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Optimizing Tablet Formulation through Integrated Use of Digital Formulation Tools and Compaction Simulation

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PURPOSE

The aim of this study was to optimize the formulation and production process of pharmaceutical tablets using an integrated approach involving algorithm-based formulation tool (ZoomLab®) and a compaction simulator (STYL'One Evo).

This comprehensive workflow was designed to enhance tablet quality and manufacturability by leveraging cutting-edge digital and experimental tools and techniques.

METHOD(S)

Ibuprofen 70 was used as the model drug in this study, characterized for particle size distribution (PSD), flow (angle of repose), and tabletability.

A free online tool, ZoomLab®, predicted the processability of ibuprofen and Kollitab DC 87L blends at various drug loadings. The tool used single-component data to predict blend properties.

A compaction simulator, STYL'One Evo, employed direct compression—blending powders without granulation—at 20% and 30% drug loading (DL) to form 10 mm round tablets, each weighing approximately 400 mg. Tabletability was assessed using the compaction simulator, following USP 1062 guidelines.

This integrated workflow enables precise adjustments to achieve optimal tablet quality.

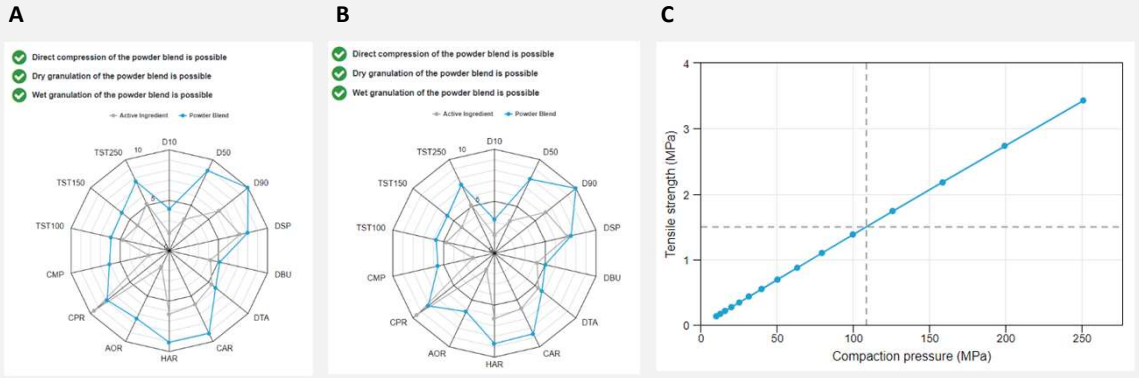

Figure 1 Predicted processability of the co-processed and ibu blend using algorithm-based tool: A) at 20% drug loading and B) 30% drug loading and C) Tabletability Profile at 30% drug loading

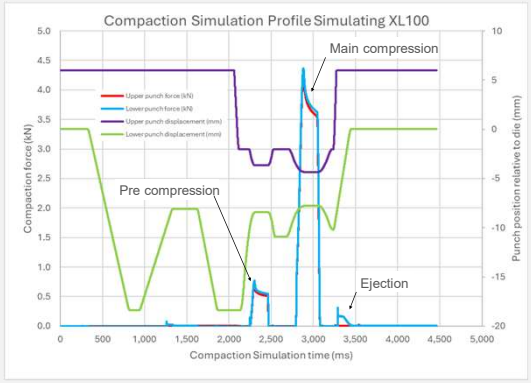

Figure 2: The compaction profile of a KORSCH XL 100 R & D rotary press simulated on the STYL'One Evo Compaction Simulator. The precompression, main compression, and ejection forces are illustrated in the lower punch force trace.

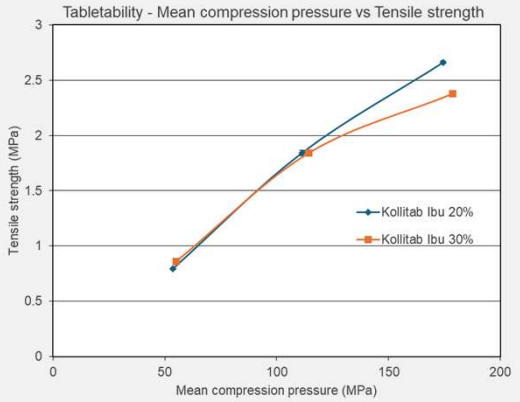

Figure 3: Tabletability profile of Ibu tablets using compaction simulator

RESULT(S)

This study uses Kollitab® DC 87L (a co-processed excipient with lactose, Kollicoat® IR, Kollidon® CL-F, and sodium stearyl fumarate) for a blend with excellent flowability, compressibility, and lubrication. The digital formulation tool identified the drug developability classification system (DCS) and predicted powder blend processability for direct compression (DC). It projected processability scores of 7.3 at 20% and 7.0 at 30% drug loading (DL), with values between 5-10 being good for DC.

Experimental runs were based on these predictions. At 114 MPa, the tensile strength was around 1.7 MPa for both DLs, matching experimental results. The compaction simulator revealed declining tablet strength at higher DLs, aligning with the predictions. Discrepancies arose at higher pressures due to increased Ibu concentration.

Ultimately, the digital tool and simulator provided valuable insights for formulation optimization.

CONCLUSION(S)

The integration of digital formulation tools and compaction simulation effectively optimized tablet formulations, achieving desired quality attributes while reducing development time and costs. This study highlights the benefits of combining digital tools with experimental techniques for superior pharmaceutical products.

Future research will assess applicability to more formulations and problem areas.

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