UNIT IV

Tablet coating

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Coated tablets are defined as “tablets covered with one or more layers of mixture of various substances such as

- Natural Or Synthetic Resins
- Gums
- Inactive And Insoluble Filler,
- Sugar
- Plasticizer
- Polyhydric Alcohol
- Waxes
- Authorized Colouring Material
- And Some Times Flavoring Material.
I. Therapy

- Avoid irritation of oesophagus and stomach
- Avoid bad taste
- Avoid inactivation of drug in the stomach
- Improve drug effectiveness
- Prolong dosing interval
- Improve dosing interval
- Improve patient compliance
Aspects of tablet coating:

II. Technology

- Reduce influence of moisture
- Avoid dust formation
- Reduce influence of atmosphere
- Improve drug stability
- Prolong shelve life
Aspects of tablet coating:

III. Marketing
- Avoid bad taste
- Improve product identity
- Improve appearance and acceptability
Basic principle of tablet coating

Tablet coating is the application of coating composition to moving bed of tablets with concurrent use of heated air to facilitate evaporation of solvent.
Type of tablet coating:

- Sugar coating
- Film coating
- Enteric coating
- Controlled release coating
- Specialized coating
  Compressed coating
  Electrostatic coating
  Dip coating
  Vacuum film coating
Pharmaceutical tablets are given a coating for a number of reasons:

- To improve the appearance and aid identification.
- To protect the tablet from moisture and other adverse conditions.
- To lubricate the tablet to ease swallowing.
- To disguise unpleasant tastes.
- To create a barrier between the active ingredient and the gastrointestinal tract.
- To control the release of drug into the body.

Coatings generally consist of a sugar or cellulose based binder, plasticizer, film forming agent and colorant. These are supplied in granulated or powder form for dispersion in aqueous or organic solvents at concentration varying from 10 -20% depending on the desired properties and formula.
Three general types of equipments are available

1. **Standard coating pan**
   - e.g., Pellegrino pan system
   - Immersion sword system
   - Immersion tube system

2. **Perforated pan system**
   - e.g., Accela cota system
   - Hicoater system
   - Glattcoater system
   - Driacoated system

3. **Fluidized bed coater**
POLISHING
STANDARD COATING PAN

Standard Coating Pan

Immersion-tube system

Glatt Immersion sword system

Pellegrini pan system
PERFORATED PANS

Accela cota system

Hi-coater system
PERFORATED PANS (continue…)

Dria coater pan

Glatt coater
FLUID BED COATING SYSTEMS
Main coating processes

1. Film coating
2. Sugar coating
3. Press coating
Traditionally sugar coatings formed the bulk of coated tablets but today film coatings are the more modern technology in tablet coating.

**Description of tablets:** Smooth, rounded and polished to a high gloss.

**Process:** Multistage Process involving 6 separate operations:
1. Seal tablet core
2. Sub coating
3. Smoothing
4. Colouring
5. Polishing
6. Printing
MULTI STAGE PROCESS

1. **Sealing tablet core** - application of a water impermeable polymer such as Shellac, cellulose acetate phthalate and polyvinyl acetate phthalate, which protects the core from moisture, increasing its shelf life.

2. **Sub coating** - by adding bulking agents such as calcium carbonate or talc in combination with sucrose solution.

3. **Smoothing process** - remove rough layers formed in step 2 with the application of sucrose syrup.

4. **Colouring** - for aesthetic purposes often titanium based pigments are included.

5. **Polishing** - effectively polished to give characteristic shine, commonly using beeswax, carnauba wax.

6. **Printing** - indelible ink for characterisation.
1- Sealing (Waterproofing)
This involved the application of one or more coats of a waterproofing substance in the form of alcoholic spray, such as pharmaceutical Shellac (traditionally) or synthetic polymers, such as CAP. (Unless a modified-release feature needs to be introduced, the amount of the sealing coat applied should be carefully calculated so that there is no negative effect on the drug release characteristics in case of immediate release product.)

(WHY Sealing?)
a- Sugar-coatings are aqueous formulations which allow water to penetrate directly into the tablet core and thus potentially affecting product stability and possibly causing premature tablet disintegration.
b- Application of many coats of partially or completely water-insoluble polymers in this step, enables sugar-coated product to exhibit modified-release pattern (extended-release or delayed "enteric"- release characteristics).
2. Subcoating

• Large quantities of sugar-coatings are usually applied to the tablet core (typically increasing the tablet weight by (50-100%)

**WHY?**

• In order to round off the tablet edge. Much of this material build-up occurs during this stage and is achieved by adding a bulking agent such as Calcium carbonate, to the sucrose solution.

