Macedonian Pharmaceutical Bulletin, 72 (Suppl 1) 129 - 130 (2026)
Online ISSN: 1857-8969
DOI: 10.33320/maced.pharm.bull.2026.72.03.062
Short communication

Scale-up of tablet compression process and its impact on tablet CQAs

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Introduction

Tablet compression represents a critical stage in pharmaceutical solid dosage manufacturing, significantly influencing product quality attributes and process efficiency.

Equipment-related parameters, particularly dwell time, compression speed and machine configuration, can affect tablet characteristics and overall process robustness.

Implementation of high-speed tablet compression equipment provides advantages regarding manufacturing efficiency, production capacity and operational performance.

Nevertheless, transition between compression equipment may alter process conditions and influence tablet physical properties due to changes in compression dynamics and dwell time conditions.

During scale-up and transition from conventional to higher-speed tablet compression equipment, dwell time becomes a critical factor since increased compression speed may alter powder densification behavior and consequently affect critical tablet quality attributes and process robustness.

Dwell time, defined as the period during which the powder bed remains exposed to compression force, represents an important parameter influencing particle rearrangement, densification behavior and interparticle bonding.

Consequently, changes in dwell time may affect tablet physical characteristics such as mass, thickness, hardness and mechanical integrity.

In pharmaceutical manufacturing, successful equipment transfer requires optimization to maintain process robustness and ensure preservation of critical quality attributes under modified operating conditions.

The aim of this study was to evaluate the influence of equipment transition and modified dwell time conditions on process robustness and tablet quality attributes.

Materials and methods

Tablet compression trials were performed during transition from a conventional tablet compression platform Horn Noack to higher-capacity compression equipment Fette 2090i in order to improve manufacturing efficiency and increase production throughput.

The influence of equipment transition and the reduced dwell time was evaluated regarding: tablet thickness; tablet weight uniformity; compression performance; process stability; operational efficiency and manufacturing robustness.

Process performance was monitored using in-process controls and manufacturing observations performed during compression trials under initial and optimized operating conditions.

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Assessment included evaluation of tablet physical properties and process behavior before and after optimization activities associated with equipment transfer.

Results and discussion

Compression performed using the existing manufacturing tablet press demonstrated satisfactory process performance under standard operating conditions. However, the transition to higher-capacity compression equipment required process adaptation due to altered compression dynamics and reduced dwell time.

Implementation of the new compression platform led to enhanced manufacturing efficiency and increased production throughput. At the same time, modified dwell time conditions influenced powder densification behavior during compression.

Comparative evaluation indicated that the transition to high-speed compression equipment resulted in decreased tablet thickness of approx. 7% (4.87–5.08 mm) relative to the previously utilized equipment (5.24-5.45 mm), consistent with reduced dwell time conditions. Process adaptation included optimization of compression force and tablet press speed in order to achieve target tablet hardness (7-15 kP) under altered dwell time conditions during scale-up to higher- speed compression equipment.

Based on the process parameters, the dwell time was calculated to be approximately 0.030-0.032 s for the Horn Noack press and approximately 0.022-0.023 s for the Fette 2090i press indicating a 30% longer compression dwell on the Horn.

No significant impact on mass uniformity was observed. All batches complied with predefined friability and disintegration requirements, confirming that these critical quality attributes remained within acceptable limits. Furthermore, the results demonstrate that appropriate process adaptation ensured preservation of product quality and supported revision of in-process control limits.

These findings highlight the importance of dwell time during equipment transition in order to maintain target product characteristics. Overall, optimization of compression parameters improved process stability and ensured consistent tablet quality despite increased compression speed and modified dwell time conditions.

Conclusion

Transition to higher-capacity tablet compression equipment is an effective strategy for improving manufacturing efficiency and production performance; however, the difference in dwell time may influence tablet quality attributes and compression behavior.

This study demonstrated that optimization of compression conditions during equipment transition contributed to improved process robustness and enabled successful adaptation to modified compression dynamics.

The findings confirm the importance of well time consideration during equipment transfer and optimization activities in pharmaceutical tablet manufacturing and support its role as a critical process parameter during implementation of high-speed compression processes.

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