W4341

PARTICLE ENGINEERING WITH A LAB SCALE SPRAY-DRYER

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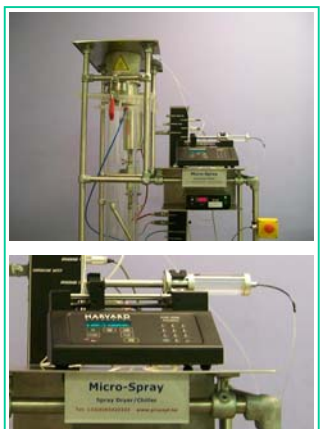
INTRODUCTION

Particle engineering is the control of particle size and morphology. This is becoming increasingly important in pharmaceutical production and development. Spray drying is finding utility in the production of specifically designed particles. However, some types of spray drying equipment has had limited utility because of low yields when high value ingredients need to be used and there has been a lack of predictability or control in generated particles of known morphology and particle size distribution.

The objective of this study is to spray dry very small amounts of sample at a very high yield and to predict the particle size distribution within a wide range of particle sizes down to approximately 2 microns.



[1] Micro-Spray

[2] Spraytec

MATERIALS & METHODS

The recently developped ProCept *"Micro-Spray"* [fig. 1] makes it possible to dry very small samples (from 0.25 ml) and to create tiny particles (< 10 micron) at high yields (> 90%). The spray dryer makes use of a special system to control the air flow. An optimized cyclone design minimizes product losses. Ultrasonic nozzles with frequencies from 25 to 120 kHz. are used for the experiments in order to create uniform sprays with a narrow size distribution.

Earlier test work [fig. 3] showed that particle size is only strongly related to feed concentration and droplet size. Though, variation of particle size is possible by working with nozzles at different frequencies, by changing the pumping rate and by varying the dissolved solids concentrations.

Lactose dissolved in water is used in this series as a model active ingredient. A few test with lipids dissolved in IPA were also done.

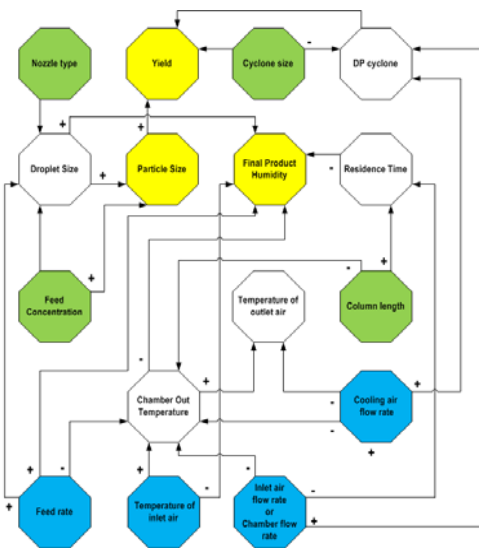
Laser diffraction is used to determine droplet size (Spraytec [fig 2]) and particle size (Mastersizer 2000).

RESULTS

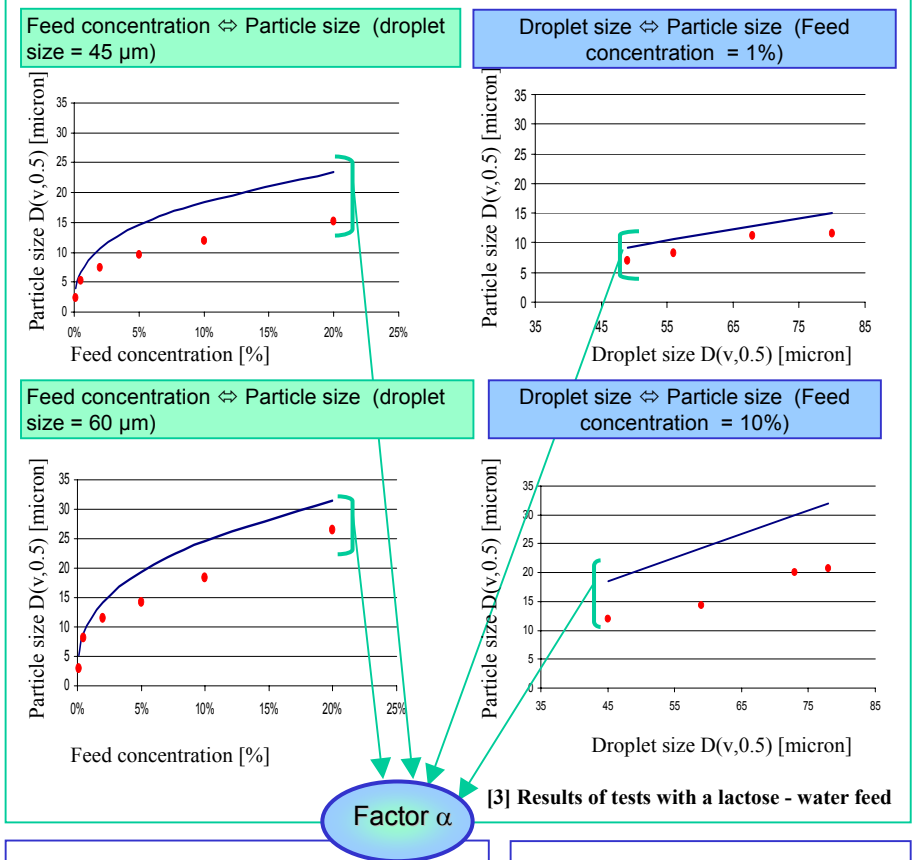
A theoretical model that gives the relation between droplet size, feed concentration and particle size is made up and compared to test results:

$$D_{part} = D_d \cdot \left(\frac{x_f / \rho_{prod}}{x_f / \rho_{prod} + (100\% - x_f) / \rho_{solv}} \right)^{1/3}$$

Droplet variation from 30 up to 80 microns combined with a sample concentration in between 0.02% and 20% makes it possible to estimate the particle size of lactose powder in a range starting from 2 up to 30 microns.



[3] Relations between spray-drying parameters



[3] Results of tests with a lactose - water feed

Test results differ on a constant basis to the model. For lactose [fig. 4] this constant factor α is equal to 0.7 and brings model and test results perfectly together.

A few tests with lipids dissolved in IPA confirm te model. In this case the constant factor α is 0.8.

The factor α only depends on the used product and solvent. Some surveying test work to determine the α factor makes it possible to predict easily the particle size of known products after spray drying with the "*Micro Spray*".

CONCLUSION

The theoretical model is made up in order to estimate the particle size. If a correction factor is used, the particle size can be predicted very accurately. This factor depends on the product and the solvent used. This research shows that the particle size is easy to control with the *Micro-Spray* spray dryer if droplet size and feed concentration are changeable and contollable.