
## 22 November 2016, Strasbourg, France
## PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

The meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP), and United States Pharmacopeia (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, the PDG thanks the experts from the three regions for their efforts in addressing the remaining questions. The 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. The 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 will be published soon on the EDQM website https://www.edqm.eu/en/international-harmonisation-614.html and the next face-to-face PDG meeting to be hosted by USP is tentatively scheduled for the week of 22 May 2017 in Rockville, Maryland, USA.

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**Note for the Editor**: Further information is available on the internet site **www.edqm.eu**
The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia is legally-binding in Member States[1]. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are thirty-eight members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the Former Yugoslav Republic of Macedonia, Turkey, Ukraine, United Kingdom and the European Union.*

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