独立行政法人
医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Press Release

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

Rockville, Maryland, U.S.A., 25-26 June 2014

The meeting of the Pharmacopoeial Discussion Group (PDG) [European Pharmacopoeia (EP), Japanese Pharmacopoeia (JP), and the United States Pharmacopeia (USP)] was hosted by the USP in Rockville, Maryland, on 25-26 June 2014.

At present, 29 of the 36 General Chapters and 46 of the 62 excipient monographs on the current work programme have been harmonized. Sign-offs at this meeting included a new general chapter "Thermal Analysis" and a revised general chapter "Polyacrylamide Gel Electrophoresis." The latter reflects recent developments and current practices and allows for greater flexibility in the use of ready-made gels. In addition, a new monograph for "Glucose Monohydrate/Anhydrous" was signed off.

In-depth discussions on 27 additional items (including the revisions) currently on the work programme took place with a view to resolving outstanding issues and advancing the items toward sign-off.

Other Topics

In light of the anticipated sign-off of the ICH Q3D guideline for elemental impurities, PDG members agreed to harmonize their general chapters on methods related to elemental impurities, with USP serving as the coordinating pharmacopoeia.

PDG members also agreed to add a general chapter on dynamic light scattering to its work program, with JP as the coordinating pharmacopoeia.

Participating pharmacopoeias also discussed harmonizing viscosity measurement methods, and agreed to conduct a feasibility study with the "Carmellose Sodium," "Hydroxyethylcellulose," and "Hydroxypropylcellulose Low Substituted" monographs.

Following on the discussion at its previous meeting, PDG members agreed on concrete actions to improve its working procedures and improve transparency to stakeholders.

As of this June 2014 meeting, a summary document of the outcome of the meeting will be made available on the websites of the three pharmacopoeias.

Next Meeting

The next face-to-face PDG meeting will be hosted by the European Pharmacopoeia on November 12-13, 2014 in Strasbourg, France.

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