



NEWS RELEASE

State-of-the-art manufacturing gives Copley Scientific's new dissolution tester the edge in enhanced mechanical calibration

21 April 2010: Nottingham, UK: Copley Scientific has launched the Dissolution Tester DIS-EMC, a new system that features Enhanced Mechanical Calibration, and which is designed to meet the latest and most rigorous calibration needs in this field. State-of-the-art manufacturing procedures bring new standards in controlling the tolerances and dimensions of the critical elements of the Test Station in which the dosage form resides. In line with current regulatory guidance, this significantly reduces the potential of the dissolution tester to contribute to testing variability.

While accepted practice in the pharmaceutical industry has been to calibrate dissolution testers using a combination of mechanical checks and performance verification tablets, there is concern about the wide acceptance ranges and variability these generate. As a result the move is towards enhanced mechanical calibration as an alternative, or at least as a precursor, to chemical calibration. In January 2010 the FDA issued guidance on "The use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (CGMP)".

Enhanced mechanical calibration requires strict control of the dimensions of, and the spatial relationships between, critical elements of the dissolution tester. Copley Scientific has identified these critical elements to be the dissolution vessel and lid, and the stirring element. Controlling these, while also maintaining stirring speed and media composition and temperature within tight limits, minimises any instrument contribution to test method variability.

It has long been recognised that dissolution vessel dimensions and irregularities are a major factor in results variability. Using vacuum forming techniques, Copley Scientific has produced a vessel with superior dimensions and which has provided a platform for the development of a new lid and stirring element. This production method guarantees an internal diameter tolerance and blemish-free spherical radius of +/- 0.13 mm (compared with the traditional unit's +/- 2 mm). Friction-free bearings in the lid and a precision-ground shaft for the stirring element have enabled a 50% reduction in tolerances relating to wobble, verticality and centering. The Dissolution Tester DIS-EMC betters the dimensional tolerances specified by the FDA by a factor of 2.

The 'audit-proof' Copley Scientific Dissolution Tester DIS-EMC provides the highest standards in dissolution testing equipment. In addition, existing users of Copley DIS 6000 and DIS 8000 Dissolution Testers can upgrade to the new DIS-EMC Tester specification by exchanging their standard Test Station for the new EMC Test Station. www.copleyscientific.com

Image, notes and contact details to follow...

State-of-the-art manufacturing gives Copley Scientific's new dissolution tester the edge in enhanced mechanical calibration.../2

High resolution image attached and/or available from Luke Newman, Kapler Communications luke@kapleronline.com Ref: COP/JOB/119

Caption: The Test Station of the Copley Scientific Dissolution Tester DIS-EMC



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 North America. 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, development 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

Press information

Trish Appleton, Kapler Communications
Knowledge Centre, Wyboston Lakes, Great North Road,
Wyboston, Bedfordshire, MK44 3BY, UK
Tel: +44 (0)1480 479280; Fax: +44 (0)1480 470343 trish@kapleronline.com

Company contact:

Mark Copley, Sales Director, 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
m.copley@copeyscientific.co.uk www.copleyscientific.com