02 February 2016, Strasbourg, France

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Rockville, Maryland, U.S.A., November 3-4 2015

The meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (Ph.Eur.), Japanese Pharmacopoeia (JP), and the United States Pharmacopeia (USP)] was hosted by USP in Rockville, Maryland, U.S.A., November 3-4 2015.

At present, 29 of the 36 General Chapters and 48 of the 62 excipient monographs on the current work programme have been harmonized. Sign-offs at this meeting include a revision to "Uniformity of Content/Mass." 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 toward sign-off.

With regard to "Chromatography chapter", as a follow-up from the previous PDG meetings, the coordinating pharmacopeia had submitted a revised Stage 3 draft based on decisions made from a teleconference with experts from the three regions in May. Comments have been received and will be further discussed with the Experts of the coordinating pharmacopeia with the goal to present a Stage 4 draft for public inquiry.

The three pharmacopoeias exchanged information on their respective approaches for the implementation of the ICH Q3D guideline. PDG confirmed their commitment to harmonize the general chapter on testing procedures for elemental impurities. The coordinating pharmacopeia presented a Stage 3 draft and comments were discussed.

PDG continued an ongoing discussion on cellulosics. For ethylcellulose, the coordinating pharmacopeia presented data comparing differing assay methods, including the published PDG stage 4 method. The recommendation was to proceed with the PDG stage 4 method, although additional discussion with the experts is needed. PDG is proposing to reach consensus by mid-February 2016 in its path forward.

Excipients Council

A meeting with the International Pharmaceutical Excipients Council (IPEC) Federation was held on November 4, 2015. Topics discussed included monographs for ethylcellulose, hydroxyethylcellulose, carmellose sodium, polyethylene glycol, povidone, copovidone, pregelatinized starch, Colloidal silicon dioxide and silicon dioxide.

The meeting highlights for this meeting can be found: International Harmonisation.

The next face-to-face PDG meeting will be hosted by European Pharmacopoeia on May 25-26, 2016 in Strasbourg, France.

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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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