



STRASBOURG, 07/11/07

Note for the Editors: Further information is available on the internet site: www.edqm.eu

PHARMACOPOEIAL DISCUSSION GROUP (PDG)

Yokohama, Japan, 28th October – 1st November 2007

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 11 General Chapters identified by the ICH Q6A Guideline. A revision of the general chapter on sterility was signed-off following Q4B recommendation to PDG for the removal of the eleven non-harmonized items that were present in the first sign-off. The remaining differences have all been eliminated and the sterility test can now be considered as fully harmonized.

A minor revision of the disintegration chapter was signed-off to accommodate for slight differences in current equipment characteristics.

New items for sign-off included the general chapter on X-Ray Powder Diffraction and the monograph for Sucrose. In addition, revisions to the monographs for Corn Starch, Potato Starch, and Wheat Starch were signed off.

At present, 25 of the 35 General Chapters and 36 of the 62 excipient monographs have been harmonized.

Revision of PDG Working Procedure: PDG has signed-off to revise its working procedure in order to adapt more rapidly to necessary revisions.

Interaction with ICH Q4B: PDG has discussed with Q4B about recently submitted packages on the Q6A General Chapters. PDG proposed that Q4B might consider extending their scope beyond the Q6A General Chapters. To this end, PDG provided a preliminary list of harmonized general chapters and excipient monographs for consideration. Furthermore, PDG proposed a procedure to formalize the communication between PDG and Q4B.

Excipients Councils: A meeting with TRIPEC (IPEC-Americas, IPEC-Europe and JPEC) was held on November 1, 2007 where progress on the harmonization of excipient monographs and associated issues were discussed.

The PDG will hold its next meeting in June 2008 in Portland, Oregon, the United States of America.

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Contact: Caroline Larsen Le-Tarnec

Public Relations Division, EDQM/European Pharmacopoeia

Tel: + 33 3 88 41 30 30 (Dial 4)

E-mail: Via the Helpdesk on the EDQM website