



**Excipient Monographs 1 Expert Committee (EM 1 EC) Meeting
Thursday – Friday, November 15 – 16, 2018
USP – U.S., Rockville**

Agenda – Draft

Goals and Anticipated Outcomes

- Review FY18 Three Year EC Accomplishments
- Review and Update EM1 Work Plan
- Excipients Strategy Meeting Follow-ups
- Inform 2020-2025 Call For Candidates (C4C) Procedure
- Monograph Discussion
 - Medium Chain Triglycerides
 - Guanidine HCl
 - Carbomers
 - POLY(DL-LACTIC-CO-GLYCOLIC ACID) (PLGA)
 - Soybean Phospholipids
- Review charts mapping all USP-NF General Chapters
- Revised Excipients Website Demo
- Discuss Donor Recognition
- Discuss Individual EM1 EC Member Experiences
- Discuss Specific Tests in monographs for excipients used in injectables
- Polysorbates Joint Subcommittee Update
- Element Specific Chapters and Tests for Revision
- Co-Processed Excipients Update
- Discuss Roadmap for excipient monograph modernization
- Expert Panel Update – <1059> Excipient Performance
- Excipient Impurities Update
- General Chapters Revision Update
- Update on Transition to new USP-NF platform

Attendees

Attendee list provided on the day of the meeting

Day 1

Thursday, November 15, 2018

8:15 a.m. Arrive at USP, register and check in

CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS

- 8:30 a.m. **1. Closed Procedural Matters and Standards of Conduct**
- a. Welcome, Opening Remarks, Introduction
 - b. Conflicts of Interest, Confidentiality, Code of Ethic
 - c. Review of Agenda for Specific Conflicts of Interest/Need for Recusal

Dr. Carvalho
Dr. Carvalho
All

END CLOSED SESSION



- 8:45 a.m. **2. Open Procedural Matters**
- a. Welcome Dr. Carvalho
 - b. Meeting Center Announcements Ms. Hawkins
 - c. Roll Call and Introduction of Members, Staff and Observers All
 - d. Announce Changes to the Attendee List, Confirm Quorum, Procedural Announcements, Recording Policy Mr. Lew
 - e. Approval of Agenda Dr. Carvalho
 - f. Approval of Previous Meeting Minutes (September 19) Dr. Carvalho
 - g. Review of Previous Meeting Action Items Mr. Lew
- 9:00 a.m. **3. FY18 Three Year EM1 EC Accomplishments** Ms. Sheehan/Dr. Wang
- Expected Outcome: Update the EC
- a. PF publications and Approved Standards – *USP40-NF 35 1S, USP40-NF35 2S, USP41-NF36*
- 9:20 a.m. **4. Review and Update EM1 usp.org Work Plan** Ms. Sheehan/Dr. Wang
- Expected Outcome: Update the EC and align on deliverables
- a. FY19 Work Plan prioritization and deliverables
 - b. Work beyond FY19 that will need EC support at some point and Milestones
 - i. Consequential Standards
 - ii. Lab projects
- 10:05 a.m. **5. Excipients Strategy Meeting Follow-ups** Dr. Carvalho/All
- Expected Outcome: Update the EC
- a. Perspective from those that attended
 - b. Action Items update
- 10:30 a.m. **Break**
- 10:45 a.m. **6. Inform 2020-2025 Call For Candidates (C4C) Procedure** Ms. Bellon
- Expected Outcome: Inform and update the EC
- a. Discuss application procedure and new process
 - b. Recruitment Ambassadors
- 11:05 a.m. **7. Monograph Discussion – Carbomers** Dr. Wang/Dr. Delaney
- Expected Outcomes: Guidance on future work/future studies
- a. Potential research project – build knowledge database
 - b. Proton NMR – Potential future update for ID
 - c. Solid state NMR – Preliminary discussion
- 12:00 p.m. **Lunch (Group Photo)**
- 1:00 p.m. **8. Revised Excipients Website Demo** Mr. Rashed
- Expected Outcome: Inform and demo the website with the EC
- 1:15 p.m. **9. Monograph Discussion – Medium Chain Triglyceride** Dr. Holloway
- Expected Outcomes: Discuss comments and seek EC feedback



