INDUSTRIAL PHARMACY-I

UNIT II-TABLETS AND LIQUID ORALS

CLASS:14

Equipment employed and defects in coating

FILM COATING

Film coating adds 2 to 5% to the tablet weight. Film coating can be done by the following three methods.

(i) **Pan-pour method:**

Viscous coating materials are directly added from some container into the rotating pan moving with the tablet bed. Tablets are subjected to alternate solution application, mixing and then drying.

Disadvantages:

- The method is relatively slow.
- It relies heavily on the skill of the operator.
- Tablets always require additional drying to remove the latent solvent.
- Aqueous film coating are not suitable for this method because localized over wetting will produce physicochemical instability.

(ii) **Pan-spray method:**

Coating material is sprayed over the tablet bed from nozzles and hot air is passed through the tablet bed to dry it. The variables to be controlled for pan-spray film coating process are:

(a) Pan variables: Uniform mixing is essential to deposit the same quantity of film on each tablet.

1. *Pan design or baffling*: Some tablet shapes mixes freely while other shapes may require a specific baffling arrangement to ensure adequate mixing.

Disadvantages: Baffles may produce chipping and breakage if not selected properly.

(b) Pan speed: Pan speed affects mixing and the velocity at which the tablet pass under the spray.

Too slow speed cause localized over-wetting resulting in tablets sticking to each other or to the pan.

Too high speeds may not allow enough time for drying before the same tablets are reintroduced to the spray. This results in a rough coating appearance on the tablets.

Optimum pan speed: 10 – 15 rpm for nonaqueous film coating

3 – 10 rpm for aqueous film coating.

(c) Spray variables

1. Rate of liquid application

2. Spray pattern

3. Degree of atomization

These three spray variables are interdependent. For spraying two types of systems are there:

(a) High-pressure, airless system and

(b) low-pressure, air atomization system.

The proper rate of liquid application depends on the mixing and drying efficiency of the system and the coating formula.

A band of spray should be spread evenly over the tablet mass. In larger pans, more nozzles must be added to cover the tablet bed width. A spray pattern that is too wide will apply coating on the pan. A spray pattern that is too narrow will produce localized over-wetting. Spray width can be adjusted by moving the nozzles closer or further away from the tablet bed.

Atomization is the process whereby the liquid stream is finely subdivided into droplets. The degree of atomization (i.e. the size and size-distribution of the droplets). Too fine atomization causes some droplets to dry before reaching the tablet surface, resulting in roughness on the tablet surface and excess dust in the pan. Too large atomization causes localized over-wetting – leads to sticking, picking or a rough " **orange peel**" effect.

(d) Process air variables:(temperature, volume, rate) are required for optimum drying of the coating by evaporation of the solvent. The balance between the supply and exhaust air flow should be such that all the dust and solvent are confined within the coating system.

(iii) **Fluidized bed process** (air suspension coating) This process have been successfully used for rapid coating of tablets, granules and capsules.

Process variables are as follows:

(a) Chamber design and air flow rate controls the fluidization pattern.

(b) Tablet shape, size and density.

(c) Volume and rate of air flow – too high rate produce attrition and breakage of tablets– too low rate mass does not move fast enough through the spray region over-wettingoccurs.

(d) Inlet and exhaust air temperature.

DEVELOPMENT OF FILM COATING

Before coating a tablet the coating formula is first cast on either a glass, teflon or aluminium foil surface. Glass is preferred for cast films. The coating is done by spreading with a glass rod. After drying, the cast films are assessed for the following properties:

(i) Physical appearance – potential colorant or opaquant separation is noted.
(ii) lack of color uniformity
(iii) insoluble additives have been properly suspended or not.
(iv) water vapor permeability
(v) film tensile strength

FILM DEFECTS:

Variations in formulation and processing conditions may result in unacceptable quality in the film coating. Some of the problems are as follows:

Picking

Overwetting or excessive film tackiness or when the drying system is inefficient – tablets stick to each other or to the coating pan. On drying, at the point of contact, a piece of the film may remain adhered to the pan or to another tablet, giving a " **picked**" appearance to the tablet surface and resulting in a small exposed area of the core tablet.

Remedy :

A reduction in the liquid application rate or,

Increase in the drying air temperature and air volume usually solve this problem.

If excessive tackiness is there then the formulation is changed.

Roughness

A rough or gritty surface is a defect often observed when the coating is applied by spray. Some of the droplets may dry too rapidly before reaching the tablet bed, resulting in droplets on the tablet of "spray dried" particles instead of finely divided droplets of coating solution. Roughness also increases with pigment concentration and polymer concentration.

Remedy

Moving the nozzle closer to the tablet bed

Reducing the viscosity of coating solution.

Bridging and filling

During drying, the film may shrink and pull away from the sharp corners of a bisect, resulting in "bridging" of the surface depression. This defect may be so severe that the monogram or the bisect is completely obscured. This is a problem in the formulation.

Remedy

Increasing the plasticizer amount in the formulation

Changing the plasticizer can decrease the incidence of bridging.

Filling: If the solution is applied too fast, over-wetting may cause the liquid to quickly fill and be retained in the monogram – this is called filling. Remedy

Judicious monitoring of the fluid application rate andthorough mixing of the tablets in the pan prevent filling.

Blistering

When coated tablets require further drying in ovens, too rapid evaporation of the solvent from the core and the effect of high temperature on the strength, elasticity and adhesion of the film may result in blistering.

Remedy: Milder drying conditions are adopted.

Hazing / Dull film (Bloom)

It can occur when too high a processing temperature is used for a particular formulation. It is particularly evident when cellulosic polymers are applied out of aqueous media at high processing temperatures. It can also occur if the coated tablets are exposed to high humidity conditions and solution of film results.

Color variation

Improper mixing, uneven spray pattern.

Insufficient coating may result in color variation.

The migration of soluble dyes, plasticizers, and other additives during drying may give the coating a mottled or spotted appearance. Remedy

Use of lake instead of dye.

Changing the plasticizer and additives.

Changing the plasticizer and additives.

Cracking

Cracking occurs if the internal stresses in the film exceed the tensile strength of the film. The tensile strength of the film can be increased by using higher molecular weight polymers or polymer blends. Internal stresses in the film can be minimized by adjusting the plasticizer type and concentration, and the pigment type and concentration.

Tablet coating Equipment:

1) The Standard coating Pan. Pelligrini system Immersion sword system Immersion tube system

2) Perforated coating pan Accelacota/coater

Hicoater

Driacoater

Glatt coater

3) Fluidized bed coater(air Suspension)

Bottom Spray(**Wurster Process)** coating technique is mainly recommended for Sustain release and enteric release products.

Two types-

High pressure airless system

Low pressure, air atomizer (Flo-coater and Aeromatic FBC are commercially available)