



DRUG DELIVERY THROUGH THE PHYSIOLOGICAL BARRIERS

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NOVEL EXCIPIENT FORMULATIONS FOR EFFECTIVE LUNG DELIVERY OF NSAIDS

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Introduction: Chronic lung diseases are among the leading causes of death worldwide. In the treatment of these diseases, non-steroidal anti-inflammatory drugs (NSAID) can be effective. It is advantageous to deliver the active pharmaceutical ingredient (API) directly to the lungs, as this preserves the efficacy of therapy at lower doses. Of the dosage forms designed for pulmonary delivery, our research has focused on the development of dry powder inhalation (DPI) formulations. We have previously developed an ibuprofen containing innovative excipient formulation alongside a modern manufacturing protocol, which we aim to further investigate. For this development, we have used two model NSAIDs, meloxicam (MX) and its water-soluble salt, meloxicam potassium (MXP). The final DPIs were expected to have a spherical shape, micro-sized particles, fast drug release and good aerodynamic properties.

Method: The developed excipient combination contained mannitol, Poloxamer-188 polymer and leucine. The DPI systems were prepared by spray drying, preceded by solution preparation for MXP and wet grinding for MX to reduce particle size. In the final product, particle size was determined by laser diffraction, shape by scanning electron microscopy (SEM), crystallinity by powder X-ray diffraction (XRPD) and differential scanning calorimetry (DSC), in vitro aerodynamic properties by Andersen cascade impactor (ACI) and Spraytec® apparatus, and in vitro dissolution in artificial lung fluid.

Results: We successfully achieved the proper particle size for pulmonary delivery (between 3 and 6 µm). According to the SEM investigation, the particles showed advantageous spherical shape. From the XRPD and DSC results we suspected a partial amorphization in the spray-dried samples, which may contributed to the greater dissolution profiles. During the in vitro dissolution tests more than 90% of MX released from the powder within the first 10 minutes, therefore achieving an improvement compared to the physical mixtures. Due to its good water-solubility, MXP showed similarly great dissolution from both the spray-dried formulations and the physical mixtures. Results from the Andersen cascade impactor for the samples containing MXP showed higher deposition on the upper stages, while the MX samples were more evenly distributed across stages. The best products exhibited an average aerodynamic diameter of less than 3 µm, a fine particle fraction greater than 60%, an emitted fraction over 95%, and thus effective lung deposition. Based on the particle size analysis by Spraytec®, the MX containing samples were suitable for lung targeting.

Conclusions: Overall, based on the studies with different active ingredients, it can be concluded that the previously developed manufacturing protocol and excipient system can be applied in the development of different API containing formulations for pulmonary delivery.

References: Party P et al. 2024. *Pharmaceutics* 16(11):1465.
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