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PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Strasbourg, France, 8-9 November 2011

The Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP) and United States Pharmacopoeia (USP)] met on November 8 and 9, 2011 in Strasbourg, France.

At present, 28 of the 35 General Chapters and 41 of the 61 excipient monographs of the current work programme have been harmonised. Excipient signoffs include revision to the Carmellose monograph. In depth discussion of advanced drafts of certain cellulose and carbohydrate monographs will pave the way for future sign-offs. Following consideration of the significantly different types of Glycerol Monostearate material manufactured in the three regions, PDG decided to remove this item from its work programme.

Other Topics

The three pharmacopoeias discussed other topics, including microbiological limits, metal impurities and the progress made in the on-going review of previously signed-off monographs to achieve a higher degree of harmonisation.

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on November 8, 2011. Topics, among others, included cellulose, viscosity of cellulose derivatives, polyethylene glycol, glycerin, povidone, copovidone, the silicon dioxide monographs, and metal impurities as well as means to further strengthen the collaboration. The group discussed the potential to add additional excipient monographs to the work plan.

Future of PDG

The three Pharmacopoeias emphasised their commitment to further strengthen international harmonisation. Building on recent successes, PDG will continue utilising 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 the Japanese Pharmacopoeia in 2012 in Tokyo, Japan.

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