



21 June 2016, Strasbourg, France

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

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 [here](#).

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*.

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

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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 Pharmacopoeia is legally-binding in Member States¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There 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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