

## Compliance Case Study #7—Broken Punches in Tablet Compressing

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This case study describes manufacturing of a tablet product in which an abrupt and unexpected change in the manufacturing process occurred. Tablet compressing became extremely difficult including breakage of tablet compressing punches. Potential causes for the problem to be investigated were identified. The observations of manufacturing operators regarding a change in the physical properties of the granulation were key to initiating the direction of the investigation. Particle size distribution data confirmed these observations. Actual observations of the manufacturing process by technicians...

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