



NEWS RELEASE

Copley Scientific inhaler testing tools help QbD implementation through faster data acquisition

25 March 2008; Nottingham, UK: New tools from Copley Scientific streamline inhaler product screening, accelerating acquisition of the data required to implement Quality by Design (QbD). These tools modify the performance of cascade impactors currently specified in USP and Ph.Eur, allowing rapid identification of the fraction of a dose that will be inhaled. Cascade impactors are routinely used for the testing of all inhaled products.

In recognition of the importance of QbD initiatives, Copley Scientific is pleased to sponsor the scientific session *QbD and PAT in Inhaled Product Development* at this year's Respiratory Drug Delivery conference (RDD 2008) held from 11-15 May in Scottsdale, Arizona.

The need for information to ensure QbD is fuelling a demand for analytical tools that can quickly deliver useful data. Copley has responded by developing accessories for cascade impactors that simplify the study of key performance characteristics. Options are available for the Andersen and Next Generation Pharmaceutical Impactors (ACI and NGI) and for the Multi-Stage Liquid Impinger (MSLI).

A new exhaust cup allows flow extraction from any stage within the NGI, with the added capability of reintroducing flow further downstream, thereby reducing the number of impactor stages utilised. A new deep cup also allows by-passing of a single stage, the sample simply passing through without impaction. For the ACI a similar effect is achieved by simply omitting stages from the standard stack; Copley now supply modified spring clamps and/or a "Quick-Clamp" that ensure an adequate seal for modified configurations. With respect to the MSLI a four stage option, in addition to the current five stage version, is also available on request.

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Using these options to coarsen the separation characteristics of the instrument reduces the number of fractions produced and the associated analytical burden. The developer can focus specifically on the fine particle fraction, the fraction that will be inhaled, or whichever size range is of most interest. Rigorous multi-stage cascade impaction provides more detailed information as it is needed.

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Ends

High resolution image attached and/or available from Luke Newman, Kapler Communications luke@kapleronline.com Ref: COP/JOB/042

Caption: Reduced stack Andersen Cascade Impactor



About Copley Scientific

Copley Scientific is recognised as the world's leading manufacturer of inhaler test equipment and is a major supplier of test equipment for pharmaceutical solid dosage forms, including tablet dissolution, disintegration, friability, hardness and powder testers. The company has offices in the UK and Switzerland and a partnership with aerosol particle science experts MSP Corporation in the US. Copley's broad range of testing products for metered-dose inhalers, dry powder inhalers, nebulizers and nasal sprays are supplied and supported worldwide through close relationships with specialist distributors. Serving the pharmaceutical and associated industries, Copley offers an extensive range of equipment for research, production, clinical trials and quality control, as well as full validation and aftersales service, providing a single source for products that meet individual needs.

www.copleyscientific.com

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