

Manufacturing Defect of tablet



Capping

• Capping is the term used, when the upper or lower segment of the tablet separates horizontally during ejection from the tablet press, or during subsequent handling.



Formulation related		Machine related	
Causes	Remedies	Causes	Remedies
Large amount of fines in the granulation	Remove some or all fines through 100 to 200 mesh screen.	Poorly finished dies	Polish dies properly
Low moisture content.	Moisten the granules.	Deep concave punches.	Use flat punches
Insufficient amount of binder or improper binder.	Increasing or change the type of binder.	Lower punch remains below the face of die during ejection.	Make proper setting of lower punch during ejection
Insufficient or improper lubricant.	Increase or change the type of lubricant.	High turret speed	Reduce speed of turret

Lamination

• Lamination is the separation of a tablet into two or more distinct horizontal layers.



Normal tablet



Lamination

Formulation related

Machine related

Causes

Remedies

Causes

Remedies

Oily or waxy materials in granules.

Modify mixing process. Add adsorbent or absorbent

Rapid relaxation of the peripheral regions of a tablet, on ejection from a die.

Use tapered dies, i.e. upper part of the die bore has an outward taper of 3° to 5° .

Too much of hydrophobic lubricant.

Use a less amount of lubricant or change the type of lubricant.

Rapid decompression

Use pre-compression step. Reduce turret speed and reduce the final compression pressure.

Capping



Lamination



Chipping

Chipping' is defined as the breaking of tablet edges, while the tablet leaves the press or during subsequent handling



Formulation related		Machine related	
Causes	Remedies	Causes	Remedies
Sticking on punch faces	Dry the granules properly or increase lubrication.	Groove of die worn at compression point	Polish to open end, reverse or replace the die.
Too dry granules.	Moisten the granules	Barreled die (center of the die wider than ends)	Polish the die to make it cylindrical
Too much binding causes chipping at bottom.	Optimize binding, or use dry binders.	Edge of punch face turned inside/inward	Polish the punch edges
		Concavity too deep to compress properly	Reduce concavity of punch faces. Use flat punches.

Cracking

Small, fine cracks observed on the upper and lower central surface of tablets, or very rarely on the sidewall are referred to as Cracks.



Formulation related		Machine related	
Causes	Remedies	Causes	Remedies
Large size of granules.	Reduce granule size. Add fines.	Tablet expands on ejection due to air entrapment	Use tapered die.
Too dry granules.	Moisten the granules properly and add proper amount of binder.		
Tablets expand.	Add dry binders.		
Granulation too cold	Compress at room temperature		



Sticking

Sticking refers to the tablet material adhering to the die wall.

STICKING EXAMPLES



Formulation related

Machine related

Causes

Remedies

Causes

Remedies

Granules not dried properly

Dry the granules properly

Concavity too deep for granulation

Reduce concavity to optimum

Too little or improper lubrication

Increase or change lubricant

Too little pressure

Increase pressure

Too much binder

Reduce or use another binder.

Compressing is too fast.

Reduce speed

Oily or waxy materials

Modify mixing process. Add an absorbent

Too soft or weak granules

Optimize the amount of binder

Picking

Picking



Picking is a more specific term that describes product sticking only within the letters, logos, or designs on the punch faces.

Formulation related		Machine related	
Causes	Remedies	Causes	Remedies
Granules not dried properly	Dry the granules properly	Rough punch faces	Polish faces
Too little or improper lubrication	Increase or change lubricant	Dividing line is too deep	Reduce depths
Low melting point substances, may soften from the heat of compression.	Use high melting point lubricants.	Pressure applied is not enough	Increase pressure to optimum
Low melting point medicament in high concentration.	Refrigerate granules and the entire tablet press.		
Too warm granules when compressing	Cool sufficiently before compression.		
Too much amount of binder	Reduce or change binder.		

Mottling

Mottling is the term used to describe an unequal distribution of colour on a tablet.



