

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Strasbourg, France, May 25-26, 2016

The meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (Ph.Eur.), Japanese Pharmacopoeia (JP), and the United States Pharmacopoeia (USP)] was hosted by EDQM in Strasbourg, France, 25-26 May 2016.

To date, 29 of the 36 General Chapters and 49 of the 67 excipient monographs on the current work programme have been harmonised. Sign-offs at this meeting include a new monograph on Hydroxyethylcellulose and two revised monographs on Ethylcellulose & Cellulose acetate.

In-depth discussions on a number of additional items currently on the work programme took place with a view to resolving outstanding issues and advancing the items towards sign-off.

The PDG continues to focus its efforts on the elaboration of two important new general chapters, "Chromatography" and "Elemental impurities". Both these chapters were discussed in detail and outstanding issues addressed.

In the case of the "Chromatography" chapter, the aim was to be able to present a Stage 4 draft for public enquiry in the near future.

As far as the "Elemental impurities" text is concerned, the three pharmacopoeias affirmed their commitment to harmonising this general chapter on testing procedures for elemental impurities and exchanged information on their respective approaches to the implementation of the ICH Q3D guideline.

In order to make best use of the scarce resources available to the three pharmacopoeias and to respond to the need to elaborate new excipient monographs of interest in the three regions, it was agreed to add five new items, Isostearyl alcohol, Myristyl myristate, Polysorbate 65, Sodium cetyl sulfate and Calcium silicate, to the work programme. With the exception of the latter (major revision for USP), these will be the first excipient monographs to be elaborated within the PDG using a prospective approach. With these additions, the PDG work program has now increased to include 67 excipients.

The highlights of this meeting can be found at: <http://www.pmda.go.jp/files/000212595.pdf>

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on 26 May 2016. Topics discussed included monographs for Hydroxyethylcellulose, Carmellose sodium, Polyethylene glycol, Povidone, Pregelatinised starch and Silicon dioxide.

Next Meeting The next face-to-face PDG meeting will be hosted by Japanese Pharmacopoeia in the week of 24 October 2016 in Tokyo, Japan.

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