INDUSTRIAL PHARMACY-I

UNIT II-TABLETS

CLASS:13

Tablet coating: Types of coating, coating materials,formulation of coating composition

Tablet coating reasons behind coating of tablets

The reasons behind coating of tablets are as follows:

1. To mask the taste, odour or colour of the drug. Improving the product appearance, particularly where there are visible differences in tablet core ingredients from batch to batch.

2. Provide physical protection, facilitates handling, particularly in high speed packaging / filling lines.

3. To provide chemical protection from its surrounding environment (particularly air, moisture and light).

4. To control the release of drug from the tablet e.g. Sustained release tablets, repeat action tablets.

5. To protect the drug from the gastric environment of the stomach with an acid resistant enteric coating.

Tablet properties (or core properties)

Tablets that are to be coated are called core. This core must possess the proper physical characteristics.

1. In pan coating process the core tablets roll in the pan or cascade in the air stream in air suspension coating. To endure the intense attrition between tablets or wall of the pan the tablets must have enough hardness.

2. Sugar coating can mask the imperfection on the surface but film coating cannot, hence, for film coating the core surface must be smooth.

3. The tablets must be in constant motion during the early drying phase or tablet agglomeration may occur. The ideal shape for coating is a sphere; the worst shape is a square flat-faced tablet

and in practice rounded, convex shaped tablet cores are taken.

4. For coating materials to adhere to the tablet the coating composition must wet the surface of the core. E.g. Hydrophobic tablet surfaces are difficult to coat with aqueous-based coating.

Tablet coating processes two types of tablet coating are popular – (i) sugar coating and (ii) film coating

Sugar coating of compressed tablets

The sugar coating process can be subdivided into six main steps: 1. Sealing 2. Subcoating 3.Smoothing (syruping) 4.Color coating 5.Polishing and 6.Printing 7.

1. **Sealing**

Objectives

(i) To prevent moisture penetration into the tablet core, a seal coat is applied. (ii) to strengthen the tablet core without a seal coat, the over wetted tablets would absorb excess moisture, leading to tablet softening, and may affect the physical and chemical stability.

Ingredients

- Alcoholic solutions of shellac (10 – 30% solid) or
- Alcoholic solution of zein,
- Alcoholic solution of cellulose acetate phthalate (cap) or
- Alcoholic solution of polyvinyl acetate phthalate.
- With aging the disintegration and dissolution time is found to increase with shellac due to polymerization
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- Zein is an alcohol soluble protein derivative obtained from corn (maize).

Subcoating

Objective: to round the edges and build up the tablet size. Sugar coating can increase the tablet weight by 50 to 100% at this step.

Method the subcoating step consists of alternately applying a sticky binder solution to the tablets followed by a dusting of subcoatingpowders and then drying. Subsequent coatings are applied in the same manner until the tablet edges have been covered and the desired thickness is achieved.

Ingredients

binder solution formulations for subcoating:- gelatin 3.3%(w/w) gum acacia (powder) 8.7%(w/w) sucrose 55.3%(w/w) water to 100%(w/w)

dusting powder formulation calcium carbonate 40.0%(w/w) titanium dioxide 5.0%(w/w) talc (asbestos free) 25.0%(w/w) sucrose powder 28.0%(w/w) gum acacia powder 2.0%(w/w)

1. **Smoothing or syruping**

Objectives to cover and fill in the imperfections in the tablet surface caused by the subcoating step.

Ingredients simple syrup solution (approximately 60 – 70%(w/w)). Often the smoothing syrups contain a low percentage of titanium dioxide (1 – 5%) as an opacifier. This gives a very bright and reflective background for the subsequent coloring step.

2. **Colour coating**

Objective to impart an elegant and uniform colour.

Ingredient syrup (60 – 70% sucrose) containing the desired color.

Method syrup solutions containing the dyes are coated upto 60 individual applications until the desired color is achieved. After each application of color the coatings are dried. In the finishing step a few clear coats of syrup may be applied.

Polishing

Objective to produce the desired luster on the surface of the tablet.

Ingredients mixtures of waxes (like beeswax, carnauba wax, candella wax or hard paraffin).

Method either this mixtures of waxes are applied as powder or as dispersions in various organic solvents in a polishing pan (canvas line pan).

Printing

In order to identify sugar-coated tablets often it is necessary to print them, using pharmaceutical grade ink, by means of a process of offset rotogravure .

<u>MATERIAL USED FOR FILM COATING</u>

1. **Film formers**

Nonentericmaterials :

- Hydroxypropyl methylcellulose (HPMC)
- Methylhydroxy ethyl cellulose (MHEC)
- Ethylcellulose (EC)
- Hydroxypropyl cellulose (HPC)
- Polyvinyl pyrrolidone (PVP)
- Sodium carboxymethyl cellulose (Sod. CMC)
- Polyethylene glycols (PEG)
- Acrylate polymers e.g. Eudragit E

Enteric materials:

- ✓ Cellulose acetate phthalate (CAP)
- ✓ Acrylate polymers (Eudragit L, S)
- ✓ Hydroxypropyl methylcellulose phthalate (HPMCP)
- ✓ Polyvinyl acetate phthalate (PVAP)

2. **Solvents**

Criteria:

1. It should either dissolve or disperse the polymer system.

2. It should easily disperse other coating solution components into the solvent system.

3. Small concentration of polymers (2 to 10%) should not result in an extremely viscous solution system (> 300 cps), creating process problems.

4. It should be colorless, tasteless, odourless, inexpensive, non-toxic, inert and non-inflammable.

5. It should have no environmental impact.

3. **Colorants**: Same as tablet.
4. **Plasticizers**

These are used to impart flexibility to the film.

e.g. castor oil, propylene glycol, glycerin, polyethyleneglycol (PEG) 200 and 400, surfactants e.g. polysorbates (Tweens), Sorbitan esters (Spans) and organic esters.

5. **Opaquant extenders:**

Very fine inorganic powders e.g. titanium dioxide (TiO_2) silicates like talc, aluminium silicate carbonates like magnesium carbonate sulfates like calcium sulfate oxides like magnesium oxide and hydroxides like aluminium hydroxides.

6.Miscellaneous coating solution components

Flavors and sweeteners Surfactants are used to solubilize immiscible or insoluble ingredients Antioxidants Antimicrobial agents.