



NEWS RELEASE

DPT Laboratories uses Malvern Spraytec in all nasal spray work

29 June 2010: Malvern, UK: Used at two different locations within contract development and manufacturing organization DPT Laboratories (San Antonio, Texas), Spraytec laser diffraction particle size analyzers from Malvern Instruments have assured their place in the company's nasal spray development and manufacturing areas by being both highly effective and very user friendly.

Dr Vitthal Kulkarni, Scientific Advisor at DPT confirmed that the Spraytec systems are used not only in product development, but also for stability studies and for routine quality control during manufacture. "We use the Spraytec systems in all our nasal spray work," he said. "They allow us to examine the homogeneity of the products in terms of the droplet size distribution and enable us to meet FDA testing requirements." FDA guidance for nasal sprays recommends the use of laser diffraction to determine the droplet size produced for a given device and formulation.

"The Spraytec is simple to use and we have been able to train our analysts very quickly," continued Dr Kulkarni. "We are particularly impressed with the software, which automates all parts of the measurement process, including extraction, allowing us to ensure effective measurement of a good spray plume. The system's standard operating procedures are especially good in the QC environment, and the fact that the software is 21CFR Part11 compliant means that it can be used throughout the development and manufacturing processes."

Spraytec is designed to provide real-time particle size measurement for particles in the size range 0.1 to 2,000 microns, allowing capture of the fine detail of aerosol formation and dynamic droplet behaviour. This allows each phase of liquid atomisation to be measured and identified during nasal spray operation, in line with the FDA guidance.

For further details about Spraytec visit www.malvern.com/spraytec_OINDP

For more information about DPT Laboratories, visit www.DPTLabs.com.

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Image, notes and contact details to follow...

High resolution image attached or available from Luke Newman,
Kapler Communications luke@kapleronline.com Ref: MAL/JOB/1904

CAPTION: The Spraytec system with nasal spray actuator



About DPT Laboratories

DPT Laboratories, a DFB company, is a contract development and manufacturing organization (CDMO) providing companies the best solutions to their sterile and non-sterile pharmaceutical development and manufacturing needs through innovation, technology, and service. Specializing in semi-solid and liquid dosage forms, DPT has a reputation for quality, unmatched technical expertise, extensive manufacturing capabilities, and an exemplary regulatory compliance record. With five cGMP facilities in San Antonio, Texas, and Lakewood, New Jersey, DPT offers full-service outsourcing solutions, including stand-alone development, site transfers, state-of-the-art manufacturing, packaging, and worldwide distribution. For more information, call 210-476-8100 or visit www.DPTLabs.com.

About Malvern Instruments

Malvern Instruments is a market leader in measuring performance controlling material properties. These include particle size, particle shape, zeta potential, molecular weight, size and conformation, rheological properties and chemical distribution. Malvern delivers the systems, support and expertise that ensure the analytical integrity and productivity needed to drive research, development and manufacturing.

Malvern's measurement solutions for scientists, technologists and engineers advance continually through customer collaboration. Complementary materials characterization systems deliver inter-related measurements that reflect the complexities of particulates and disperse systems, nanomaterials and macromolecules. Combining intelligently implemented technologies with in-depth industry applications knowledge and support, Malvern provides customers with the competitive advantage they demand.

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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