate, calcium stearate, silicon dioxide, shellac, corn starch

4. what are the important qualities for an excipient?
   - Be safe in the amount used in the drug.
   - Not affect the bioavailability of the drug
   - Be manufactured in accordance with good standards
5. Which are the excipients used in the formulation of a tablet?

   1. Diluents
   2. Granulating agents
   3. Binding agents
   4. Disintegrating agents
   5. Lubricants
   6. Adsorbents

6. What are diluents?

The diluents are used in formulation of a tablet when the quantity of medicament in each tablet is very small.

7. Give examples for diluents?

Lactose, sucrose, sodium chloride, dextrose and starch, mannitol, sorbitol, dibasic calcium phosphate dehydrate, calcium sulphate dihydrate.

8. What are Binders/ binding agents?

Binders hold the ingredients in a tablet together.

Binders ensure that tablets and granules can be formed with required mechanical strength, and give volume to low active doses tablets.

9. Give some examples for binding agents used in a tablet formulation?

Usually used binders are starches, sugars, cellulose or modified cellulose such as microcrystalline cellulose, hydropropyl cellulose, lactose, or sugar alcohols like xylitol, sorbitol.

10. How binders are classified?

   1. Solution binders
   2. Dry binders
11. What are Solution binders?

Solution binders are dissolved in a solvent (for example water or alcohol) and used in wet granulation processes.

12. Give Examples for Solution?

gelatin, cellulose, cellulose derivatives, polyvinyl pyrrolidone, starch, sucrose and polyethylene glycol

13. What are Dry binders?

Dry binders are added to the powder blend, either after a wet granulation step, or as part of a direct powder compression (DC) formula.

14. Give Examples Dry binders?

Dry binders include cellulose, methyl cellulose, polyvinylpyrrolidone

15. What are Disintegrants?

Disintegrants are substance added in the formulation to ensure disintegration of the tablets into smaller particles when swallowed. They are added in oral or sublingual tablets. They expand and dissolve when wet causing the tablet to break apart in the digestive tract, releasing the active ingredients for absorption.

16. Types of Disintegrants?

- Water uptake facilitators
- Tablet rupture promoters

They ensure that when the tablet is in contact with water, it rapidly breaks down into smaller fragments, thereby facilitating dissolution.

17. Give examples for disintegrants?

crosslinked polyvinyl pyrrolidone, sodium starch glycolate, crosslinked sodium carboxymethyl cellulose (crosscarmellose).

18. How the Disintegrants act?

- By swelling
- By producing effervescence
- By melting at body temperature
19. what are Antiadherents?

Antiadherents are substances used to reduce the adhesion between the powder (granules) and the punch faces and thus prevent sticking to tablet punches.

20. Give examples for Preservatives used in pharmaceutical formulations?

Some typical preservatives used in are:
- antioxidants like vitamin A, vitamin E, vitamin C, retinyl palmitate, and selenium
- the amino acids cysteine and methionine, citric acid and sodium citrate
- synthetic preservatives like methyl paraben and propyl paraben, sodium benzoate

21. Why lubricants are added to a formulation?

Are added to improve the appearance of tablets, flow property of granules and to prevent the sticking of the materials to the dies and punches.

22. How the lubricants act?

Lubricants prevent ingredients from clumping together and from sticking to the tablet punches or capsule filling machine. Lubricants also ensure that tablet formation and ejection can occur with low friction between the solid and die wall.

23. Give examples for lubricants?

Common minerals like talc or silica, and fats, e.g. vegetable stearin, magnesium stearate or stearic acid are the most frequently used lubricants in tablets or hard gelatin capsules.

24. what are Sorbents?

Sorbents are used for tablet/capsule moisture-proofing by limited fluid sorbing (taking up of a liquid or a gas either by adsorption or by absorption) in a dry state.

25. what are Glidants?

Glidants are used to promote powder flow by reducing interparticle friction and cohesion. These are used in combination with lubricants as they have no ability to reduce die wall frictions.
26. Give examples for glidants?

colloidal silicon dioxide, talc,.

27. What are sweeteners?

Sweeteners are added to make the ingredients more palatable, especially in chewable tablets such as antacid or liquids like cough syrup. Therefore, tooth decay is sometimes associated with cough syrup abuse. Sugar can be used to disguise unpleasant tastes or smells.

