# Carriers for Dry Powder Inhalers – Characterisation by Vapour Sorption and Thermal Analysis

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Formulations in dry powder inhalers mostly consist of interactive mixtures of fine drug particles with particle diameters of 0,5 to 5 µm adhered to coarse carrier particles (diameter about 100 µm). The problem of the interactive mixtures is that only a fraction of the delivered dose of the micronised drug reaches the lungs. This fraction is influenced by the inhaler design, the inhaled air flow rate and the adhesion force between the drug and the carrier, depending on the properties of both substances. The common carrier material is lactose-monohydrate, sometimes also glucose is used. As alternatives sugar alcohols like mannitol [1] and trehalose are proposed.

In this investigation the characterisation of lactose-monohydrate and mannitol from different producers and of different production processes as well as own spray dried products is shown. The crystallized and sieved qualities InhaLac® 70 and InhaLac® 230 with different particle sizes and Lactohale® LH100 which are monocrystals serve as examples for lactose-monohydrate. In the case of mannitol the crystalline Mannitol 60 and the spray dried Pearlitol SD 200 is used.

With the water vapour sorption test system (SPS11) it can be found that lactose-monohydrate is less hygroscopic than mannitol. All different types of lactose-monohydrate show a lower maximum water uptake at a humidity of 98% in comparison to mannitol. Beside the chemical structure the particle size seems to be important, because InhaLac® 70 with a median diameter of about 150 µm shows a lower water uptake than the smaller InhaLac® 230 ($x_{50}$ = 45 µm). This leads to the assumption that not the water absorption, but the water adsorption to the surface is measured. Examinating the two types of mannitol shows that the crystalline quality Mannitol 60 has a smaller water uptake than the spray dried Pearlitol SD200 which corresponds probably to the area of surface. The self produced spray dried and therefore amorphous lactose shows, as expected, a high water uptake at a relative humidity of about 50%, followed by a water loss because of recrystallization to lactose-monohydrate.

Other methods like differential scanning calorimetry (DSC) and thermogravimetric analysis (TGA) were used to find differences in crystallinity and water content between the carriers.

Further experiments will show if the results of this investigation can be related to measurements of the fine particle fraction of interactive mixtures determined with the Next Generation Impactor.

[1] Urbanetz N. A., Proc. 4th World Meeting ADRITELF/APGI/APV, Florence, 8/11 April 2002, 1047-1048