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Development of a chlorpromazine containing dry powder inhaler for targeting systemic effect

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Dry powder inhalers (DPIs) are used to delivery drugs directly to the lungs. While primarily used in the treatment of respiratory diseases, such as asthma and COPD, they also offer potential for systemic drug delivery. With pulmonary delivery the liver's first-pass metabolism can be avoided, thereby reducing the required effective dose and potentially minimizing side effects.

Our aim was to develop a chlorpromazine-containing (CPZ) DPI using nano-spray drying with appropriate excipients. In addition to the active ingredient, we used pullulan and leucin as excipients to achieve adequate aerodynamic properties. To optimize the production protocol and minimize the number of samples in the testing phase we applied the Placket-Burman and Box-Behnken experimental designs during the preliminary experiments. The spray-drying was executed using the Büchi Nano Spray Dryer B90. We expected the finished DPI formulations to have spherically shaped, micro-sized particles and suitable aerodynamic properties.

In DPI, the particle size was determined by laser diffraction, the shape by scanning electron microscopy, the crystallinity of the materials by X-ray powder diffraction, the chemical structure by Fourier transform infrared spectroscopy, the *in vitro* aerodynamic properties by Andersen cascade impactor, and the cytotoxicity using the A549 cell line. During the *in vivo* experiments the DPI was administered into the lungs of male rats and the CPZ concentration in the lungs and systemic circulation was examined.

In conclusion, we successfully developed a highly optimized production process for CPZ-containing DPIs, achieving exceptionally high fine particle fraction (FPF>95%), precise deposition, and excellent aerodynamic properties (MMAD>2 µm).

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