

Tablet Processing Problems and It's Remedies

Prof. S.S. Raut

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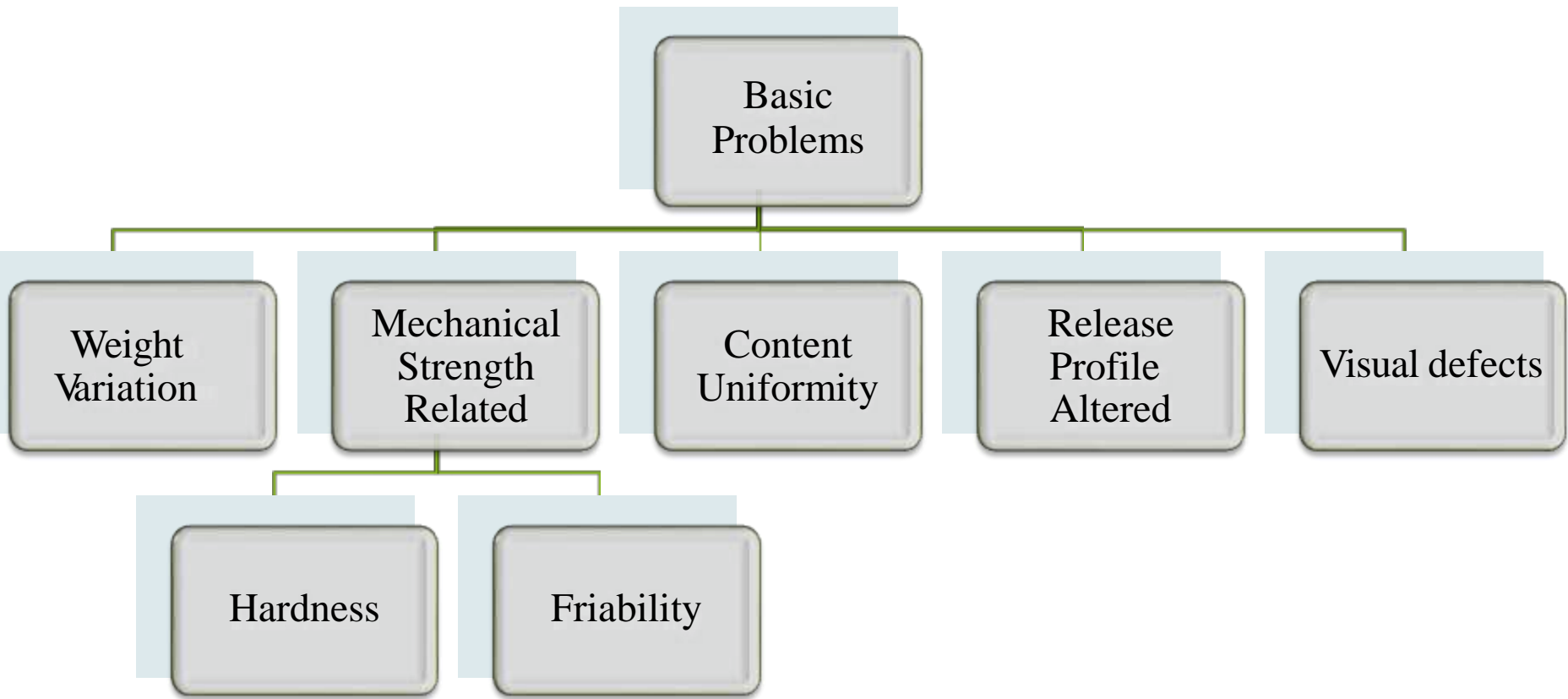
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INTRODUCTION

- An industrial pharmacist usually encounters number of problems during manufacturing.
- Majority of visual defects are due to inadequate fines or inadequate moisture in the granules ready for compression or due to faulty machine setting.
- Functional defects are due to faulty formulation.

