

# Jordan University of Science and Technology

## Modification of alpha-lactose monohydrate as a direct compression excipient using roller compaction

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**Abstract:** Roller compaction was used to prepare a direct-compressed lactose excipient using crystalline  $\alpha$ -lactose monohydrate. The effect of various roller compaction process parameters (compaction pressure, compaction repetition, and speed ratio) on the characteristics of compacted  $\alpha$ -lactose monohydrate was investigated. Results were compared with data obtained using industrial spray-dried lactose and lactose samples with different degrees of crystallinity. XRPD analysis revealed that roller compaction reduced the crystallinity of  $\alpha$ -lactose monohydrate, and the resulting material is similar to spray-dried lactose in behavior as a direct compression excipient. Roller compaction introduced desirable characteristics to the raw  $\alpha$ -lactose monohydrate by inducing changes in crystallinity and particle morphology. Scanning electron microscopy results indicated that the compaction process converted some of the original torpedo-shaped crystals of  $\alpha$ -lactose monohydrate into a more cylindrical shape with rounded edges. Compaction pressure and repetition of compaction have a significant effect on the modification of the crystallinity of the processed, raw  $\alpha$ -lactose monohydrate.