• Antiadherents e.g. Talc may be added after partial drying to prevent sticking of the tablets together.
3- Smoothing

• The subcoating stage results in tablets with rough surfaces. To facilitate the color application (which requires smooth surface), subcoated tablets are smoothed out by a thick sucrose syrup coating.

4- Coloring

• Color coatings usually consist of thin sucrose syrup containing the requisite coloring materials. (water-soluble dyes or water-insoluble pigments may be used) This step must be done into a clean pan deprived of any residues from the previous operations.
5- Polishing
• After the coloring step, the tablet surfaces tend to be smooth but somewhat dull in appearance. To achieve glossy finish, final stage involving application of waxes (beeswax carnuba wax) is employed.

6- Printing
• Different tablets could be identified by manufacturer's logo, product name, dosage strength or other appropriate code. For sugar-coated tablets, such identification could be only achieved by printing process using special edible inks.
Brufen® POM
- Available in 200mg and 400mg strength

Premarin® POM
- Conjugated oestrogens 625mcg (maroon) and 1.25mcg (yellow)

Colofac® P
- Mebeverine hydrochloride 100mg Round, white, sugar coated

Kalms® GSL
- 45mg Hops powder, 90mg Gentian powdered extract, and 135mg Valerian powdered extract
SUGAR COATED PROCESS

Coated particle
Coated material
Layer build up
Sugar coated particle
Coated particle
Modern approach to coating tablets, capsules, or pellets by surrounding them with a thin layer of polymeric material.

- **Description of tablets**: Shape dictated by contour of original core.
- **Process**: Single stage process, which involves spraying a coating solution containing the following:
  1. Polymer
  2. Solvent
  3. Plasticizer
  4. Colourant

The solution is sprayed onto a rotating tablet bed followed by drying, which facilitates the removal of the solvent leaving behind the deposition of thin film of coating materials around each tablet.
Advantages

Produce tablets in a single step process in relatively short period of time. Process enables functional coatings to be incorporated into the dosage form.

Disadvantages

There are environmental and safety implications of using organic solvent as well as their financial expense.

Types of film coating

A. Immediate release

B. Modified release
## Polymers for film coating

<table>
<thead>
<tr>
<th>Immediate-release coating polymers</th>
<th>Modified-release coating polymers</th>
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<tbody>
<tr>
<td><strong>1- Cellulose derivatives:</strong></td>
<td><strong>Extended-release coating polymers</strong></td>
</tr>
<tr>
<td>- The most widely used of</td>
<td>They are dissolved in organic solvent or</td>
</tr>
<tr>
<td>cellulosic polymers is HPMC</td>
<td>dispersed in aqueous medium</td>
</tr>
<tr>
<td>(WHY?)</td>
<td><strong>1- Cellulose derivatives:</strong></td>
</tr>
<tr>
<td>- it is readily soluble in</td>
<td>Highly substituted cellulosic ether, thus</td>
</tr>
<tr>
<td>aqueous media</td>
<td>rendering the polymer water-insoluble, e.g.</td>
</tr>
<tr>
<td>- forms film with good</td>
<td><strong>Ethyl cellulose</strong> (EC).</td>
</tr>
<tr>
<td>mechanical properties (strength,</td>
<td></td>
</tr>
<tr>
<td>flexibility and adhesion to the</td>
<td></td>
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<tr>
<td>tablet core)</td>
<td></td>
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<tr>
<td>- easy application of the coat</td>
<td></td>
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<tr>
<td>- Other examples are MC &amp; HPC</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td><strong>2- Vinyl derivatives:</strong></td>
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<tr>
<td>- PVP, it has a limited use in film coating because of its inherent tackiness.</td>
<td></td>
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<tr>
<td>- A copolymer of PVP and vinyl acetate forms better films.</td>
<td></td>
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</tbody>
</table>
2. Plasticizers

Plasticizers are generally added to film coating formulations to modify the physical properties of the polymer to make it more usable. One important property is their ability to decrease film brittleness.

Examples of plasticizers are:

- **Polyols**, such as polyethylene glycol 400
- **Organic esters**, such as diethyl phthalate
- **Oils/glycerides**, such as fractionated coconut oil.

