In the current Quality by Design paradigm, the development of a pharmaceutical product requires a thorough understanding of the design space to enable the built in of quality in the product.

Methods
- Two capsule based devices (Handihaler® and Cyclohaler®)
- Lactose (Lactohale®, DFE Pharma) blended with 2 % budesonide
- A coarse grade of lactose complemented with different types of fine graded lactose.
- A development space was created with type of fine grade lactose (d50 of the fine grade varying from 5-15 µm) and amount of this fine grade (1.5-20 wt%) as factors and Fine Particle Fraction (FPF) and Hausner Ratio (HR) as the responses.
- Target was set on FPF (18-25%) and HR (Fair or passable).

Results
The results were analyzed by a surface response design and gave a response plot for both HR and FPF as function of type and amount of fines. Overlap contour plots were constructed of both responses based on above stated borders and these are depicted in Figure 1.

Discussion
For the constraints set, both types of DPI devices do show achievable design spaces. Handihaler has the largest white areas, with the largest at a fair flow constraint, whereas the Cyclohaler shows the largest white area in the passable flow range.

Conclusions
In this study, Handihaler has in general a larger design space than Cyclohaler. At might be advisable to combine the choice for Handihaler with the choice of a piston capsule filling system and Cyclohaler with tamping or disc-dosing filling system because this allows for the largest design area.

References