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## **Effect of Inert Core Material on the Processability and Quality Characteristics of Coated Pellets**

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Coated pellets offer several advantages related to safety and effectiveness of the medicinal product such as reproducibility of gastric emptying and of absorption, and predictable plasma levels with lower probability of dose dumping due to modified release [1,2]. Layered pelletizing involves a process in which drug in solution, dispersion or powdered form is loaded onto inert starting cores. Starter inert cores have several benefits, such as they serve as nuclei with standardized shape, therefore the product shows more exactly defined surface for functional coating [3].

The objective of this study was to investigate the effects of formulation and manufacturing parameters on the pellet quality after the layering and coating process applying 3 types of inert core materials (sugar, microcrystalline cellulose, and isomalt). An additional objective was to investigate and compare the effect of the core material on the in vitro drug release of water soluble and poorly water-soluble drugs when they were coated with a permeable polymer membrane.

The drug layering and coating process were followed by non-destructive tests such as image analysis and NIR spectroscopy. Flowability, hardness, friability, wettability and morphology of starting cores as well as of finished products were investigated.

According to the non-destructive analysis and physical tests, all pellets manufactured from different core materials demonstrated satisfactory quality attributes. Since the type of inert core material may significantly influence the dissolution profile, the solubility characteristics of both the drug and core material should be considered.

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