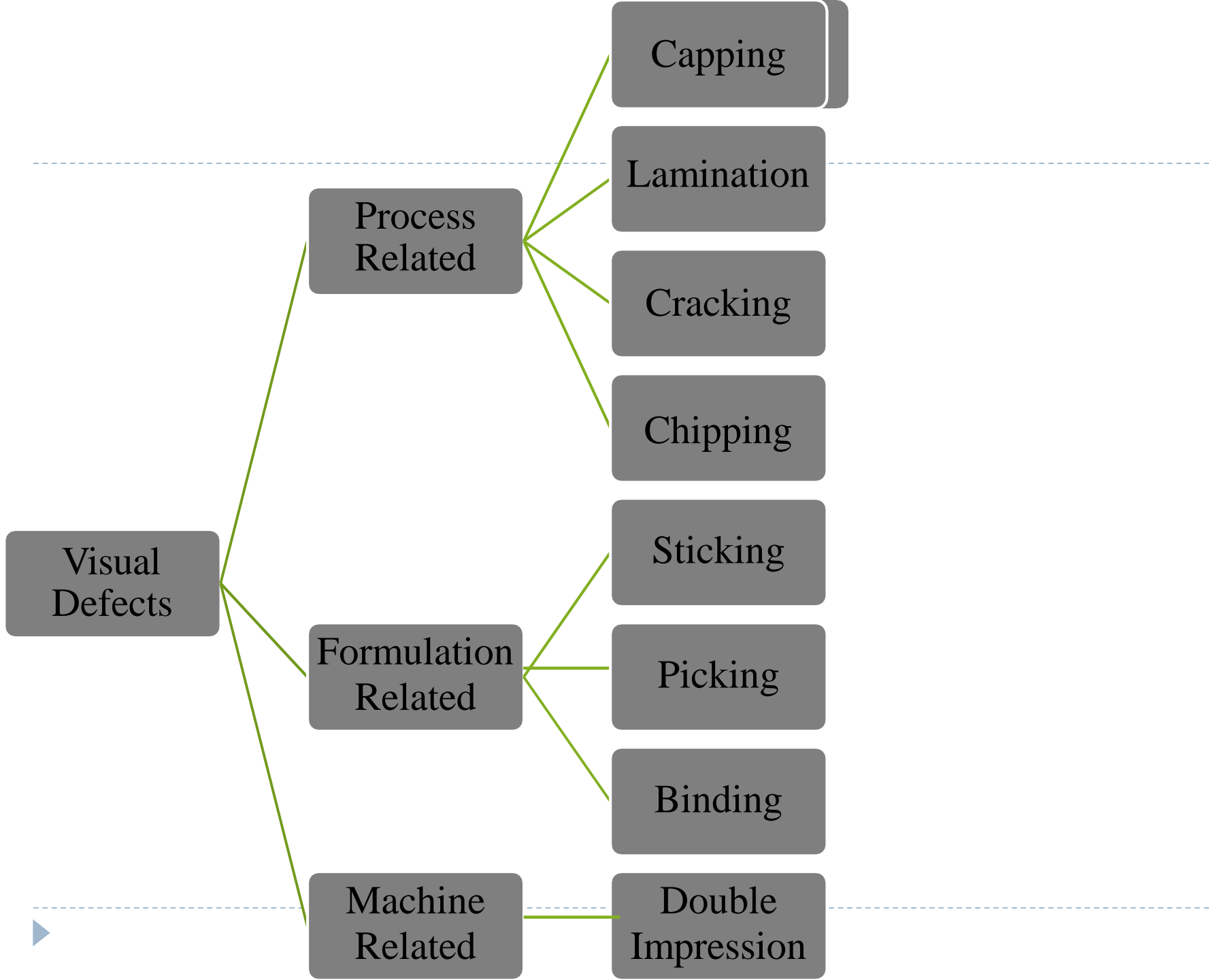




The Imperfections known as: **'VISUAL DEFECTS'** are either related to Imperfections in any one or more of the following factors:

- I. **Formulation design**
- II. **Tableting process**
- III. **Machine**





Capping

The upper or lower segment of the tablet separates horizontally, either partially or completely from the main body and comes off as a cap, during ejection from the tablet press, or during subsequent handling.

Reason:

Due to the air–entrapment in a compact during compression, and subsequent expansion of tablet on ejection of a tablet from a die.

