

2015-2020 General Chapters Chemical Analysis Expert Committee (GCCA EC)
Wednesday - Thursday, Sept 25 - 26, 2019
9:00 a.m. – 5:00 p.m., 9:00 a.m. – 2:30 p.m.
USP-U.S., Rockville

Agenda – Draft

Goals and Anticipated Outcomes

The primary goal of this meeting is to go over action items generated during the previous meeting to monitor their status, update the Committee on activities involving the different Subcommittees, and introduce new topics for discussion according to the work plan.

Attendees

Attendee list provided on the day of the meeting

Day 1

Wednesday, September 25, 2019

8:45 a.m. Arrive at USP, register and check in

CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS

- 9:00 a.m. **1. Closed Procedural Matters and Standards of Conduct**
(Informational)
- a. Welcome, Opening Remarks, Introduction Ms. Lewen
 - b. Conflicts of Interest, Confidentiality, Code of Ethics Mr. Freebern
 - c. Review of Agenda for Specific Conflicts of Interest/Need for Recusal All
- 9:05 a.m. **2. Expert Committee Ballot Items**
(Informational)
- a. <191> *Identification Test-General* Ms. Botros
 - b. <467> *Residual Solvents – Special Ballot (IRA)* Dr. Biba
 - c. <31> *Volumetric Apparatus* Mr. Hernández-Cardoso
 - d. <791> *pH* Mr. Hernández-Cardoso
 - e. <858> *Raman Spectroscopy* Ms. Botros
 - f. <1120>/<1858> *Raman Spectroscopy–Theory and Practice* Ms. Botros

END OF CLOSED SESSION

- 9:20 a.m. **3. Open Procedural Matters**
(Informational & Decision-making)
- a. Welcome Ms. Lewen
 - b. Meetings Center Announcements Ms. White
 - c. Recording Policy and any other Procedural Announcements Mr. Freebern

- d. Introduction of Members, Government Liaisons
Observers, and Staff All
 - e. Establish Quorum Ms. Lewen
 - f. Approval of Agenda Ms. Lewen
 - g. Approval of Minutes of Previous Meeting Ms. Lewen
 - h. Action Items from Previous Meeting Mr. Freebern
- 9:30 a.m. **4. Regulatory** Dr. Pappa
(Discussion)
- a. The Analytical Procedure Lifecycle Expert Panel
- 10:15 a.m. **Break**
- 10:30 a.m. **5. Spectroscopy**
(Discussion)
- a. <761> and <1761> *NMR Spectroscopy* Mr. Shelbourn, Ms. Botros
 - b. <857> and <1857> *Ultraviolet-Visible Spectroscopy* Mr. Hammond
 - c. <853> *Fluorescence Spectroscopy* Mr. Hammond, Dr. Biba
 - d. <852> *Atomic Absorption Spectroscopy* Mr. Shelbourn
- 11:15 a.m. **6. Chromatography**
(Discussion)
- a. *Stimuli* Article-Residual Solvents Determination by SIFT-MS Dr. Biba
 - b. <467> *Residual Solvents – IRA* Dr. Biba
- See Harmonization section: <621>*
- 12:00 p.m. **Lunch**
- 1:00 p.m. **7. Impurities**
(Discussion)
- a. <232> *Elemental Impurities - Limits* Dr. Zaidi
 - b. USP Element Specific Chapters Ms. Lewen, Dr. Zaidi
 - c. *Stimuli* Article on Elemental Impurities Mr. Shelbourn
 - d. Organic Impurities in Drug
Substances and Drug Products Dr. Swiss, Mr. Hernández-Cardoso
- 2:00 p.m. **8. Water** Dr. Soli, Dr. Bevilacqua, Mr. Slabicky
(Discussion)
- a. <645> *Water Conductivity*
 - b. <643> *Total Organic Carbon, Sterile Water*
 - c. <1231> *Water for Pharmaceutical Purposes*
 - d. TOC limit for SWFI-Roundtable – Summary
- See Harmonization section: Sterile Water for Injection Monograph*

- 3:00 p.m. **Break**
- 3:30 p.m. **9. Quality Standards for Pharmaceutical Continuous Manufacturing Expert Panel** (Discussion) Dr. Matos, Dr. Biba, Ms. Botros
- 4:00 p.m. **10. Analytical Methodologies Based on the Light Scattering Phenomena Expert Panel** (Informational) Dr. Swiss, Dr. Biba
- a. <1430.3> *Analytical Methodologies Based on Scattering Phenomena-Dynamic Light Scattering* – Public Comments
 - b. <1430.6> *Analytical Methodologies Based on Scattering Phenomena-Particle Counting by Light Scattering* – Public Comments
 - b. <1430.7> *Analytical Methodologies Based on Scattering Phenomena-Nephelometry and Turbidimetry* – Public Comments
- 4:30 p.m. **Meeting Day 1 Adjournment**

Day 2
Thursday, September 26, 2019

- 9:00 a.m. **11. Harmonization Topics** (Discussion)
- a. <233> *Elemental Impurities-Procedures* Dr. Zaidi
 - b. <621> *Chromatography* Dr. Pappa
 - c. *Sterile Water for Injection* Drs. Bevilacqua, Dr. Soli, Mr. Slabicky
- 10:00 a.m. **Break**
- 10:30 a.m. **12. Workplan and Legacy Document** (Informational & Decision-making) Ms. Lewen
- a. Workplan
 - b. Legacy Document
- 12:00 p.m. **Lunch**
- 1:00 p.m. **13. General Chapters Strategy** Dr. Pappa
- 2:00 p.m. **14. Council of Experts Topic** (Informational)
- a. Call for Candidates for the 2020-2025 Cycle Dr. Zaidi
- 2:30 p.m. **Meeting Adjourns**