

MODULE 2:Tablets
Lecture 3

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DISCLAIMER

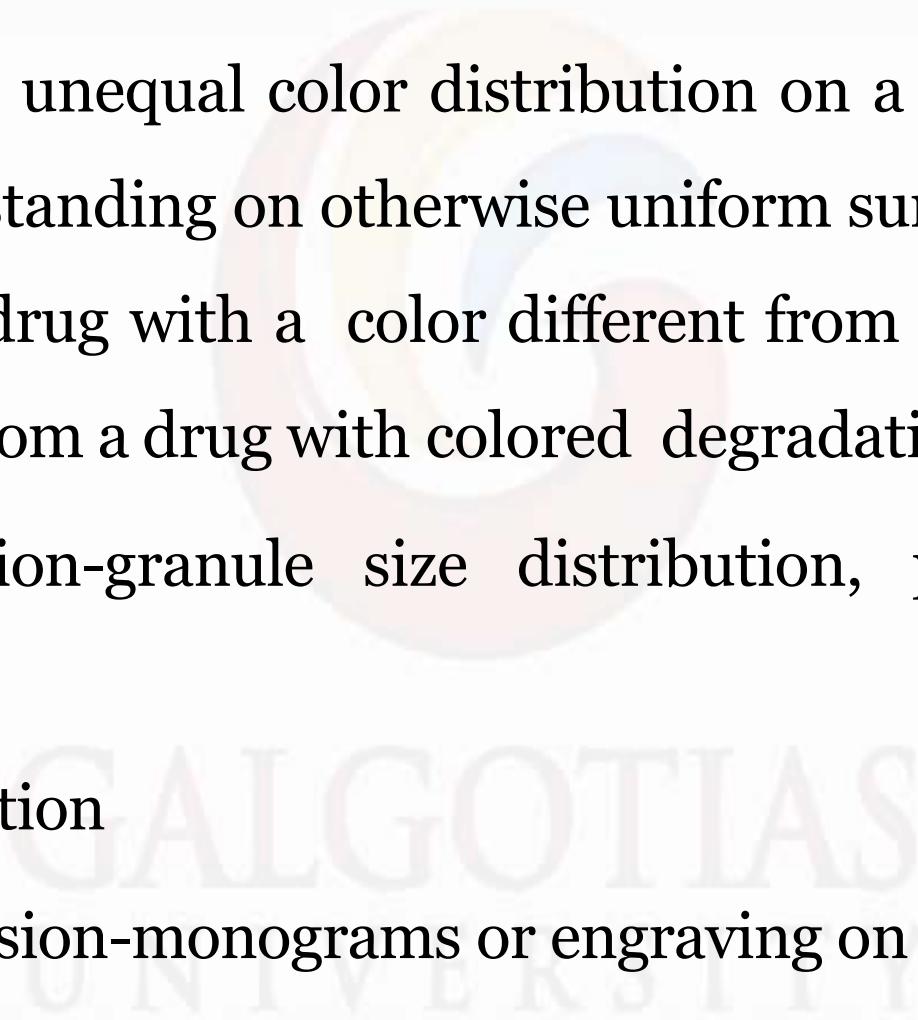
All the content material provided here is only for teaching purpose

The logo of Galgotias University is a stylized, circular emblem. It features a central white swirl that transitions into a blue swirl, which then transitions into a yellow swirl, and finally into a red swirl. The entire emblem is set against a light blue background.