- a. IRA PF44(5) comments
- 1:35 p.m. **10. Monograph Discussion – Guanidine HCl** Dr. Holloway
Expected Outcomes: Discuss and seek EC feedback
 - a. Cyanide Test
- 1:50 p.m. **11. Monograph Discussion – PLGA** Dr. Zhang
Expected Outcomes: Discuss and seek EC feedback
 - a. New monograph development update
 - b. Five potential monographs and Sponsor
- 2:30 p.m. **12. Review charts mapping all USP-NF General Chapters (Open Discussion)** All
Expected Outcomes: Awareness and review of the General Chapters Chart (pg 8583 – 8537 for Excipients Chart). Feedback requested
- 2:45 p.m. **Break**
- 3:00 p.m. **13. Monograph Discussion – Soybean Phospholipids** Dr. Wang
Expected Outcome: Expected Outcome: Discuss and seek feedback from EC
 - a. Nomenclature
- 3:35 p.m. **14. Discuss Specific Tests in monographs for excipients used in injectables** All
Expected Outcome: Discuss what tests need to be included during a revision and labeling
 - a. Example to discuss: Citric Acid monograph (Monograph Sections on Specific Tests and Additional requirements)
- 4:10 p.m. **15. Polysorbates Joint Subcommittee Update** Dr. Moore
Expected Outcomes: Update from Joint SC
- 4:30 p.m. **16. Discuss Donor Recognition** Ms. Torbey/All
Expected Outcomes: Provide background and brainstorm ways of recognizing donors in order to incentivize and encourage industry to work with USP.
- 5:00 p.m. **Adjourn – Day 1, Transportation to Hotel**
- 6:00 p.m. **Dinner at:**
La Canela (walkable from the Hotel)
141-D Gibbs St.
Rockville, MD 20850

Day 2
Friday, November 16, 2018



8:30 a.m.	17. Discuss Individual EM1 EC Member Experiences Expected Outcome: Discuss and optimize working procedures a. Information management within EC and program unit (internal to USP) b. Liaison interaction, communication with Collaborate/emails, etc. c. Management of using broad scientific expertise vs individual expertise for monographs	Dr. Moreton
9:15 a.m.	18. Element Specific Chapters and Tests for Revision Expected Outcome: Discuss and seek feedback from EC a. Deletion or Update	Dr. Holloway
10:30 a.m.	Break	
10:45 a.m.	19. Co-Processed Excipients Update Expected Outcome: Update EC and discuss next steps a. Feedback from EP and upcoming working group	Dr. Wang
11:00 a.m.	20. Discuss Future Roadmap for Excipient Monograph Modernization (Open Discussion) Expected Outcomes: Discuss a roadmap for excipient monograph modernization and the development of new technologies for excipients, per Strategy Meeting action item and finalized algorithm including both public health impact/sustainability. a. Possible Stimuli Article or Peer Reviewed Article b. EC members to review article by Shangraw (1987) – Attention: Pg 2426 – 2429 on committees	All
12:00 p.m.	Lunch	
1:00 p.m.	21. Expert Panel Update – <1059> Excipient Performance Expected Outcome: Update and inform the EC	Dr. Holloway/Dr. Moreton
1:20 p.m.	22. Excipient Impurities Update Expected Outcome: Discuss and seek feedback on path forward from EC a. Survey Status/Results b. Review Comments	Dr. Holloway
1:55 p.m.	23. General Chapters Revision Update Expected Outcome: Update and inform the EC a. General Chapter <11> <i>USP Reference Standards</i>	Ms. Chang
2:20 p.m.	24. Update on Transition to new USP-NF platform and upcoming enhancements Expected Outcome: Update and inform the EC	Dr. White
2:45 p.m.	25. Meeting Wrap-Up	Dr. Carvalho



3:00 p.m. **Adjourn**

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