



NEWS RELEASE
27 June 2007

Simulated breathing for nebuliser testing from Copley Scientific

Copley Scientific has launched a new Breath Simulator that is designed to generate the breathing profiles now required for testing pharmaceutical nebulisers.

A recent European Medicines Agency (EMA) guidance highlights the importance of characterising nebuliser performance in terms of drug output and particle size distribution for the purposes of determining safety and efficacy. Based on work performed by the European Pharmaceutical Aerosol Group (EPAG) an associated monograph is currently under review for inclusion in the European Pharmacopoeia (2.9.44. Preparations for Nebulisation: Characterisation).

Copley's Breath Simulator BRS 1000 is a microprocessor-controlled instrument that generates an air flow profile which simulates adult tidal breathing. Its sinusoidal waveform and 1:1 inhalation/exhalation ratio specifically conforms to the draft monograph.

The system has a tidal volume of 500 ml, and variable frequency from 10 to 25 breaths per minute. Tests can be based on cycle number (1 to 9999 breaths) or cycle time (0 to 8 hours). A simple user-interface with menu-driven operation is accessed via a membrane keypad.

Conventionally, nebulisers and the drugs that they deliver have been tested as separate entities, with nebuliser testing conducted according to European Committee for Standardisation EN 13544-1. The EMA's unprecedented introduction in 2006 of regulatory guidance on nebulisers recognises that overall performance depends on both device *and* drug. The new regulations make nebuliser testing more consistent with current practise for other inhalation delivery platforms. www.copleyscientific.com

Ends

Image, notes and contact details follow...

High resolution image attached and/or available from Trish Appleton, Kapler Communications trish@kapleronline.com Ref: COP/JOB/009

Caption: The Copley Breath Simulator BRS 1000 with schematic of sampling apparatus for nebulisers (inset)



About Copley Scientific

Copley Scientific is a major provider of test equipment for pharmaceutical solid dosage forms, including tablet dissolution, disintegration, friability, hardness and powder testers, and is recognised as the world's leading manufacturer of inhaler test equipment. 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

For further information

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