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Processing problems

- ❑ **Capping** is the partial or complete separation of the top or bottom crowns of a tablet from the main body of the tablet.
- ❑ **Lamination** is separation of a tablet into two or more distinct layers. Both of these problems usually result from air entrapment during processing.
- ❑ **Picking** is removal of a tablet's surface material by a punch.
- ❑ **Sticking** is adhesion of tablet material to a die wall. These two problems result from excessive moisture or substances with low melting temperatures in the formulation



- ❑ **Mottling** is an unequal color distribution on a tablet, with light or dark areas standing on otherwise uniform surface. This results from use of a drug with a color different from that of the tablet excipients or from a drug with colored degradation products.
- ❑ Weight variation-granule size distribution, poor flow,punch variation
- ❑ Hardness variation
- ❑ Double impression-monograms or engraving on punch

Capping



The Causes and Remedies of Capping related to ‘Formulation’

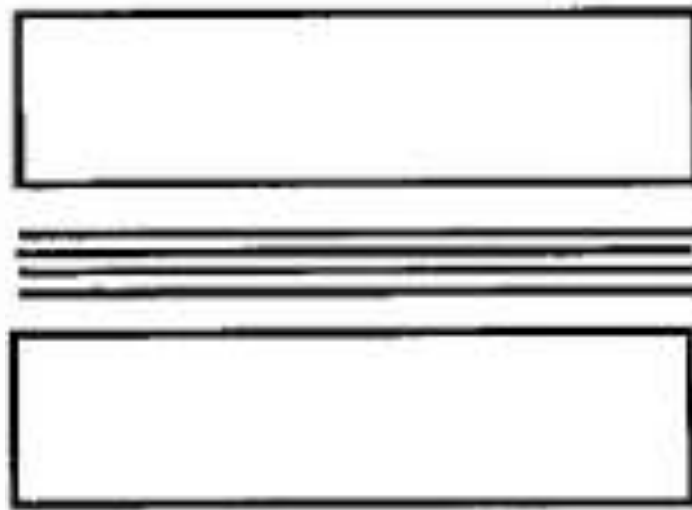
Sr. No.	CAUSES	REMEDIES
1.	Large amount of fines in the granulation	Remove some or all fines through 100 to 200 mesh screen
2.	Too dry or very low moisture content (leading to loss of proper binding action).	Moisten the granules suitably. Add hygroscopic substance e.g.: Sorbitol, Methylcellulose or PEG-4000.
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.

Lamination

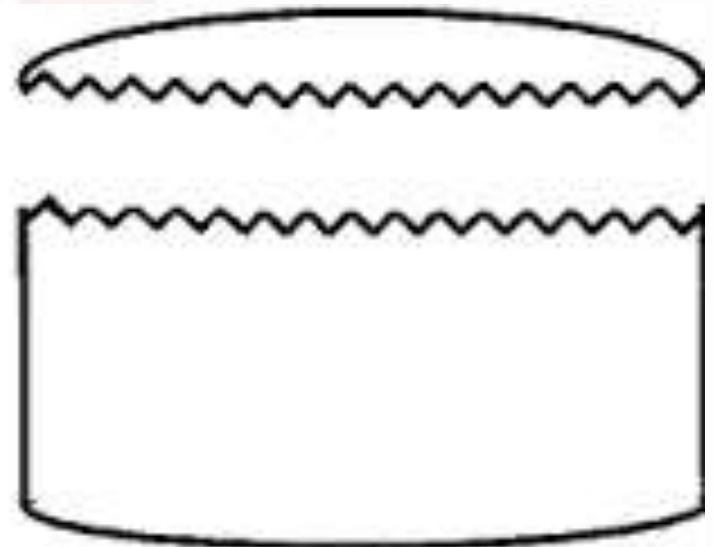


The Causes and Remedies of Lamination related to 'Formulation'

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.



(a) Lamination




(b) Capping

Sticking & Picking



The Causes and Remedies of Sticking



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.