28. Why Flavours are added to a medicament?

Flavours can be used to mask unpleasant tasting active ingredients and improve the likelihood that the patient will complete a course of medication. Flavourings may be natural (e.g. fruit extract) or artificial. [1]

29. Give examples for adding flavours in a formulation?

- a bitter product may use mint, cherry or anise
- a salty product may use peach, apricot or liquorice
- a sour product may use raspberry or liquorice
- a excessively sweet product may use vanilla

30. What is the use of adding Colours in a formulation?

Colours are added to improve the appearance of a formulation. Colour consistency is important as it allows easy identification of a medication

EXCIPIENT INGREDIENTS IN MEDICATIONS

Aspartame - An artificial sweetening agent derived from aspartic acid.

Aspartic Acid - A crystalline amino acid found naturally in sugar beets and sugar cane.

Benzyl alcohol - Made synthetically from benzyl chloride which is derived from toluene (a tar oil).

Cellulose - (ethylcellulose, methylcellulose, hydroxymethylcellulose, hydroxypropyl, microcrystalline) – Obtained from fibrous plant material (woody pulp or chemical cotton).

Cetyl alcohol - Derived from a fat source (spermaceti, which is a waxy substance from the head of the sperm whale).
Croskemellose sodium - An internally cross-linked sodium carboxymethylcellulose for use as a disintegrant in pharmaceutical formulations. Comes from wood pulp or cotton fibers to form carboxymethylcellulose. It contains no sugar or starch.

Dextrans - Partially hydrolyzed corn or potato starch.

Dextrates - Mix of sugars resulting from the controlled enzymatic hydrolysis of starch.

Dextrins - Result from the hydrolysis of starch by heat or hydrochloric acid (from corn). It can also be obtained from wheat, rice or tapioca.

Dextrose - Powdered corn starch.

Fructose - Obtained naturally from fruits or honey; hydrolyzed cane or beet sugar.

Gelatin - Obtained from the skin, white connective and bones of animals (by boiling skin, tendons, ligaments, bones, etc with water).

Glycerols - Obtained from fats and oils as byproducts in the manufacture of soaps and fatty acids (may also be listed as mono-glycerides or di-glycerides).

Glycols - Products of ethylene oxide gas.

Hypromellose – A brand of hydroxypropyl methylcellulose (see cellulose).

Iron oxide (rust) - Used as a coloring agent.

Kaolin - A clay-like substance.

Lactitol - Lactose derivative; a sugar alcohol.

Lactose - Also known as milk sugar, is used in the pharmaceutical industry as a filler or binder for the manufacture of coated pills and tablets. Commercially produced from cow’s milk.

Maltodextrins - A starch hydrolysate that is obtained from corn in the United States but can also be extracted from wheat, potato or rice.

Mannitol - Derived from monosaccharides (glucose or mannose).

Methyl Paraben – Comes from the combination of denatured wood alcohol and benzoic acid (benzoic acid occurs naturally in cherry bark, raspberries, tea, anise and cassia bark).

Polysorbates - Chemically altered sorbitol (a sugar alcohol).
Polyvinyl alcohol – A water soluble synthetic alcohol (synthesized by hydrolysis of polyvinyl acetate).

Povidone (crosnopovidone, copovidone) - synthetic polymers

Pregelatinized starch - A starch that has been chemically or mechanically processed. The starch can come from corn, wheat, potato or tapioca.

Shellac - A natural wax product used in tablet or capsule coating.

Sodium lauryl sulfate – A derivative of the fatty acids of coconut oil.

Sodium starch glycolate - Sodium salt of carboxymethyl ether of starch. Usually from potato but can be from corn, wheat or rice.

Stearates (calcium, magnesium) - Derived from stearic acid (a fat; occurs as a glyceride in tallow and other animal fats and oils, as well as some vegetables; prepared synthetically by hydrogenation of cottonseed and other vegetable oils).

Sucrose - Sugar also known as refined sugar, beet sugar or cane sugar.

Titanium dioxide - Chemical not derived from any starch source used as a white pigment.

Triacetin – A derivative of glycerin (acetylation of glycerol).

Silicon dioxide – A dispersing agent made from silicon.