In general, only water-miscible plasticizers can be used for aqueous-based spray systems.
3. Colourants

Any permitted colourants in a film coat formula are invariably water-insoluble colours (pigments). Pigments have certain advantages over water-soluble colours: they tend to be more chemically stable towards light, provide better opacity and covering power, and optimize the impermeability of a given film to water vapour.

**Examples of colourants are:**

- iron oxide pigments
- titanium dioxide
- aluminum Lakes.
4. Solvents

Modern techniques now rely on water as a polymer solvent because of the significant drawbacks that readily became apparent with the use of organic solvents.
<table>
<thead>
<tr>
<th>MATERIAL USED FOR FILM COATING</th>
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<tbody>
<tr>
<td><strong>Nonenteric materials:</strong>  e.g.</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose (HPMC)</td>
</tr>
<tr>
<td>Methylhydroxy ethyl cellulose (MHEC)</td>
</tr>
<tr>
<td>Ethylcellulose (EC)</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose (HPC)</td>
</tr>
<tr>
<td>Polyvinyl pyrrolidone (PVP)</td>
</tr>
<tr>
<td>Sodium carboxymethyl cellulose (Sod. CMC)</td>
</tr>
<tr>
<td>Polyethylene glycols (PEG)</td>
</tr>
<tr>
<td>Acrylate polymers e.g. Eudragit E</td>
</tr>
<tr>
<td><strong>Enteric materials:</strong>  e.g.</td>
</tr>
<tr>
<td>Cellulose acetate phthalate (CAP)</td>
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<tr>
<td>Acrylate polymers (Eudragit L, S)</td>
</tr>
<tr>
<td>Hydroxypropyl methylcellulose phthalate (HPMCP)</td>
</tr>
<tr>
<td>Polyvinyl acetate phthalate (PVAP)</td>
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</tbody>
</table>
The vast majority of film coated tablets are produced by a process which involves spraying of the coating material on to a bed of tablets. Accela Cota is one example of equipment used for film coating.
Accela Cota
# DIFFERENCE BETWEEN FILM COATING & SUGAR COATING

<table>
<thead>
<tr>
<th>Film coating</th>
<th>Sugar coating</th>
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<tbody>
<tr>
<td><strong>Tablet appearance</strong></td>
<td><strong>Tablet appearance</strong></td>
</tr>
<tr>
<td>✓ Retains shape of original core</td>
<td>✓ Rounded with high degree of polish</td>
</tr>
<tr>
<td>✓ Small weight increase of 2-3% due to coating material</td>
<td>✓ Larger weight increase 30-50% due to coating material</td>
</tr>
<tr>
<td>✓ Logo or ‘break lines’ possible</td>
<td>✓ Logo or ‘break lines’ are possible</td>
</tr>
<tr>
<td><strong>Process</strong></td>
<td><strong>Process</strong></td>
</tr>
<tr>
<td>✓ Can be automated e.g. <strong>Accela Cota</strong></td>
<td>✓ Difficult to automated e.g. traditional coating pan</td>
</tr>
<tr>
<td>✓ Easy training operation</td>
<td>✓ Considerable training operation required</td>
</tr>
<tr>
<td>✓ Single stage process</td>
<td>✓ Multistage process</td>
</tr>
<tr>
<td>✓ Easily adaptable for controlled release allows for functional coatings.</td>
<td>✓ Not able to be used for controlled release apart from enteric coating.</td>
</tr>
</tbody>
</table>
PRESS COATING

- use of compression to form coat around a pre-formed core

- used mainly to separate chemically incompatible materials
  also dual...
To separate chemically incompatible materials, one or more being placed in the core and the other(s) in the coating layer. However, there is still an interface contact left between the two layers.

In cases where even this is important then the process of pre-coating can be taken one stage further.

It is possible to apply two press coatings to a tablet core using suitable equipment.

This equipment produces press-coated tablets with perfect separation between active core and coating, as the two can be separated by an inert middle layer.
This photo shows multiple defects. The initial problem was erosion of the tablet edge due to a soft or friable tablet or because the pan was turning too fast or both. Peeling and breakage also appear here.
Just one broken tablet can distribute particles to all the other tablets and mar their appearance. These tablets likely broke because they had poor hardness.
This photo shows a very porous tablet that prevented the coating from adhering to the surface. These tablets should have been coated longer, and the atomization pressure should have been reduced to decrease the slight orange peel, or textured, surface.
in this photo to excessive moisture within the tablet, which prevented the coating from adhering. However, the tablet coating also pulled the granulation out of the tablet, a picking defect. That is usually caused by over-wetting the tablet or by a tablet that is too soft.