Tablet defects

Tablet defects or manufacturing defects of tablet are not acceptable.
Tablet defects are either related to functional defects or visual defects or both.
Tablet defects are associated with imperfections in any one or more of the following factors:
1. Formulation of Tablet
2. Tableting equipment
3. Manufacturing process of Tablet

Tablet coating

Coating tablets is not just about making medications easier to take and simpler to ship in large quantities.

Objectives of tablet coating

a. To mask the bitter taste and unpleasant odour of some drugs
b. To improve product appearance for aesthetic or commercial purposes (aiding in brand identification)
c. To prevent drug-induced irritation at a specific site within the gastrointestinal tract, e.g. the stomach for non-steroidal anti-inflammatory drugs (NSAIDs).
d. To protect the drug from the external environment (particularly air, moisture, and light) in order to improve stability.
e. To enhance ease of swallowing large dosage forms
f. To facilitate handling, particularly in high-speed packaging/filling lines, and automated counters in pharmacies, where the coating minimizes cross-contamination due to dust elimination.
g. To facilitate rapid identification of a product by the manufacturer, the dispensing pharmacist and the patient.
h. To reduce the risk of interaction between incompatible materials
i. To retard loss of volatile ingredients
j. To modify and/or control the rate of drug release as in repeat-action, delayed-release (enteric-coated) and sustained release products.
k. To control the site of action of drugs e.g., colon delivery
l. To avoid inactivation of drug in the stomach e.g., enteric coating.
m. To mask the disagreeable odor, color or taste of the tablet.
n. To offer a physical and/or chemical protection to the drug.
o. To control and sustain the release of the drug from the dosage form.
p. To incorporate another drug which create incompatibility problems.
q. To protect an acid-labile drug from the gastric environment.
r. Increasing the mechanical strength of the dosage form.
s. Masking Flavor: Many medications come with a less than favorable taste or odor that comes from the ingredients. Film coated tablets make the pill more palatable and comfortable to swallow for the end-user.
t. Physical Protection: It is crucial that ingredients remain uncontaminated from outside physical or chemical sources during distribution or transportation. Our tablet coating machinery help maintain the dosage form and protect the medication from any contamination.
u. Timed Release: Depending on the medication, it might need to be released more slowly and over time. The right coating makes this process simple and delivers better results for the end user.
v. Incorporation: There are often medications that must be combined, but only after they've been administered. Tablet coating makes it possible to incorporate multiple types of medications into one pill without mixing them until the proper time.
w. Dosage: There are occasionally times when a prescription advises the end user to split the tablet or pill and take the pieces separately. The right application of tablet coatings allows for the split to occur without shattering the entire pill.
x. Gastric Defence: How do you stop stomach acid from just dissolving any medication you take? The gastric environment in any stomach is a rough place, but tablet coatings or films can protect your medication from the acidity of your stomach.
y. Increased Strength: Pills and tablets need to be sturdy enough to survive the path they take to end up in your medicine cabinet. Tablet coating delivers the delicate balance of a pill that is strong enough to survive the rigors of travel and vulnerable enough to be absorbed by the body.

An ideal film coating material should possess the following characteristics:
• It should be soluble in a solvent of choice.

• It must produce an elegant coat.
• It should be stable in presence of heat, light or moisture.
• It should not possess disagreeable color, taste or odor.
• It should be non-toxic and pharmacologically inert.
• It should be compatible with coating additives.

Core requirements for successful tablet coating

i. Tablets to be coated should normally be compressed with deep concave punches and die sets. This allows easy coverage of the tablet by the applied coating material.
ii. The core tablet should be compressed harder than uncoated tablets because they must withstand the additional processing operations.
iii. They must be free from dust to ensure uniformly smooth coating.

