



Pharmacopoeial Discussion Group Meeting

Meeting Highlights

6 November 2020

Videoconference

Hosted by the USP

1. Harmonisation Topics Signed off

Due to the COVID-19 pandemic, individual work program sign-offs were handled by correspondence after the videoconference. As ever committed to transparency, the PDG has published the full signed-off texts on each pharmacopoeia's website (link).

1.1. Revised General Chapter

1.1.1. G-14 X-Ray Powder Diffraction (Rev.1) (EP)

The PDG agreed to sign off on this text which had been revised to bring it up to date and make it more scientifically rigorous.

1.2. Revised Excipient Monograph

1.2.1. E-09 Croscarmellose Sodium (Rev. 1) (USP)

The PDG agreed to sign off on this text, which had been revised to include a new identification (ID) test by infrared (IR) spectroscopy, delete a non-specific ID test and replace the original flame test for sodium ID with a wet chemistry test using potassium pyroantimonate.

1.2.2. Other Monographs

The PDG agreed to sign off on correction of 7 excipient monographs and to amend sign-off coversheets for 2 excipient monographs to correct errors in harmonised texts or to reflect the different local texts as follows.

E-03 Benzyl Alcohol (Rev. 2, Corr. 2) (EP)

E-25 Magnesium Stearate (Correction of Sign-off Coversheet) (USP)

E-27 Methyl Parahydroxybenzoate (Rev.1, Corr. 2) (EP)

- E-31 Polysorbate 80 (Correction of Sign-off Coversheet) (EP)
- E-38 Sodium Chloride (Rev. 3, Corr. 2) (EP)
- E-43 Wheat Starch (Rev. 3, Corr. 1) (EP)
- E-48 Ethyl Parahydroxybenzoate (Rev.1, Corr. 2) (EP)
- E-49 Propyl Parahydroxybenzoate (Rev.1, Corr. 2) (EP)
- E-50 Butyl Parahydroxybenzoate (Rev.1, Corr. 1) (EP)

2. Maintenance of ICH Q4B annexes and engagement of the pharmacopoeias of the countries/regions of non-founding ICH Regulatory Members

As host of the next PDG meeting, the European Pharmacopoeia (Ph. Eur.) summarised the latest information on this project which aims to achieve broader interchangeability between pharmacopoeial methods in different pharmacopoeias, including those published by non-founding and non-standing ICH regulatory members. It was noted that feedback had been received indicating that ICH would be disposed to agree to the proposed pilot at the upcoming ICH Management Committee and Assembly meetings on 18 November 2020. The PDG had agreed to present slides prepared by the Ph. Eur. at the next ICH Assembly meeting.

Post meeting note: Following this meeting, the Ph. Eur. presented the proposal on behalf of the PDG and the ICH Assembly endorsed the PDG pilot approach.

The PDG would publish more information on the topic of the ICH Q4B annexes in a dedicated press release.

3. Discussion/Decisions on the way forward for topics requiring specific emphasis

3.1. General Chapters

3.1.1. G-20 Chromatography (EP)

Following public consultation and final comments on this new PDG text, the co-ordinating pharmacopoeia provided an update on its status and presented a proposal for the next steps. Discussions were ongoing with the possibility of concluding in 2021.

3.1.2. G-07 Elemental Impurities (USP)

The co-ordinating pharmacopoeia updated the status of this item and was still reviewing the comments received from stakeholders during its public consultation and from the other two pharmacopoeias.

3.2. Excipients

3.2.1. E-45 Sucrose (USP)

The co-ordinating pharmacopoeia presented extensive public comments received on the PDG Stage 2 proposal for Sucrose, noting that it would

follow up with its stakeholders and get back to the PDG with a consolidated opinion. No similar comments had been received by the other two pharmacopoeias.

3.2.2. E-62 Sterile Water for Injections (USP)

The co-ordinating pharmacopoeia presented a progress report and study results for the harmonised text. While other issues were addressed, the discussions centered on updating the TOC test. In-depth discussions on the data provided would be needed before further progress could be made on the topic.

3.2.3. Identification Section (E-01 Alcohol/E-02 Dehydrated Alcohol, E-51 Glycerin) (EP, USP)

The co-ordinating pharmacopoeia reviewed the status of these items, noting that limit tests for impurities were not considered part of the ID section in its monographs. The USP specified that the inclusion of limit tests in the Identification section of USP monographs had been requested by the FDA for monographs with high patient safety concerns, including the monographs on Glycerin and Alcohol. The regulatory framework for legal testing requirements differed between the countries/regions and would lead to differences in the monographs.

4. Endotoxin Assays Using Recombinant Reagents (USP)

The co-ordinating pharmacopoeia reviewed the status of the corresponding texts in the three pharmacopoeias and would perform a gap analysis of the different approaches of the pharmacopoeias to get a clearer picture of the commonalities and differences. JP reported that the General Information Chapter “Bacterial Endotoxins Test and Alternative Methods Using Recombinant Protein-Reagents for Endotoxin Assay <G4-4-180>” would be published in JP18 in June 2021 as scheduled.

The Ph. Eur. had published general chapter 2.6.32. *Test for bacterial endotoxins using recombinant factor C* in Ph. Eur. Supplement 10.3 with an implementation date of 1 January 2021.

5. Next Meeting

The next annual meeting will be hosted by the Ph. Eur. on 5 and 6 October 2021, either in Strasbourg, France or by videoconference.