



NEWS RELEASE

Catalent Pharma Solutions uses Malvern Spraytec for routine screening of nebulizer formulations

5 June 2009: Malvern, UK: A cross-validation study by Catalent Pharma Solutions has shown the Malvern Spraytec laser diffraction-based particle size analyzer to be a robust, efficient and cost-effective alternative to cascade impaction techniques for routine screening of nebulizer formulations. The study was conducted by researchers from Catalent's Respiratory, Analytical and Biotechnology group, based in North Carolina's Research Triangle Park (USA).

In the Catalent study, which was first presented at Drug Delivery to the Lungs 19 (DDL19, Dec 08, Edinburgh, Scotland) both the Spraytec and the Next Generation Impactor (NGI) were used to determine the particle size distributions of two formulations delivered from two different nebulizers. Results from both measurement techniques for the fine particle fraction – the fraction of a dose that deposits in the lungs – were equivalent, demonstrating that the complementary technique of particle size analysis by laser diffraction is directly comparable with cascade impactor measurements.

The use of particle sizing techniques is critical in understanding inhaled drug and device performance. While cascade impactor testing remains essential for validation and submission purposes, the results of the study show that laser diffraction can be used for routine testing. It offers fast, efficient access to the information needed to quantify device/formulation performance and to assess the ranges available for safe and effective development as encouraged by QbD. As such it is a valuable tool for cutting the costs and timelines associated with inhalation product development.

Spraytec offers the robust operation and rapid data acquisition needed to reliably measure aerosolized droplet size distributions in real-time during spraying. Measurements can be carried out very rapidly and over a broad range of particle sizes (typically 0.1 – 2000 microns), delivering detailed dynamic information. www.malvern.com/spraytec

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Image, notes and contact details to follow...

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High resolution image attached or available from Trish Appleton,
Kapler Communications trish@kapleronline.com Ref: MAL/JOB/1713

CAPTION: The Spraytec laser diffraction particle size analyzer designed specifically for spray measurement



About Malvern Instruments

Malvern Instruments provides a range of complementary materials characterization tools that deliver inter-related measurements reflecting the complexities of particulates and disperse systems, nanomaterials and macromolecules. Analytical instruments from Malvern are used in the characterization of a wide variety of materials, from industrial bulk powders to nanomaterials and delicate macromolecules. A broad portfolio of innovative technologies is combined with intelligent, user-friendly software. These systems deliver industrially relevant data enabling our customers to make the connection between micro (such as particle size) and macro (bulk) material properties (rheology) and chemical composition (chemical imaging).

Particle size, particle shape, zeta potential, molecular weight, chemical composition and rheological properties measurements are now joined by advanced chromatography solutions (GPC/SEC), extending Malvern's technologies for protein molecular weight, size and aggregation measurements, and synthetic polymer molecular weight and distribution. The company's laboratory, at-line, on-line and in-line solutions are proven in sectors as diverse as cement production and pharmaceutical drug discovery.

Headquartered in Malvern, UK, Malvern Instruments has subsidiary organizations in all major European markets, North America, China, Korea and Japan, a joint venture in India, a global distributor network and applications laboratories around the world. www.malvern.com

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