Types/ Techniques of Tablet Coating

- Sugar Coating
- Film Coating
- Organic Coating
- Enteric Coating
- Aqueous Film Coating
- And more

1. Sugar coating

Tablet coating developed originally from the use of sugar to mask the taste and provide an attractive appearance to at the core. The process involves the deposition of aqueous sugar solutions onto the surface of the core tablet.
A typical sugar-coating process involves the following steps:
1. Sealing (A seal coat is applied over the tablet to prevent moisture penetration into the tablet core. Shellac was previously used as a sealant. But due to polymerization problems, it was replaced by zein (a corn protein derivative).
2. Subcoating (This step is done to round the edges and increase the tablet weight).
3. Smoothing (or Grossing)
4. Colouring/ Colour coating (Gives the tablet its final color)
5. Polishing (or Glossing) (Powdered wax (beeswax or carnauba) is applied to provide a desired luster)
6. Printing
Sugar coats are often shiny and highly coloured.

Film coating

Film coating involves the deposition of a thin layer of film-forming polymeric material on the tablet core. Film coating has proved successful as a result of the many advantages offered, including:

i. Minimal weight increase (typically 2–3% of tablet core weight)
ii. Significant reduction in processing times
iii. Capacity to include organic solvents if required
iv. Increased process efficiency and output
v. Increased flexibility in the choice of film-forming polymers
vi. Improved resistance to chipping of the coating

Film coating can also be used to coat other formulations including capsules, beads, granules, drug powders, and crystals. A spray atomization technique is more commonly utilized.
The process involves spraying of a solution of polymer, pigments and plasticizer onto a rotating tablet bed to form a thin, uniform film on the tablet surface.
The choice of polymer mainly depends on the desired site of drug release (stomach/ intestine), or on the desired release rate.
Some of the non-enteric coating polymers are Hydroxyproply methyl cellulose (HPMC), Methyl hydroxyethyl cellulose, Ethylcellulose, Povidone, etc, while the commonly used enteric coating polymers are Cellulose acetate phthalate, Acrylate polymers (Eudragit L& Eudragit S), HPMC phthalate, etc.

3. Compression coating

Compression coating also referred to as press coating or dry coating is the process by which a fine dry granulation is compressed onto a tablet core of drug. Compression coating is essentially a dry process and thus may be suitable for

coating tablets containing heat and moisture liable drug(s) such as aspirin and penicillins. This coating process has also been used to separate two incompatible active pharmaceutical ingredients; one contained in the tablet core and the other in the coating. Repeat action and sustained action tablets are produced by this coating method. Although traditionally a less popular process, compression coating has gained increased interest in recent years as a means of creating specialized modified-release products.

4. Microencapsulation

The process involves the application of relatively thin coating to a small particle of solids, liquids or even gases in a micron dimension. The microcapsules thus formed range dimensionally between 3 – 800 μm in diameter with about 10 – 90 % w/w core.

Classification and Types of Tablet Coating Equipment

There are several types of tablet coating machines currently in the market. Depending on the working principles, these machines may be classified into:

a. Standard Coating Pan/ conventional pan system
    i. Pear-shaped
    ii. Hexagonal
    iii. Spherical
b. Perforated Coating Pan
    i. Accela-Cota/Hi-coater Systems
    ii. Driacoater
    iii. Glatt coater
c. Fluidized Bed Coater

Quality Control and Evaluation Parameters for Coated Tablets

The following quality control tests could be performed on coated tablets.

1. Appearance characteristics – colour, size, physical defect and imprinting
2. Disintegration test
3. Dissolution tests
4. Drug content
5. Uniformity of tablet weight
6. Uniformity of content
7. Hardness/ crushing strength test
8. Friability test
9. Stability studies
10. Water vapour stabilities
11. Adhesion test
12. In vivo drug release in different experimental animals

Disadvantages of Tablet Coating

- Tablet coating process is tedious and time-consuming
- The process increases the cost of formulation
- Tablet coating may interfere in pharmacodynamic properties of drug formulation
- The process may sometimes result in various coating defects like chipping, cracking etc.
- The process remained complicated and thus requires the expertise of highly skilled technician.

