



**STRASBOURG, 15/06/09**

*Note for the Editors:* Further information is available on the internet site: [www.edqm.eu](http://www.edqm.eu)

## **PHARMACOPOEIAL DISCUSSION GROUP (PDG)**

*Yokohama, Japan, 7-11 June 2009*

The Pharmacopoeial Discussion Group [European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), United States Pharmacopoeia (USP)] met in association with the Expert Working Groups of the International Conference on Harmonization (ICH).

Harmonization has been achieved on 9 of the 10 General Chapters identified by the ICH Q6A Guideline. Revisions have been signed for 3 Paraben monographs, replacing the TLC Related substances test and the titration assay by HPLC.

At present, 26 of the 34 General Chapters and 40 of the 63 excipient monographs have been harmonised. In the course of indicating the harmonisation statement in the three pharmacopoeias, PDG has reviewed 7 texts and identified typical discrepancies: A path forward to resolution has been agreed that will also facilitate further harmonisation projects.

### ***Interaction with ICH***

The scope of the overall harmonization activity was expanded successfully with the submissions of Tablet friability and Polyacrylamide gel electrophoresis to the ICH. Three remaining chapters, Analytical Sieving, Bulk and Tapped Density, and Capillary Electrophoresis will be submitted prior to the next ICH meeting in October.

### ***Interaction with Industry***

PDG met with industry representatives on Tuesday evening, June 9, 2009. Topics for discussion included

- Individual reports from pharmacopoeias
- Completed harmonization texts
- ICH submissions resulting from extended scope as decided at the Brussels meeting
- Industry proposals for further harmonisation

Industry associations welcomed the progress made since the last meeting. Industry also appreciated the information on a pilot project on prospective harmonisation of active pharmaceutical ingredients (APIs) between the EP and USP. At this point in time, it is anticipated that the first draft monograph will be published for comments in the second half of 2009.

### ***Heparin***

The three pharmacopoeias continued efforts to further enhance their heparin monographs to protect the public from adulteration of these materials.

### **Excipients Council**

A meeting with TRIPEC (IPEC-Americas, IPEC-Europe and JPEC) was held on June 11, 2009 where harmonization of excipient monographs and potential additions to the work program were discussed.

The PDG will hold its next face-to-face meeting in October 2009 in St. Louis, USA.

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