Pharmacopeial Discussion Group Meeting

Meeting Highlights

September 12-13, 2017
USP-Rockville
Rockville, Maryland, USA

1. Introduction of New PDG Structure

As a continuation of initial discussions that took place at the October 2016 PDG meeting in Tokyo, PDG has agreed to the implementation of significant changes to the work structure. These include:

1. Restructuring meeting format to engage more at the technical level and introduce more direct exchange between the experts in the regions via teleconference to resolve issues with specific PDG topics. This has resulted in a change in the format and frequency of the face-to-face meetings to occur once a year with one interim video teleconference with the purpose of the main meetings to focus more on strategic direction setting.
2. Therefore, the agenda of the PDG meetings and as a consequence the meeting highlights has been revised to reflect this new approach.
3. PDG has streamlined its working procedure resulting in the elimination of two stages to reduce the level of complexity which will increase efficiency and improve focus in the discussion.
4. PDG has begun both a strategic review of harmonization areas and individual work items currently in progress and for future consideration.
5. Harmonization of several items will be continued in other collaborative venues, such as bilateral discussion or adopt/adapt mechanisms as mentioned in the Good Pharmacopoeial Practices (GPhP). These items will not be part of the trilateral work program until further notice: EP, JP, and USP will continue to closely share information and progress on these items external to PDG.

2. Harmonization Topics Signed-off

2.1. General Chapters

2.1.1. New

G-03 Conductivity (USP)

PDG signed-off on this new text.

2.2. Excipients

2.2.1. Revised

2.2.1.1. E-06 Calcium Phosphate Dibasic Anhydrous (JP)

PDG signed off on this text which updated the assay and Loss on Ignition (LOI) specifications.

2.2.1.2. E-10 Microcrystalline Cellulose (USP)

PDG signed off on this text which includes a more specific Identification (ID) test using Infrared (IR) spectroscopy.

2.2.1.3. E-21 Hypromellose (JP)

PDG signed off on this text which improved the assay gas chromatography (GC) method by replacing the packed column with a capillary column.

2.2.1.4. E-26 Methylcellulose (JP)

PDG signed off on this text which improved the assay GC method by replacing the packed column with a capillary column.

3. PDG Work Programme

3.1. Discussion / Decision on Way Forward for Topics Requiring Specific Emphasis

3.1.1. G-07 Elemental Impurities (USP)

The coordinating pharmacopoeia has addressed the comments provided by the other pharmacopeias on the previous draft and submitted an updated draft to PDG for consideration to public inquiry.

3.1.2. E-16 Crospovidone (EP)/E-32Povidone (JP)/E-54 Copovidone (JP)

Based on a request from a regulator to update the Povidone monographs for the inclusion of a more selective assay method, one of the participating pharmacopoeias submitted a request for revision for inclusion of the Gel Permeation Chromatography (GPC) method for assay and impurities to PDG. The other pharmacopoeias will provide comments.

3.1.3. E-28 Petrolatum (USP)/E-29 Petrolatum, White (USP)

The coordinating pharmacopoeia provided additional progress on the

package for public inquiry. The limit for Polycyclic Aromatic Hydrocarbons (PAH) is proposed.

3.1.4. E-30 Polyethylene Glycol (USP)

The coordinating pharmacopoeia had submitted a request for revision to PDG for ID by IR. PDG accepted the revision proposal and comments will be addressed by the coordinating pharmacopoeia.

3.1.5. E-36 Silicon Dioxide (JP)/E-37 Silicon Dioxide, Colloidal (JP)

A PDG pharmacopoeia completed blinding of test samples for Silicon Dioxide/Silicon Dioxide, Colloidal in order to support a round robin testing of a proposed IR method to distinguish these two materials. PDG is awaiting data from the trade association IPEC Federation.

3.2. Revision Proposals

3.2.1. E-09 Croscarmellose Sodium (USP)

The coordinating pharmacopoeia sent a request for revision to include an ID by IR including validation summary to the participating pharmacopoeias. The latter will provide comments.

3.2.2. E-45 Sucrose (EP)

A PDG pharmacopoeia sent a request for revision to include an HPLC assay and impurities test. The other pharmacopoeias will provide comments.

3.3. Suppression from the Work Programme

The following items have been identified for suppression per the description highlighted in Subsection 5 of the Topic: Introduction of the New PDG Structure.

1. G-08 Inhalation
2. B-04 Protein Determination
3. E-33 Saccharin/E-34 Saccharin Sodium/E-35 Saccharin Calcium

In addition, PDG identified the following items as being only bilaterally harmonized and therefore suppressed from the work programme.

1. G-12 Porosimetry by Mercury Intrusion
2. G-17 Uniformity of Delivered Dose of Inhalations
3. G-18 Microcalorimetry
4. G-19 Density of Solids
5. E-12 Cellulose Acetate
6. E-53 Calcium Carbonate

As of consequence, 28 of the 31 General Chapters and 45 of the 62 excipient monographs on the current work programme have been harmonized between the PDG Pharmacopoeias.

4. Next Face-to-Face Meeting

The next meeting will tentatively take place October 2-3, 2018 in Strasbourg, France.