

Tablet Processing Defects & Their Remedies

By

Swarnakshi Upadhyay

Assistant Professor

School of Pharmaceutical Sciences

CSJM University

Introduction



A tablet is a solid dosage form. It comprises a mixture of active substances and excipients, usually in powder form, which is pressed or compacted from a powder into a solid dose.



An ideal tablet should be free from any visual defect or functional defect. Defects in tablet are related to imperfections in any one or more of the following factors:

Tableting Process

Formulation

Machine

Tablet defects



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.

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.	Deep concavities cause cracking while removing tablets	Use special take-off
Tablets expand.	Add dry binders.		
Granulation too cold	Compress at room temperature		

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.

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

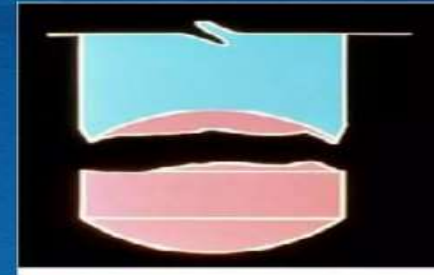
Picking



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.		

Binding

Sticking of the tablet to the die and does not eject properly out of the die



Formulation related		Machine related	
Causes	Remedies	Causes	Remedies
Too moist granules.	Dry the granules properly.	Poorly finished dies.	Polish the dies properly.
Insufficient or improper lubricant.	Increase or change lubricant	Rough dies due to abrasion, corrosion.	Investigate other steels.
Too coarse granules.	Reduce granular size.	Undersized dies	Rework to proper size.
Too hard granules for the lubricant to be effective.	Modify granulation. Reduce granular size.	Too much pressure in the tablet press.	Reduce pressure.
Granular material too warm.	Reduce temperature.		

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.

Double impression

It is due to free rotation of punches which have some engraving or monogram on the punch faces. During his 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

Causes	Remedies
Free rotation of either upper punch or lower punch during ejection of a tablet.	<ul style="list-style-type: none">-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.

Problems and remedies for tablet coating

Problem	Definition	Causes	Remedy
BLISTERING	It is local detachment of film from the substrate forming blister.	Effect of temperature on the strength, elasticity and adhesion of the film.	Use mild drying condition.
CRATERING	It is defect of film coating whereby volcanic-like craters appears exposing the tablet surface	Inefficient drying. Higher rate of application of coating solution.	Use efficient and optimum drying conditions. Increase viscosity of coating solution to decrease spray application rate.
PICKING AND STICKING	It is It is defect where isolated areas of film are pulled away from the surface when the tablet sticks together or to the pan and then detached from one another or from the pan.	Inefficient drying. Higher rate of application of coating solution.	Increase the inlet air temperature Decrease the rate of application of coating solution.

Problems and remedies for tablet coating

Problem	Definition	Causes	Remedy
PITTING	It is defect whereby pits occur in the surface of a tablet core without any visible disruption of the film coating	Inappropriate drying (inlet air) temperature	Increase the drying (inlet air) temperature
BLOOMING	It is defect where coating becomes dull immediately or after prolonged storage at high temperatures	High concentration and low molecular weight of plasticizer.	Decrease plasticizer concentration and increase molecular weight of plasticizer.
COLOR VARIATION	A defect which involves variation in colour of the film.	Improper mixing, uneven spray pattern, insufficient coating, migration of soluble dyes-plasticizers and other additives during drying.	Go for geometric mixing, reformulation with different plasticizers and additives or use mild drying conditions.

Problems and remedies for tablet coating

Problem	Definition	Causes	Remedy
ORANGE PEEL EFFECT	It is surface defect resulting in the film being rough and non glossy. Appearance is similar to that of an orange.	Rapid Drying High solution viscosity	Use mild drying conditions. Decrease viscosity of solution.
BRIDGING	This occurs when the coating fills in the lettering or logo on the tablet	<ul style="list-style-type: none"> •High spray rate •High viscosity of solution, •High percentage of solids in the solution, •Improper atomization pressure. 	<ul style="list-style-type: none"> •Reduce spray rate •Reduce viscosity •Reduce percentage of solid •Use proper atomization pressure
CRACKING or SPLITTING	It is defect in which the film either cracks across the crown of the tablet (cracking) or splits around the edges of the tablet (Splitting).	Use of higher molecular weight polymers or polymeric blends.	Use lower molecular weight polymers or polymeric blends. Also adjust plasticizer type and concentration.

