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## Experimental Investigation into the Tribocharging Behaviour of Cellulose and Lactose-Based Dry Powder Inhaler Formulations

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## Abstract

The electrostatic charge or triboelectrification of pharmaceutical powder during handling significantly influences product quality, manufacturing effectiveness, and safety. Similarly, dry powder inhaler (DPI) formulations experience electrostatic charging during inhalation. DPI formulations usually consist of a blend of active pharmaceutical ingredients (APIs) and carrier particles, affecting the inhalable powder's delivery efficacy and stability. APIs are usually organic compounds with high electrical resistivity and prevent charge dissipation. Electrostatic charges residing on the formulation are primarily responsible for the API's poor flowability and adherence to the DPI wall. Therefore, electrostatic charge during inhalation may undermine the effectiveness of DPI formulations. Karner et al. (2014) and Urbanetz (2013) investigated the effect of particle shape, surface roughness, and aerosolization airflow rate on triboelectric charging. Naik et al. (2016) studied the triboelectrification of binary mixtures of excipients using both experimental and computational methods. Rescaglio et al. (2019) also explored how relative humidity affected triboelectric charge. Previous research has shown a relationship between charge production and powder properties. However, due to the multivariate nature of static electrification, further research is necessary to understand and explore strategies to reduce electrostatic charging in DPI formulations.

This study aims to investigate and quantify the charge transfer resulting from the interaction between APIs and commonly used surfaces in dry powder inhalers DPIs. This research measures the magnitude and polarity of the charge present in cellulose and lactose-based formulations. The Anton Paar powder shear cell is utilized for wall friction shear testing of active pharmaceutical ingredients. This powder shearing experiment is specifically carried out to study the relevance of the effect of wall friction on tribocharging. It involves first the shearing the lid of the wall shear testing device on the powder at the desired normal stress and then transferring, separately the lid and the powder cell to a Faraday cup connected to an electrometer for charge detection and measurement. A custom shear cell made of insulating material was developed to prevent charge migration during the experiment. Further research was conducted to investigate the tribocharging phenomena associated with wall impact. This experiment aims to elucidate how frequent collisions between API particles and the walls of the DPI during inhalation contribute to the electrostatic charging of these particles.

We intend to build a framework for identifying the triboelectric charging of APIs inside DPIs. Further, we will extend this work to improve the DPI formulation to control the tribocharging related issues

Keywords: Electrostatic charging, Active Pharmaceutical ingredients, Dry powder inhalers, Shear cell, wall friction, wall impact.

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