Tablet Coating

A typical film-coating formulation contains the following materials:

1. Polymer
2. Plasticizer
3. Colourants
4. Solvent/ Vehicle

Polymers are substances whose molecules have high molar masses and are composed of many repeated subunits. They are formed by chemical reactions in which a large number of molecules called monomers are joined sequentially, forming a chain. In the majority of film-coating formulations, the polymer is the major component in

the coating solution. Consequently, this material will have the greatest impact on the final properties of the coating. Some of the key attributes that the film-coating polymer must possess include:
i. Solubility in a wide range of solvent systems
ii. Solubility requirement for the intended use e.g. free water-solubility, slow water solubility or pH-dependent solubility
iii. Stability against light, oxygen, moisture, heat and the substrate being coated
iv. Continuous film formation capability with adequate mechanical properties
v. High compatibility with other film-coating additives and the tablet being coated
vi. Low viscosity at the preferred concentration (for adequate atomization)
vii. Nontoxic with no pharmacological activity
viii. Capacity to produce an elegant looking product even in the presence of additives

Polymers used in film coating fall into the following categories.
1. Cellulose ethers e.g., Hydroxy Propyl Methyl Cellulose (HPMC), Hydroxy Propyl Cellulose (HPC), Ethyl Cellulose (EC), Methyl Cellulose
2. Vinyl polymers e.g., polyvinyl pyrrolidone
3. Glycols e.g., high molecular weight polyethylene glycol
4. Acrylic acid polymers e.g., Eudragits

Plasticizers

Plasticizers are relatively low molecular weight materials which are added to film-coating formulations to modify the physical properties of polymers.
Examples of plasticizers commonly used in film coating processes include:

a. Polyols, such as glycerol (glycerin), polyethylene glycols (PEG 200 – 6000 grades) and propylene glycol.
b. Organic esters, such as Diethyl phthalate (DEP), Dibutyl phthalate (DBP), Dibutyl sebacate (DBS), Triethyl citrate (TEC), Acetyltriethyl citrate (ATEC), Acetyltributyl citrate (ATBC), Tributyl citrate (TBC), and Triacetin (glyceryl triacetate; TA).
c. Oils/ glycerides, such as fractionated coconut oil, castor oil, and distilled acetylated monoglycerides (AMG).

Colourants

Colourants are included in many film-coating formulations to:
a. Improve product appearance and enable product identification
b. Modify the gas permeability of a film
c. Decrease the risk of counterfeiting the product
d. Protect the active ingredient against light by optimizing the opacifying properties of pigments.

While it is possible to use either water-soluble colourants (known as dyes) or water-insoluble colourants (known as pigments), the water-insoluble colourants are preferred in film-coating formulations based on the fact that they:

a. Exhibit better light stability
b. Provide better opacity and covering power
c. Provide a means of optimizing moisture barrier properties of the applied film coatings
d. Do not suffer from the disadvantageous phenomenon of mottling (caused by solute migration) that can be observed with water-soluble colourants.

As with sugar coating colours, film-coating colourants must comply with regulations promulgated by the national legislation of the country where the products are to be marketed.

Solvents/ Vehicles

Solvents are used to dissolve or disperse coating materials and convey them to the surface of the tablet core. Initially, film-coating processes were very much dependent on the use of organic solvents in order to achieve the rapid drying characteristics demanded by the process. Unfortunately, concerns with operator's safety, environmental, and cost-related issues have provided the momentum for the current utilization of aqueous-based film coating as the preferred option. However, the use of solvents has continued, especially when:

i. The coating process will not accommodate the use of water (i.e., drying is poor);
ii. The adhesion achieved with aqueous systems is unacceptable;
iii. Certain critical ingredients (e.g., polymer) are neither water-soluble nor available as a latex system; and
iv. Exposure to an aqueous process would cause stability problems for the product being coated.

Miscellaneous coating solution component

While polymers, plasticizers, colourants, and solvents constitute the major ingredients in film-coating formulations, other materials might be used occasionally in low concentrations for specific formulations.

Flavours and sweeteners may be added to mask unpleasant odour of some drugs or to make them more palatable.