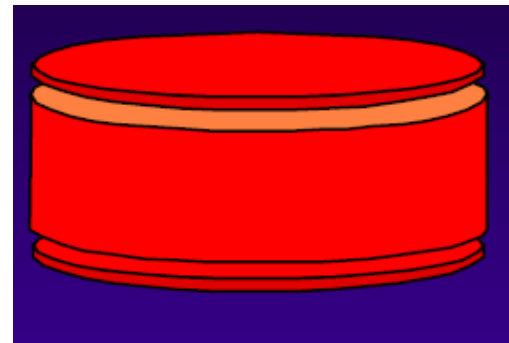


Fig: Capping

The Causes and Remedies of Capping related to 'Formulation'

Sr. No.	CAUSES	REMEDIES
1.	Large amount of fines in the granulation	Remove some or all fines through 100 to 200 mesh screen
2.	Too dry or very low moisture content (leading to loss of proper binding action).	Moisten the granules suitably. Add hygroscopic substance e.g.: Sorbitol, Methylcellulose or PEG-4000.
3.	Not thoroughly dried granules.	Dry the granules properly.
4.	Insufficient amount of binder or improper binder.	Increasing the amount of binder OR Adding dry binder such as pre-gelatinized Starch, Gum acacia, powdered Sorbitol, PVP, hydrophilic Silica or powdered Sugar.
5.	Insufficient or improper lubricant.	Increase the amount of lubricant or change the type of lubricant.
6.	Granular mass too cold to compress firm.	Compress at room temperature.

The Causes and Remedies of Capping related to 'Machine'

Sr. No.	CAUSES	REMEDIES
1.	Poorly finished dies	Polish dies properly. Investigate other steels or other materials.
2.	Deep concave punches or beveled-edge faces of punches.	Use flat punches.
3.	Lower punch remains below the face of die during ejection.	Make proper setting of lower punch during ejection.
4.	Incorrect adjustment of sweep-off blade.	Adjust sweep-off blade correctly to facilitate proper ejection.
5.	High turret speed.	Reduce speed of turret (Increase dwell time).



Lamination

Separation of a tablet into two or more distinct horizontal layers.

Reason:

- Air-entrapment during compression and subsequent release on ejection.
- The condition is exaggerated by higher speed of turret.

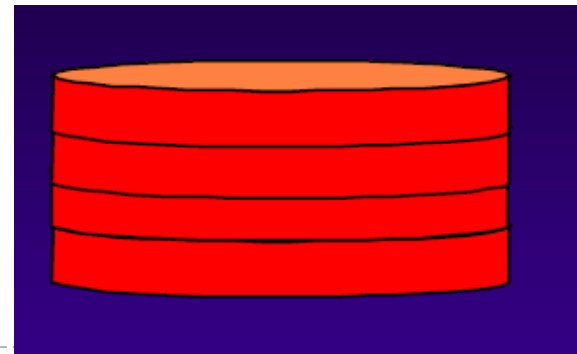


Fig: Lamination^[1]

The Causes and Remedies of Lamination related to 'Formulation'

Sr. No.	CAUSES	REMEDIES
1.	Large amount of fines in the granulation	Remove some or all fines through 100 to 200 mesh screen
2.	Too dry or very low moisture content (leading to loss of proper binding action).	Moisten the granules suitably. Add hygroscopic substance e.g.: Sorbitol, Methylcellulose or PEG-4000.
3.	Not thoroughly dried granules.	Dry the granules properly.
4.	Insufficient amount of binder or improper binder.	Increasing the amount of binder OR Adding dry binder such as pre-gelatinized Starch, Gum acacia, powdered Sorbitol, PVP, hydrophilic Silica or powdered Sugar.
5.	Insufficient or improper lubricant.	Increase the amount of lubricant or change the type of lubricant.



The Causes and Remedies of Lamination related to 'Machine'

Sr. No	CAUSES	REMEDIES
1.	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°.
2.	Rapid decompression	Use pre-compression step. Reduce turret speed and reduce the final compression pressure.

Chipping

Breaking of tablet edges, while the tablet leaves the press or during subsequent handling and coating operations.

Reason:

Incorrect machine settings, specially
Mis-set ejection take off.



