



NEWS RELEASE

Copley Scientific introduces new test equipment for generic product development at RDD 2018

05th April 2018: Nottingham, UK: Generic developers looking to apply the recently proposed draft US Pharmacopoeia (USP) monograph for Albuterol Inhalation Aerosols will find relevant new testing equipment at the Copley Scientific stand at Respiratory Drug Delivery 2018 (April 22nd to 26th, Tucson, Arizona). The new TPK™ 2100 Critical Flow Controller, a highly automated unit for reproducible, cost-efficient dry powder inhaler (DPI) testing, will also make its US debut. Copley Scientific is proud to be sponsoring this key event in the inhalation calendar and experts from the company will be in attendance throughout to discuss any aspect of inhaler testing.

Albuterol, a popular generic target also known as Salbutamol, is a β_2 agonist (bronchodilator) used globally for the treatment of asthma and chronic obstructive pulmonary disease. Product specific USP monographs and FDA guidances directly support the development of important generic drugs but frequently call for the application of unique test equipment, associated with the original product development. The proposed USP monograph for Albuterol Inhalation Aerosols, which was released in January 2018, specifies a non-standard sampling apparatus for delivered dose uniformity (DDU) testing, and an alternative to the standard USP induction port for aerodynamic particle size distribution (APSD) measurement using an Andersen Cascade Impactor (ACI). Copley Scientific will use the conference to launch new equipment to directly meet these requirements along with an accessory that allows the use of existing mouthpiece adapters, to simplify interfacing the inhaler with the induction port.

Copley Critical Flow Controllers are an internationally recognised standard for DPI testing that enable the set-up, control and documentation of all the parameters associated with both DDU and APSD measurement. The third generation TPK™ 2100 breaks new ground in terms of ease of use, improved reproducibility, and enhanced data output and recording. It exemplifies a suite of innovative designs that Copley has introduced over the last year to minimise the potential impact of user variability in inhaler testing and boost analytical productivity.

To find out more about the new test equipment for Albuterol or the TPK™ 2100 drop by the stand at RDD 2018. Alternatively contact: sales@copeyscientific.co.uk or visit: www.copleyscientific.com



CAPTION: Albuterol Inhalation Aerosol Sampling Apparatus for delivered dose uniformity (DDU) testing as described in the proposed USP monograph

ENDS

About Copley Scientific

Copley Scientific is widely recognised as the world's leading manufacturer and supplier of inhaler test equipment and is a major provider of testing systems for other pharmaceutical dosage forms. The company also supplies equipment for detergent testing.

Copley Scientific's pharmaceutical product range includes test equipment for all types of orally inhaled and nasal drug products - metered-dose inhalers, dry powder inhalers, nebulizers and nasal sprays - with a particular focus on solutions for delivered dose uniformity and aerodynamic particle size distribution measurement. It also includes testers for tablets (dissolution, disintegration, friability and hardness) capsules, powders, suppositories, semisolids and transdermals.

Used from R&D through to QC, this extensive range of equipment is supported by a full validation and aftersales service. Copley Scientific has offices in the UK and Switzerland and works in partnership with aerosol particle science experts MSP Corporation in North America; specialist distributors extend localised support across the world. This network provides expert help and training to every customer, directly enhancing the application of all Copley Scientific products. www.copleyscientific.com



For further information

Press information/Company contact:

Anna Sipitanou, Business Development Manager, Copley Scientific Limited
Colwick Quays Business Park, Private Road No. 2, Colwick, Nottingham, NG4 2JY, UK

Tel: +44 (0)115 961 6229

Fax: +44 (0)115 961 7637

a.sipitanou@copleyscientific.co.uk

www.copleyscientific.com

European Office (Austria, France, Germany, Italy, Switzerland)

Copley Scientific AG

Erlenstrasse 27, Postfach 152, CH-4106 Therwil, Switzerland

Tel: +41 (0)61 725 25 35

Fax: +41 (0)61 721 31 87

sales@copleyscientific.ch

www.copleyscientific.com