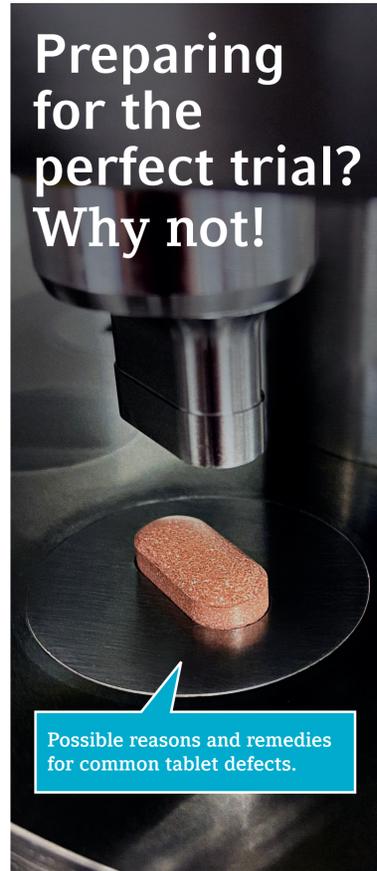


Troubleshooting Guide Tableting



Problem	Capping & Lamination	Sticking to punches	Cracking	Chipping	Binding
Description	Horizontal splitting of tablet at the top (capping) or anywhere but the top (lamination)	Granulate of a formulation is sticking to the face of the press punch	Small, fine cracks observed on the upper and lower surface or on the sidewall	Occurs when the edges of the tablets break during the press process or during the handling and coating	The term is used when the tablets adhere, seize, or tear in the die
Possible reason	<ul style="list-style-type: none"> - Too many fine particles in the granulate - Separation of the granulate - Too much of hydrophobic lubricant - No suitable lubricant - Not enough or not suitable binder - Low moisture content - API content too high - Compression force too high - Speed of the tablet press too high - Too much air trapped in the pre-compression - Tablet press tool defective 	<ul style="list-style-type: none"> - The granulate was not completely dried - Lubricant content too low - Too much binder used - Oily or waxy materials used - Too soft or weak granulates - Compression too high or too low - The product became too warm - Rough or scratched punch faces 	<ul style="list-style-type: none"> - The granulate is too large - The granulate is too dry - Tablets expand - Granulation too cold - Tablet expands on ejection due to air entrapment 	<ul style="list-style-type: none"> - Sticking on punch faces - Too dry granulate - Too much binding causes chipping at bottom - Edge of punch face turned inside/inward - Concavity too deep to compress properly 	<ul style="list-style-type: none"> - Too much moisture in the granulate - Too little lubricant in the granulate - Granulate too hard for the lubricant to be effective - Granulate material sticks to the die - Punch is not suitable anymore
Remedy	<ul style="list-style-type: none"> - Change the quantities in the granulate - Use enough and an efficient binding agent - Adjust used lubricant - Add adsorbent agent - Moisturize or dry the granulates - Reduce amount of API - Adjust the pressure for compression (use pre-compression) - Decrease speed of the tablet press - Use more suitable punches (conical) 	<ul style="list-style-type: none"> - Completely dry the granulate - Use enough and an efficient lubricant - Add suitable binder - Modify mixing process and add an adsorbent - Adjust the compression force - Produce a thinner tablet (height) - Polish the surface of the punch 	<ul style="list-style-type: none"> - Reduce granulate size by adding more fine particles - Moisturize or dry the granulate and add binder - Improve granulation, add dry binders - Adjust ambient temperature - Use conical die 	<ul style="list-style-type: none"> - Use suitable binding agent or use dry binders - Dry the granulate properly or increase lubricant - Add hygroscopic substances - Reduce concavity of punch faces - Use flat punches - Polish the punch edges 	<ul style="list-style-type: none"> - Increase drying time of the granulate - Use enough and an efficient lubricant - If too warm, reduce temperature - Increase space for ejection - Replace punch

Problem	Weight variations	Tablet hardness	Friability	Mottling of tablet	Prolonged dissolution/disintegration
Description	High variation of tablet weight	Tablet breaks during ejection or handling of the tablets	High degree of abrasion after mechanical stress	Is used to describe an inhomogeneous distribution of color in a tablet	API is not released within required time
Possible reason	<ul style="list-style-type: none"> - High variation in granulate density - Die not completely filled - High variation of granulate particle size - Flowability insufficient - Press speed too high/filling time too short 	<ul style="list-style-type: none"> - Variation in bulk density - Inhomogeneity of granulate particle size - Tablet hardness varies with the weight of the tablet - The ejection blade is too old or damaged 	<ul style="list-style-type: none"> - Too large particles in the granulate break apart at higher compression forces - Entrapped air can cause the tablet to break apart - Tablet breaks during ejection - Lower compression may not be enough to bind particles together 	<ul style="list-style-type: none"> - A colored drug used along with colorless or white-colored excipients - A dye migrates to the surface of granulate while drying - Improperly mixed dye, especially during direct compression - Improper mixing of a colored binder solution 	<ul style="list-style-type: none"> - Too much binder - No disintegrant - Too hard compression force used - No water soluble excipients are used
Remedy	<ul style="list-style-type: none"> - Weight differences can be reduced by granulation and compaction - Avoid free fall of the granulate (to prevent decomposition) - Use flowing enhancers to optimize flowability of the granulate or powder blend - Reduce press speed / increase filling time 	<ul style="list-style-type: none"> - Achieve homogeneous bulk density - Use enough and an efficient binding agent - Control the tablet weight - Use suitable ingredients for good compacting properties - Increase the compression force - The eject blade must be checked or replaced 	<ul style="list-style-type: none"> - Powder should be more cohesive - Use enough and an efficient binding agent - Use suitable binders - Control tablet weight - Slowing the press will extend dwell time and give the air more time to escape - Control settings on tableting machine - Check tableting tool 	<ul style="list-style-type: none"> - Use suitable colorants - Change the solvent system & binder - Reduce drying temperature and aim for smaller particle size for granulate - Mix properly and reduce particle size to prevent decomposition - Incorporate dry color additive during powder blending step, then add fine powdered adhesives and mix properly – finally add granulating liquid 	<ul style="list-style-type: none"> - Use less binder - Use disintegrant or superdisintegrant - Decrease compression force - Reformulate or use proper disintegrant

 = The problem can be solved by adjusting the machine settings.

More support?
Why not!
Contact us.

M technicalservice@biogrund.com
T +49 (0) 6126-952 63-0 Europe
T +1 (502) 901-2980 United States
T +7 (495) 116-0386 Russia