The Causes and Remedies of Chipping related to 'Formulation'

Sr. No.	CAUSES	REMEDIES
1.	Sticking on punch faces	Dry the granules properly or increase lubrication.
2.	Too dry granules.	Moisten the granules to plasticize. Add hygroscopic substances.
3.	Too much binding causes chipping at bottom.	Optimize binding, or use dry binders.



The Causes and Remedies of Chipping related to 'Machine'

Sr. No.	CAUSES	REMEDIES
1.	Groove of die worn at compression point.	Polish to open end, reverse or replace the die.
2.	Barreled die (center of the die wider than ends)	Polish the die to make it cylindrical
3.	Edge of punch face turned inside/inward.	Polish the punch edges
4.	Concavity too deep to compress powder blend.	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'.

Reason:

It is observed as a result of rapid expansion of tablets, especially when deep concave punches are used.



The Causes and Remedies of Cracking related to 'Formulation'

Sr. No.	CAUSES	REMEDIES
1.	Large size of granules.	Reduce granule size. Add fines.
2.	Too dry granules.	Moisten the granules properly and add proper amount of binder.
3.	Tablets expand.	Improve granulation. Add dry binders.
4.	Granulation too cold.	Compress at room temperature.



The Causes and Remedies of Cracking related to 'Machine'

Sr. No.	CAUSES	REMEDIES
1.	Tablet expands on ejection due to air entrapment.	Use tapered die.
2.	Deep concavities cause cracking while removing tablets	Use special take-off.



Sticking

- Tablet material adhering to the die wall.
- Filming is a slow form of sticking and is largely due to excess moisture in the granulation.

Reason:

Improperly dried or improperly lubricated granules.



Fig: Sticking on punch face

The Causes and Remedies of Sticking related to 'Formulation'

Sr. No.	CAUSES	REMEDIES
1.	Granules not dried properly.	Dry the granules properly. Make moisture analysis to determine limits.
2.	Too little or improper lubrication.	Increase or change lubricant.
3.	Too much binder	Reduce the amount of binder or use a different type of binder.
4.	Hygroscopic granular material.	Modify granulation and compress under controlled humidity.
5.	Oily or waxy materials	Modify mixing process. Add an absorbent.



The Causes and Remedies of Sticking related to 'Machine'

Sr. No.	CAUSES	REMEDIES
1.	Concavity too deep for granulation.	Reduce concavity to optimum.
2.	Too little pressure.	Increase pressure.
3.	Compressing too fast.	Reduce speed.



Picking

- Small amount of material from a tablet is sticking to and being removed off from the tablet-surface by a punch face.
- The problem is more prevalent on the upper punch faces than on the lower ones.



Fig: Picking

Picking

Reason:

Picking is of particular concern when punch tips have engraving or embossing letters. Granular material is improperly dried.



The Causes and Remedies of Picking related to 'Formulation'

Sr. No.	CAUSES	REMEDIES
1.	Excessive moisture in granules.	Dry properly the granules, determine optimum limit.
2.	Too little or improper lubrication.	Increase lubrication; use colloidal silica as a 'polishing agent', so that material does not cling to punch faces.
3.	Low melting point substances, may soften from the heat of compression and lead to picking.	Add high melting-point materials. Use high melting point lubricants.
4.	Low melting point medicament in high concentration.	Refrigerate granules and the entire tablet press.
5.	Too warm granules when compressing.	Compress at room temperature. Cool sufficiently before compression.
6.	Too much amount of binder.	Reduce the amount of binder, change the type or use dry binders.



The Causes and Remedies of Picking related to 'Machine'


Sr. No.	CAUSES	REMEDIES
1.	Rough or scratched punch faces.	Polish faces to high luster.
2.	Embossing or engraving letters on punch faces such as B, A, O, R, P, Q, G.	Design lettering as large as possible. Plate the punch faces with chromium to produce a smooth and non-adherent face.
3.	Bevels or dividing lines too deep.	Reduce depths and sharpness.
4.	Pressure applied is not enough; too soft tablets.	Increase pressure to optimum.