The Causes And Remedies

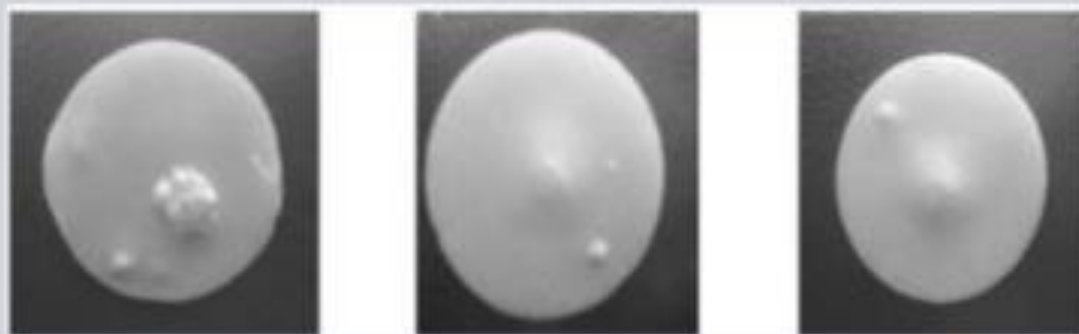
Causes	Remedies
A coloured drug used along with colourless or white-coloured excipients.	Use appropriate colourants.
A dye migrates to the surface of granulation while drying.	Change the solvent system, Change the binder, Reduce drying temperature and Use a smaller particle size.
Improperly mixed dye, especially during 'Direct Compression'.	Mix properly and reduce size if it is of a larger size to prevent segregation.
Improper mixing of a coloured binder solution.	Incorporate dry colour additive during powder blending step, then add fine powdered adhesives such as acacia and tragacanth and mix well and finally add granulating liquid.

PROBLEMS AND REMEDIES FOR TABLET COATING

❖ BLISTERING

It is local detachment of film from the substrate forming blister.

- **Reason:** Entrapment of gases in or underneath the film due to overheating either during spraying or at the end of the coating run



Causes

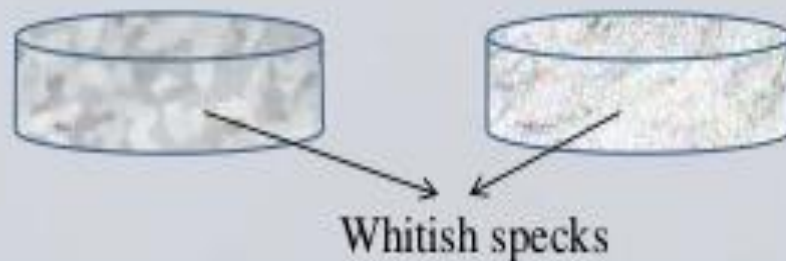
- Effect of temperature on the strength, elasticity and adhesion of the film.

Remedies

- ✓ Use mild drying condition.

❖ BLUSHING

- It is defect best described as whitish specks or haziness in the film
- **Reason:** It was thought to be due to precipitation of polymer worsened by the use of high coating temperature.



Causes

- High coating temperature.
- Use of sorbitol in formulation which causes largest fall in the thermal gelation temperature of the polymers

Remedies

- ✓ Decrease the drying air temperature.
- ✓ Avoid use of sorbitol with the polymers.

❖ STICKING AND PICKING

- Sticking involves sticking of the tablets with each other and with pan walls.
- Picking is the case of sticking involves adhering of some portion of coated layer to pan or to another tablet at the point of contact.



Causes

- Higher rate of application of coating solution
- Inefficient drying.

Remedies

- ✓ Use optimum and efficient drying conditions.
- ✓ Increase the inlet air temperature.
- ✓ Decrease the rater of application of coating solution by increasing viscosity of coating solution.

❖ TWINNING:

- This term is used when two tablets stick together.
- **Reason:** Common problem when shape of tablet is capsule shaped.



Causes

- Coating suspension can not be evaporated.

