This multidisciplinary study of magnesium stearate-coated lactose-based DPIs has made impressive progress since the first webinar, which was held in June this year to introduce the project. The three project partners – lactose specialist DFE Pharma, powder processing technology manufacturer Hosokawa Micron and machine-building expert Harro Hoefliger – will soon be presenting their findings from Phase 2 of the study. The highlights include promising new insights into permeability and compressibility thresholds for a low RSD. The final phase, which will include the addition of an API, is expected to be concluded in spring 2022.

Research into lactose-based DPI formulations with magnesium stearate enters new phase

Promising new insights from unique multidisciplinary research

The unique multidisciplinary study into magnesium stearate-coated lactose-based DPI formulations by DFE Pharma, Hosokawa Micron and Harro Hoefliger has now entered a new phase. These three leading companies with complementary areas of expertise – in lactose, powder processing technology and capsule-filling/dosing machines, respectively – are keen to give pharmaceutical players a head start in the development process so that they can tap into this rapidly growing market. In the latest phase of the study, the partners have explored how coating lactose with magnesium stearate affects the flow properties and filling. Their promising new insights will be presented at DDL in December 2021.

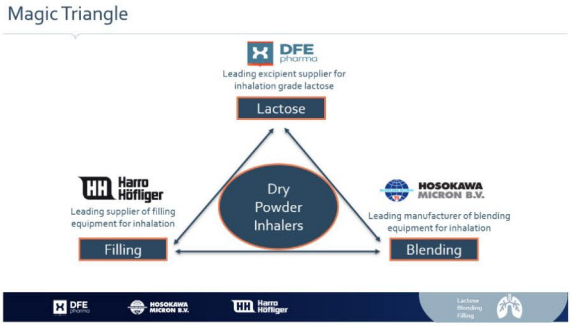

Figure 1: The magic triangle

The market of dry powder inhaled (DPI) formulations that include magnesium stearate-coated lactose is growing rapidly. However, the development process is complex. The successful delivery of the active ingredient into the lungs depends on numerous interconnected factors during the production process. As a consequence, the smallest change in the formulation can have a major effect on the end result. Just over a year ago, DFE Pharma, Hosokawa Micron and Harro Hoefliger joined forces to set up a multidisciplinary study aimed at generating valuable data-driven insights of their own as the basis for offering even better advice and support to their pharmaceutical customers.

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In June 2021, the three partners held a joint webinar that was attended by over 200 formulation specialists, R&D experts and other pharma industry professionals from around the world. The webinar provided an overview of the study in general and explained the phased approach. The partners also presented their findings from the first phase, including how changing various parameters affects the behavior of the lactose-based powder in the blending, production, filling and dosing process.
The team have made impressive progress since then. In the second phase of the study, trials were conducted using different grades of lactose fines, with different mixing/blending speeds and times, and both with and without a magnesium-stearate coating. The analysis work is currently being finalized and the results are nearly ready. The progress will be summarized in a 10-minute on-demand presentation during DDL2021 in December, followed by another joint webinar by all three partners in the first quarter of 2022.
Based on the data, the team are already able to conclude that the addition of magnesium stearate to lactose changes the flowability. Needless to say, when it comes to mixing and filling, customers are looking for a relative standard deviation (RSD) that is as low as possible.

Figure 2: study outline

The project team have conducted similar tests with other types of fillers, including a drum filler and a dosator. By identifying and quantifying the thresholds, the partners aim to make the development and production process more predictable for pharma customers – resulting in various benefits, including a shorter time to market and less waste during processing.
The study is now moving into its final phase, which will be conducted using DFE Pharma's lactose and Hosokawa's powder mixing technology. This phase will take place on-site at Harro Hoefliger's state-of-the-art facility to gain maximum benefit from the team's expertise in handling formulation-related activities including high-shear blending with APIs and also filling. The developed formulation will be analyzed for flow properties, blend uniformity, assay, emitted dose and aerodynamic particle size distribution (ASPD) along with short-term stability studies.
This final phase is expected to be completed by spring 2022. More details will be revealed in the presentation and publication at DDL 2021. In the meantime, any companies that are currently developing their own applications and have questions – or would like to test any aspect of the process in a lab setting – are welcome to contact the relevant project partners for tailor-made advice.

Click here to get directed to the website dedicated to the study. <