



Strasbourg, 24/06/2011

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Cincinnati, Ohio, USA, 14-15 June 2011

The Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP) and United States Pharmacopoeia (USP)] met on June 14-15, 2011 in Cincinnati, Ohio, USA.

At present, 28 of the 35 General Chapters and 41 of the 62 excipient monographs of the current work programme have been harmonised. The General Chapter for Microcalorimetry is newly harmonized. Revised General Chapters include *Bacterial Endotoxins* and *Bulk and Tapped Density*. Excipient sign-offs include revisions to *Benzyl Alcohol*, *Potato Starch*, *Wheat Starch*, *Calcium Phosphate Dibasic*, and *Calcium Phosphate Dibasic Anhydrous* monographs. The latter four revisions are the outcome of PDG's review of previously harmonised excipient monographs.

Other Topics

The three pharmacopoeias discussed other topics, including microbiological limits, additives in excipients, and metal impurities. Also, PDG decided to add the *Isomalt* monograph to its work programme.

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on June 14, 2011. Topics, among others, included cellulose, viscosity of cellulose derivatives, polyethylene glycol, glycerin, povidone, copovidone, the silicon dioxide monographs, and metal impurities.

Future of PDG

The three Pharmacopoeias emphasized their commitment to further strengthen international harmonisation. PDG will utilise its monthly teleconferences for discussion of technical topics in addition to monitoring status updates. The next face-to-face PDG meeting will be hosted by EDQM on November 8-9, 2011 in Strasbourg, France.

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