Remedies

- ✓ Reducing spray rate
- ✓ Increasing pan speed

❖ ORANGE PEEL/ROUGHNESS

- It is surface defect resulting in the film being rough and nonglossy. Appearance is similar to that of an orange.
- **Reason:** Inadequate spreading of the coating solution before drying



Causes

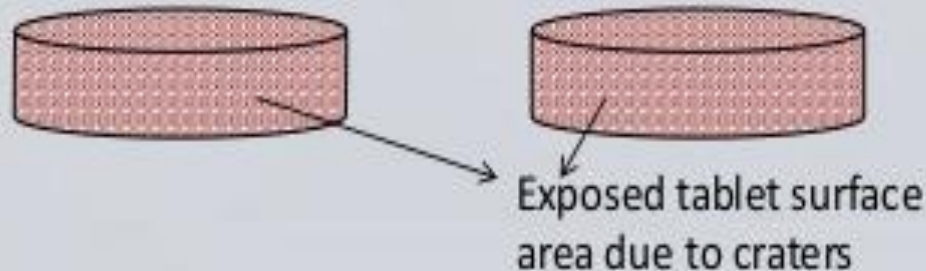
- Rapid Drying
- High solution viscosity

Remedies

- ✓ Use mild drying conditions.
- ✓ Use additional solvents to decrease viscosity of solution.

❖ CRATERING

- It is defect of film coating whereby volcanic-like craters appears exposing the tablet surface
- **Reason:** The coating solution penetrates the surface of the tablet, often at the crown where the surface is more porous, causing localized disintegration of the core and disruption of the coating.



Causes

- Inefficient drying.
- Higher rate of application of coating solution.

Remedies

- ✓ Use efficient and optimum drying conditions.
- ✓ Increase viscosity of coating solution to decrease spray application rate.

❖ COLOUR VARIATION:

- A defect which involves variation in colour of the film.
- **Reason:** Alteration of the frequency and duration of appearance of tablets in the spray zone or the size/shape of the spray zone.



Causes

- Improper mixing, uneven spray pattern, insufficient coating, migration of soluble dyes-plasticizers and other additives during drying.

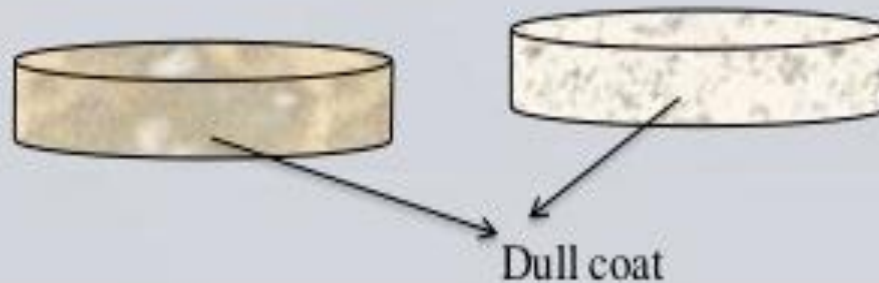
Remedies

- ✓ Go for geometric mixing, reformulation with different plasticizers and additives or use mild drying conditions.

❖ BLOOMING

It is defect where coating becomes dull immediately or after prolonged storage at high temperatures.

- **Reason:** It is due to collection on the surface of low molecular weight ingredients included in the coating formulation. In most circumstances the ingredient will be plasticizer.



Cause

- High concentration and low molecular weight of plasticizer.

Remedy

- ✓ Decrease plasticizer concentration and increase molecular weight of plasticizer.

❖ PITTING

It is defect whereby pits occur in the surface of a tablet core without any visible disruption of the film coating.

- **Reason:** Temperature of the tablet core is greater than the melting point of the materials used in the tablet formulation.



Causes

- Inappropriate drying (inlet air) temperature.

Remedies

- ✓ Modifying the drying (inlet air) temperature such that the temperature of the tablet core is not greater than the melting point of the batch of additives used.

Tablet weight



Sources of variation:

Product variation	Due to inconsistent powder density and particle size.
Machine condition	Due to a tablet press that is poorly prepared or operated are legion.
Tooling condition	Depending on punch working length.
Powder flow and feed rates	Not good flowability and irregular feed-rates.

A top-down view of a spiral-bound notebook with a white cover and lined pages. The notebook is open to a page with the words "ANY QUESTIONS?" written in a bold, hand-drawn style. "ANY" is written in black marker, and "QUESTIONS?" is written in blue marker. The notebook is placed on a textured, brown fabric surface. In the top-left corner, there is a white ceramic coffee cup filled with a golden-brown liquid. A blue marker with a black cap lies horizontally across the bottom of the notebook. A black smartphone is partially visible in the top-right corner. The entire scene is set against a white background with faint, repeating watermarks of a camera icon and the text "123RF".

ANY
QUESTIONS?