Surfactants or dissolution enhancers such as polyoxyethylene sorbitan derivatives may be added to

i. Emulsify water-insoluble plasticizers
ii. Improve substrate wettability and enhance spreadability of the film during application
iii. Stabilize suspensions

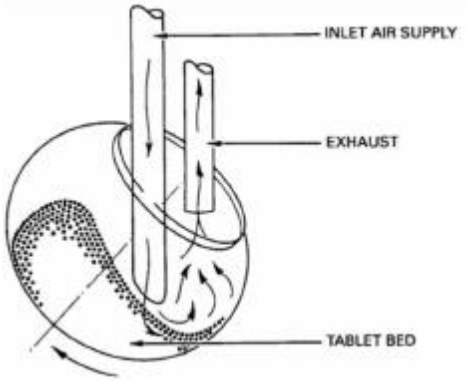
Additionally, some film coatings may also contain preservative/ antimicrobials (e.g., carbamates, alkylisothiazloinone, benzothiazoles etc.), adhesion enhancers (such as polydextrose, maltodextrin, and lactose), antifoaming agents (e.g., dimethylpolysiloxane), antioxidants (e.g., oximes, phenols etc.), pore – forming agents (e.g., sucrose or sodium chloride with ethylcellulose-coated salicylic acid tablets) and waxes. In rare instances, the film coat itself may contain active drug substance. All ingredients used in film-coating formulations must comply with the relevant regulatory and pharmacopoeial requirements current in the intended marketing area.

Equipment used in film coating

Coating equipment used for film coating process can be broadly classified into three general categories: conventional/ standard coating pans, perforated coating pans and fluidized bed equipment.

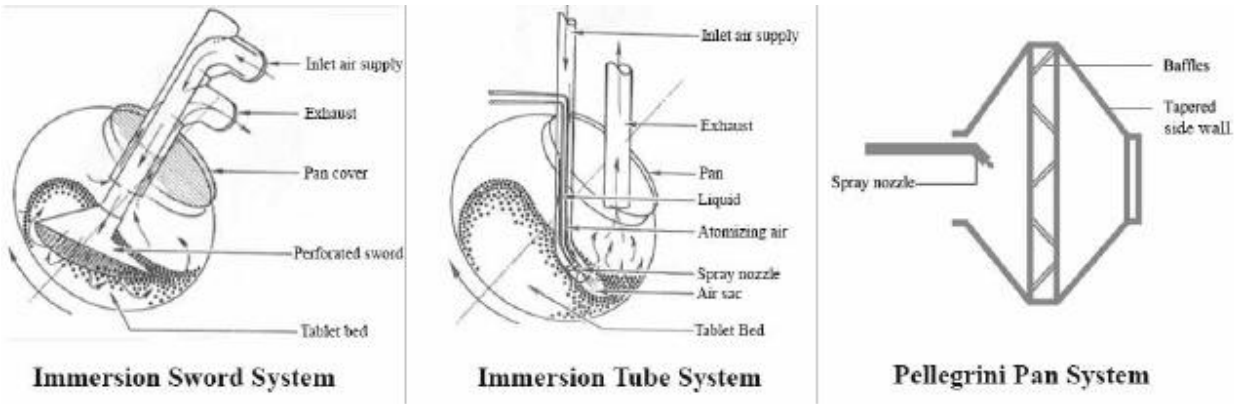
a. Conventional coating pans

The conventional coating pan system consists of a spherical, hexagonal. or pear-shaped pan that rotates on an inclined axis. The rotational movement of the pan causes the substrates to tumble and make multiple passes through the spray application zone. Heat is blown across the surface of the tumbling tablets and exhaust air is withdrawn.