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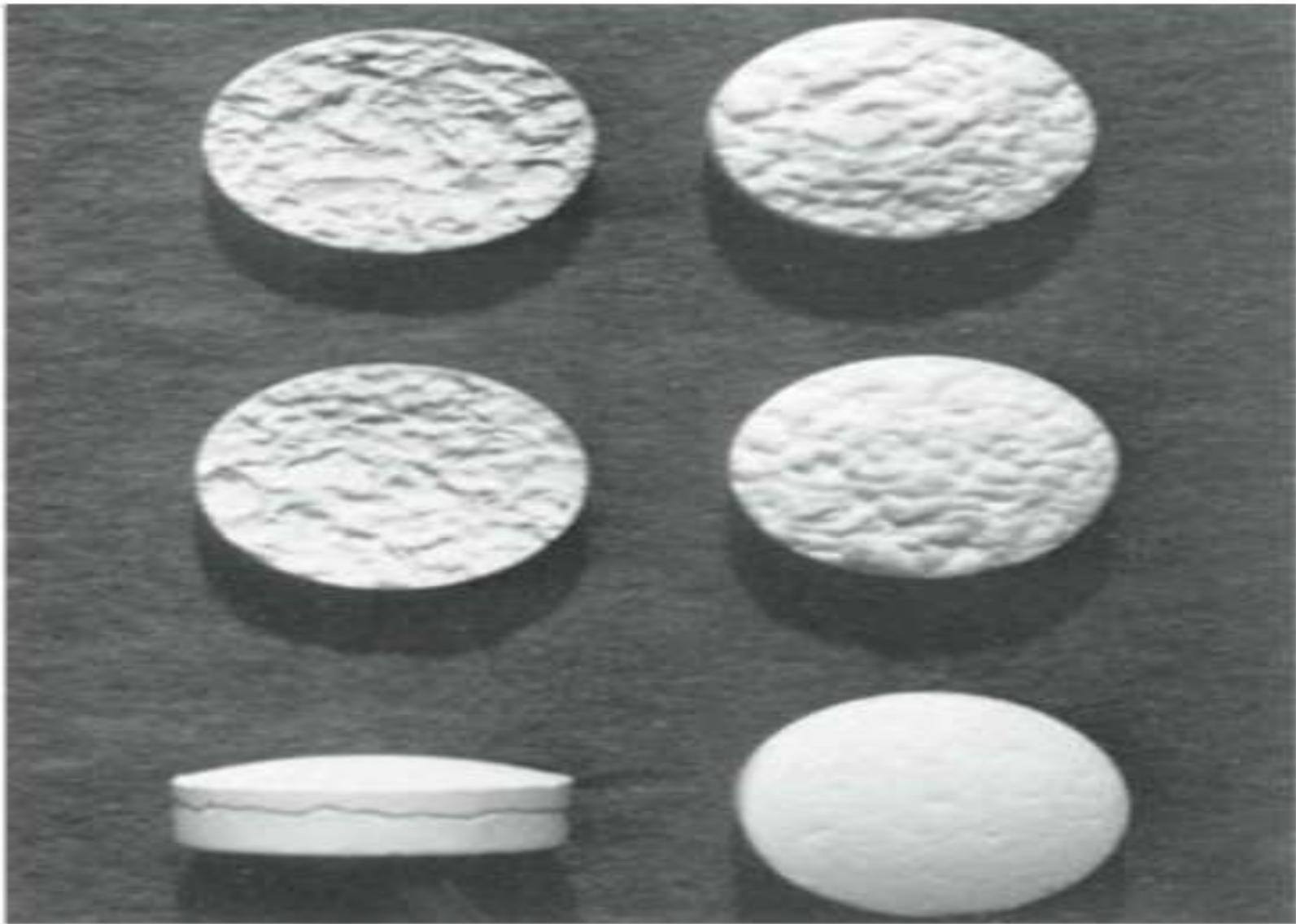


FIGURE 8.27 Tablets that have split on aging because of conditions of manufacture or storage.

The Causes and Remedies of Chipping

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.

The Causes and Remedies of Cracking related to 'Formulation'

Sr. No.	CAUSES	REMEDES
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.

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 Picking

Sr.	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

Sr. No.	CAUSES	REMEDES
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.

The Causes and Remedies of Binding

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.

References

- The theory and practice of Industrial pharmacy, by Leon Lachmann and Herbert A.Lieberman,3rd edition, Page no: 294 to 336.
- Kibbe, A.H., ed. Handbook of Pharmaceutical Excipients. 3rd Edition ed. 2000, American Pharmaceutical Association & Pharmaceutical Press: Washington, DC & London, UK.