Binding

- Sticking of the tablet to the die and does not eject properly out of the die.
- Tablets adhere, seize or tear in the die.
- A film is formed in the die and ejection of tablet is hindered.
- With excessive binding, the tablet sides are cracked

Reason:

- Usually due to excessive amount of moisture in granules,
 - lack of lubrication and/or use of worn dies.
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The Causes and Remedies of Binding related to 'Formulation'

Sr. No.	CAUSES	REMEDIES
1.	Too moist granules and extrudes around lower punch.	Dry the granules properly.
2.	Insufficient or improper lubricant.	Increase the amount of lubricant or use a more effective lubricant.
3.	Too coarse granules.	Reduce granular size, add more fines, and increase the quantity of lubricant.
4.	Too hard granules for the lubricant to be effective.	Modify granulation. Reduce granular size.
5.	Granular material very abrasive and cutting into dies.	If coarse granules, reduce its size. Use wear-resistant dies.
6.	Granular material too warm, sticks to the die.	Reduce temperature. Increase clearance if it is extruding.

The Causes and Remedies of Binding related to 'Machine'

Sr. No.	CAUSES	REMEDIES
1.	Poorly finished dies.	Polish the dies properly.
2.	Rough dies due to abrasion, corrosion.	Investigate other steels or other materials or modify granulation.
3.	Undersized dies. Too little clearance.	Rework to proper size. Increase clearance.
4.	Too much pressure in the tablet press.	Reduce pressure. OR Modify granulation.

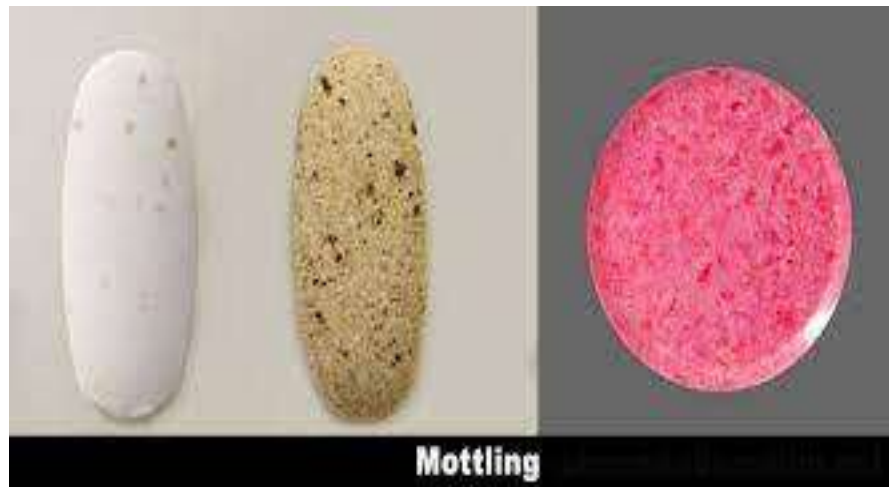


Mottling

Unequal distribution of color on a tablet, with light or dark spots.

Reason:

Colored drug, whose color differs from the color of excipients used for granulation of a tablet.



Mottling

Sr. No.	CAUSES	REMEDIES
1.	A coloured drug used along with colourless or white- coloured excipients.	Use appropriate colourants.
2.	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.
3.	Improperly mixed dye, especially during 'Direct Compression'.	Mix properly and reduce size if it is of a larger size to prevent segregation.
4.	Improper mixing of a coloured blending binder solution.	Incorporate dry colour additive during powder step, then add fine powdered adhesives such as acacia and tragacanth and mix well and finally add

Double Impression

- Involves only those punches, which have a monogram or other engraving on them.
- If the upper punch is uncontrolled, it can rotate during the short travel to the final compression stage and create a double impression.



Double Impression

- Receives the imprint of the punch.
- The lower punch freely drops and travels uncontrolled for a short distance before riding up the ejection cam to push the tablet out of the die
- Now during this free travel, the punch rotates and at this point, the punch may make a new impression on the bottom of the tablet, resulting in 'double impression'.



The Causes and Remedies of Double Impression

Sr. No.	CAUSE	REMEDIES
1.	Free rotation of either upper punch or lower punch during ejection of a tablet.	-Use keying in tooling, i.e. inset a key alongside of the punch, so that it fits the punch and prevents punch rotation. -Newer presses have anti-turning devices, which prevent punch rotation.



Thank You