Typical examples of such modifications include the design of conventional coating pans with

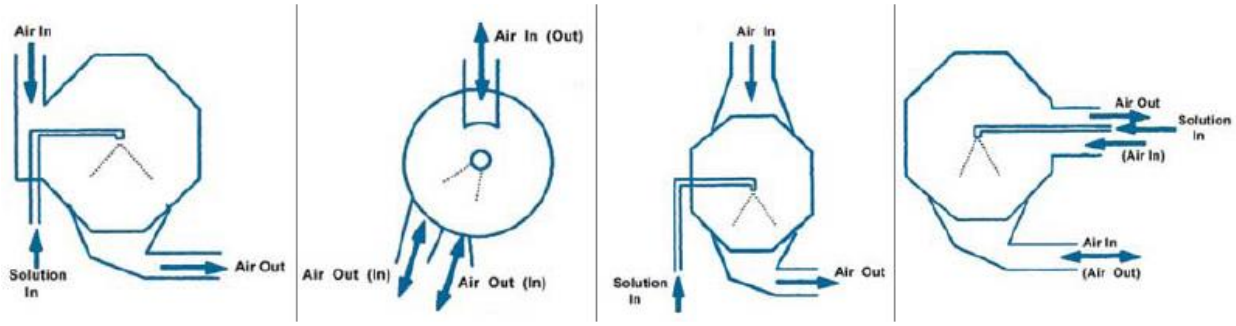
1. Immersion sword system
2. Immersion tube system
3. Baffled pan and diffuser (Pellegrini pan system)



b. Perforated coating pans

Perforated coating pan consists of a perforated or partially perforated drum that rotates on its horizontal axis in an enclosed housing. The equipment was developed to maximize the interaction between the tablet bed and the drying air, which it does by drawing the air through the tumbling product bed as opposed to supplying air to the bed surface only. Examples of perforated coating pans include:

1. Accela-cota (Thomas Engineering, USA)
2. Hi-coater (Freund-Vector Japan and USA)
3. Driacoater (Driam Metallprodukt GmbH, Germany)
4. Glatt perforated coating pan (Glatt., Switzerland, Germany and USA)
5. Huttlin Butterfly Pan, HBP (G S, Italy)
6. IDA Coating equipment (Dumoulin, France)



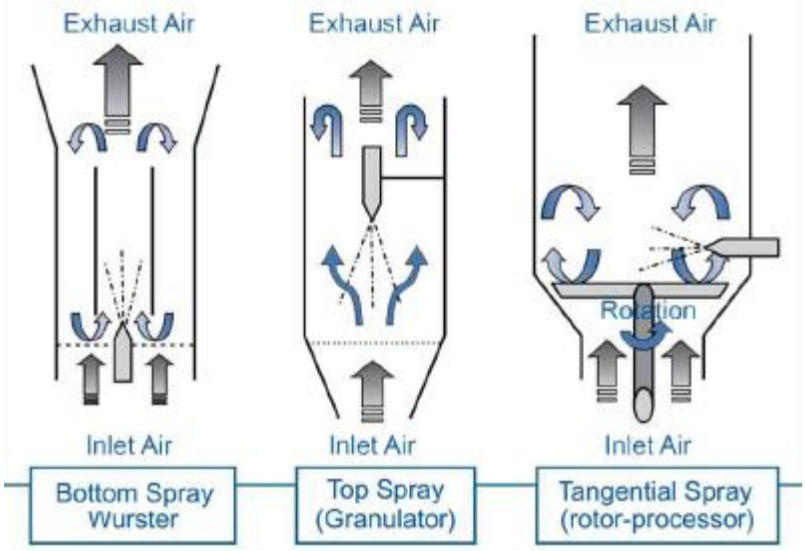
Various designs of perforated pans

c. Fluidized bed equipment

In a fluid bed system, the objects being coated are suspended in an upward stream of air, maximizing the surface available for coating. The coating is applied by an atomizer, and this is dried by the fluidizing air.

Film coating can be applied to the fluidized material by a variety of techniques –

1. Top spray (granulation or conventional mode)
2. Bottom spray (Wurster)
3. Tangential spray (rotary granulator)


Exhaust Air
Exhaust Air
Exhaust Air
Rotation
Inlet Air
Inlet Air
Inlet Air
Bottom Spray Wurster
Top Spray (Granulator)
Tangential Spray (rotor-processor)