Pharmacopoeial Discussion Group Meeting

Meeting Highlights

24-26 October 2016

PMDA

Tokyo, Japan

1. Harmonisation Topics Signed-off

1.1. General Chapters

1.1.1. New

1.1.1.1. Q-07 Colour (Instrumental method) (EP)

PDG signed off this new text.

1.1.2. Revised

1.1.2.1. B-01 Amino Acid Determination, Rev. 1 (USP)

PDG signed off on this text which clarifies the language in the protein standard samples for hydrolysis in methods 6 and 7.

1.2. Excipients

1.2.1. Revised

1.2.1.1. E-64 Isomalt, Rev. 1 (EP)

PDG signed off on this text which clarifies the modification of the preparation of test and reference solutions.

2. Major Harmonisation Topics

2.1.1. **ICH Q3D: Guideline for Elemental Impurities** (Implementation in the 3 regions)

Each pharmacopoeia shared updates on the strategy to support the implementation of the ICH Q3D Elemental Impurities Guideline in their respective regions, including assessing the effects of removing or retaining specific elemental impurity specifications in individual

monographs.

3. Harmonisation Progress on PDG Work Programme

3.1. Topics undergoing harmonisation

3.1.1. G-03 Conductivity (USP)

The coordinating pharmacopoeia would organise a technical teleconference based on comments received from other pharmacopoeias.

3.1.2. G-07 Metal Impurities (USP)

The coordinating pharmacopoeia addressed major comments from other pharmacopoeias and provided a revised stage 3 draft. The other pharmacopoeias are in the process of providing comments on the revised stage 3 draft.

3.1.3. G-20 Chromatography (EP)

The coordinating pharmacopoeia provided a stage 4 draft in view of its public enquiry. One of the participating pharmacopoeias remains to confirm agreement on the stage 4 draft.

3.1.4. E-08 Carmellose Sodium (USP)

The coordinating pharmacopoeia will provide a stage 4 package based on comments from the participating pharmacopoeias. Those comments include differences of scientific opinion on the assay. Comments were also received on the viscosity proposal from stakeholders.

3.1.5. E-23 Lactose anhydrous/ E-24 Lactose monohydrate/ E-63 Lactose for Inhalation (USP)

Coordinating pharmacopoeia provided an assay and impurity method validation package which will be reviewed by the participating pharmacopoeias.

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

The coordinating pharmacopoeia provided an update on their progress for the stage 4 package. The appropriate limit for polycyclic aromatic hydrocarbons still remains an issue under discussion.

3.1.7. E-30 Polyethylene Glycol (USP)

The coordinating pharmacopoeia provided additional updates on progress made for the two projects, i.e. the IR identification and the development of a method for aldehydes. The coordinating pharmacopoeia is also evaluating an aldehyde procedure received from a stakeholder.

3.1.8. E-43 Wheat Starch (EP)

The coordinating pharmacopoeia will provide a stage 4 draft after confirmation from one of the participating pharmacopoeias.

3.1.9. E-46 Talc (USP)

The coordinating pharmacopoeia provided updates on the progress of the work of the newly formed talc methods expert panel. The expert panel defined the working scope of types of asbestos to be evaluated for their absence and are currently evaluating methods deemed necessary to satisfy the adopted scope.

3.1.10. E-59 Propylene Glycol (EP)

The coordinating pharmacopoeia provided the feedback on the comments received during the public enquiry and continue the practical work on validation of the modified GC assay.

3.1.11. E-61 Starch, Pregelatinised (JP)

The coordinating pharmacopoeia briefed a summary of the results of the round robin study organised by the IPEC Federation and is awaiting feedback from the participating pharmacopoeias.

3.2. Revision Proposals

3.2.1. G-13 Particle-size analysis by laser light diffraction (EP)

The coordinating pharmacopoeia will review the comments sent by the participating pharmacopoeias.

3.2.2. E-60 Sodium Lauryl Sulfate (USP)

An agreement has been found on the assay procedure. The modification of the identification section by addition of an infrared test is under discussion; in addition, one of the participating pharmacopoeias is examining the possibility of adding a TLC test to improve the specificity.

4. Prospective Harmonisation of Excipient monographs

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.

5. Next Meeting

The next meeting was tentatively proposed for the week of 22 May 2017 in Rockville, Maryland, USA.