Three leading companies with complementary areas of expertise have joined forces to conduct a unique multidisciplinary study into lactose-based DPI formulations including magnesium stearate. Their findings will give generic players a head start in the development process so that they can tap into this rapidly growing market. Lactose specialist DFE Pharma, powder processing technology manufacturer Hosokawa Micron and machine-building expert Harro Hoefliger will be presenting the key insights from their research to interested parties during a joint webinar on the 30st of June.

**Webinar to present findings from unique multidisciplinary research trials**

# Practical insights into lactose-based DPI formulations, with and without magnesium stearate

Lactose-based dry powder inhaled (DPI) formulations are already well established in the market for the treatment of asthma and COPD. There is now a growing trend towards developing DPI formulations that are ternary mixtures including magnesium stearate as well as lactose and active pharmaceutical ingredients (APIs). The market for formulations of this kind is expanding rapidly and offers huge scope for generic players. However, the successful delivery of the active ingredient into the lungs depends on numerous interconnected factors during the production process. Therefore, the smallest change in the formulation can have a major effect on the end result.

Many pharmaceutical companies are keen to develop their own products for this rapidly growing DPI market. Due to the complexity associated with these formulations, it is difficult for a formulator to understand the impact of every single compound on the final formulation. The most common questions that arise are:

- What qualities and combination of coarse and fine lactose should be used?
- How does the addition of fines impact on the final formulation?
- What affect does magnesium stearate have on the final formulation?
- Which types of blenders are suitable for use?
- How do blending parameters affect the final formulation?
- What type of filling technology can be used?
- How do the filling parameters affect the final formulation?

Due to the lack of available information about this process, the development work is often a matter of trial and error which can expose manufacturers to unforeseen problems further down the line. All of these problems can lead to lengthy – and costly – delays in the development process.

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This was the main reason for three leading companies with complementary expertise – lactose specialist DFE Pharma, powder processing technology manufacturer Hosokawa Micron and machine-building expert Harro Hoefliger, which is specialized in pharmaceutical and medical devices and in particular capsule filling machines – to join forces to conduct a unique multidisciplinary research trial. The three companies serve many of the same pharmaceutical customers and have regularly worked together to tackle challenges for specific customers, so this joint project is a natural extension of that collaborative approach. By testing various formulations of magnesium stearate-coated lactose in the blending and filling process, they are gaining valuable data-driven insights of their own which will enable them to offer even better advice and support to pharmaceutical customers. Their findings will give generic players a head start in the development process, enabling them to reduce their costs and shorten their time to market.

The study has been running for over a year, involving a project team of around a dozen people across the three companies. In a series of trials, the partners have tested and analysed how changing various parameters affects the behaviour of the powder in the production and dosing process. DFE Pharma provided several different qualities and concentrations of fine lactose to Hosokawa Micron. These were initially blended without the addition of magnesium stearate to establish the baseline levels. The trial batch runs were then repeated to coat the various types of lactose particles with magnesium stearate and compare the results in terms of cohesiveness and stickiness. Next, the various grades of blended powders were supplied to Harro Hoefliger, where experts performed in-depth tests to investigate the influence of the different qualities and concentrations on the capsule-filling and dosing process.

The study is now in the final phase, during which all steps are being repeated but this time with the addition of the active ingredient too. Once all the tests have been completed, the results will be analysed and the findings will be made available to customers and other interested parties.

"Today's customers are looking for a total solution. Our integral approach offers them access to a unique ecosystem of three market leaders with knowledge and expertise that extends beyond the traditional boundaries," comments Bert Dekens from Hosokawa Micron. "All three of us have already gained considerable experience of what does and doesn't work in practice when it comes to magnesium stearate-coated lactose, but we will now be able to back this up with our own solid data about how all the individual steps in the process interact."

Marco Laackmann from Harro Hoefliger agrees: "The results from this research will significantly strengthen our understanding of the coating process and the correlation between lactose quality, blending, flowability and dosing. We are looking forward to translating these findings into practical advice in our discussions with customers."

"By providing access to our insights, our aim is to create a basis for knowledge sharing and discussion," states Harry Peters from DFE Pharma. "By engaging in dialogue as early on in the development process as possible, we can help customers to fine-tune their DPI formulation so that it works with their existing blending and filling equipment, for example, rather than starting with the formulation and having to adapt the machinery accordingly. This saves them a lot of valuable time and money on the road to success."

The detailed findings will be published in a scientific article, plus the companies will be holding a joint webinar June 30. 2021, to present their insights to members of the industry.

Click here to sign up to receive an automatic notification once the date of the webinar is announced. <