

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Tokyo, Japan, 24-26 October 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 JP in Tokyo, Japan, 24-26 October 2016.

To date, 30 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 general chapter on Colour (Instrumental method) and a revised general chapter on Amino Acid Determination.

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, PDG thanks the efforts of experts from the three regions in addressing the remaining questions. PDG is confident that it will issue a Stage 4 draft for public enquiry in the near future.

As far as the "Elemental impurities" text is concerned, the three pharmacopoeias continue to affirm their commitment to harmonising this general chapter on testing procedures for elemental impurities. PDG has made significant progress in advancing to a Stage 4 draft for public enquiry given the importance of this general chapter.

Progress has been made on four of the recently added items, Isostearyl alcohol, Myristyl myristate, Polysorbate 65, and Sodium cetyl sulfate. JP has been confirmed as the coordinating pharmacopoeia for these monographs and the draft texts provided to USP will also be provided to EP for comment in accordance with the PDG procedure.

The highlights of this meeting can be found at:

<http://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0008.html>

Next Meeting The next face-to-face PDG meeting will be hosted by USP tentatively proposed the week of 22 May 2017 in Rockville, Maryland, USA.

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