



**Excipient Monographs 2 Expert Committee (EM 2 EC) Meeting  
Wednesday – Thursday, October 17 – 18, 2018  
Briggs Parker, Wiley, Marshall Rooms  
USP Headquarters, Rockville, Maryland**

**Agenda – Draft**

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**Goals and Anticipated Outcomes**

- Review FY18 Three Year EC Accomplishments
- Review and Update EM2 Work Plan
- Revised Excipients Website Demo
- Excipients Strategy Meeting Follow-up
- Discuss 2020-2025 Call For Candidates (C4C) Procedure
- Recruitment Ambassador Update
- Discuss 2020-2025 Council of Experts (CoE)
- PDG Monograph Discussion
- Update on Transition to new USP-NF platform
- PDG Update
- Indication of Harmonization Review
- Expert Panel Updates
- General Chapters Revision Update
- Element Specific Chapters Discussion
- Excipient Impurities Update
- Japanese Pharmacopeia Update

**Attendees**

*Attendee list provided on the day of the meeting*

**Day 1**

**Wednesday, October 17, 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. Houck  
Chair  
All

**END CLOSED SESSION**

- 8:45 a.m. **2. Open Procedural Matters**
- a. Welcome
  - b. Meeting Center Announcements
  - c. Roll Call and Introduction of Members, Staff and Observers
  - d. Announce Changes to the Attendee List, Confirm Quorum, Procedural Announcements, Recording Policy
  - e. Approval of Agenda

Dr. Houck  
Ms. Hawkins  
All  
Mr. Lew  
Dr. Houck



- f. Review of Previous Meeting Action Items Mr. Lew
- 9:00 a.m. **3. FY16-18 EM2 EC Accomplishments** Ms. Sheehan/Dr. Liu  
Expected Outcome: Update the EC  
a. PDG sign-offs  
b. Stage 4 and Stage 2 publications  
c. PF publications and Approved Standards – USP40-NF 35 1S, USP40-NF35 2S, USP41-NF36
- 9:20 a.m. **4. Review and Update EM2 usp.org Work Plan** Ms. Sheehan/Dr. Liu  
Expected Outcome: Update the EC  
a. FY19 Work Plan prioritization
- 9:40 a.m. **5. Revised Excipients Website Demo** Mr. Rashed  
Expected Outcome: Inform and demo the website with the EC
- 10:00 a.m. **6. Excipients Strategy Meeting Follow-up** Dr. Houck/All  
Expected Outcome: Follow-up to the Strategy meeting  
a. Update on outcomes from August 1 – 2 Strategy meeting  
b. Perspective from those that attended  
c. Action Items update
- 10:30 a.m. **Break**
- [CLOSED TO ALL OBSERVERS]**
- 10:45 a.m. **7. E-23/24/63 Lactoses** Dr. Liu/Dr. Tu  
Expected Outcome: Discuss path forward  
a. Assay/Impurity –method evaluation and questions  
b. Performance tests for inhalation grades
- 11:10 a.m. **8. E-30 Polyethylene Glycol** Dr. Liu/Dr. Block/Dr. Serr  
Expected Outcome: Update from the Joint SC  
a. Phase 1: IR, EG/DEG (add tests for MW 1000 – 8000), Ethylene Oxide and Dioxan, and Aldehydes  
b. Phase 2: Viscosity and different grades, MW determination
- 11:35 a.m. **9. Polysorbates / E-68 Polysorbate 65** Dr.Liu/Dr. Sun  
Expected Outcome: Update from the Joint SC  
a. Assay method development for different grades  
b. Preliminary testing  
**[END CLOSED SESSION]**
- 12:00 p.m. **Lunch (Group Photo)**
- 1:00 p.m. **10. Discuss 2020-2025 Call For Candidates (C4C) Procedure** Ms. Bellon  
Expected Outcome: Inform and update the EC  
a. Discuss application procedure  
b. New application process



- 1:30 p.m. **11. Recruitment Ambassador Update** Dr. Wu
- 1:45 p.m. **12. Discuss 2020-2025 Council of Experts (CoE)** Dr. Houck/Ms. Sheehan  
Expected Outcome: Update the EC and seek feedback  
a. Report out from the CoE  
b. Update on next cycle for Excipients  
c. Harmonization Subcommittee Distribution
- 2:30 p.m. **Break**
- 2:45 p.m. **13. Update on Transition to new USP-NF platform** Dr. White  
Expected Outcome: Update and inform the EC
- [CLOSED TO ALL OBSERVERS]**
- 3:05 p.m. **14. Povidones** Dr. Liu/Dr. Wu  
Expected Outcome: Discuss and seek feedback from EC  
a. 2-Pyrrolidone limit  
b. Formic acid  
c. GPC method for Assay and Impurities
- 3:35 p.m. **15. Carmellose Family of Monographs** Dr. Liu/Dr. Cabelka  
Expected Outcome: Discuss how to approach the different ID tests  
a. ID  
b. Carmellose Sodium S1 draft proposal  
**[END CLOSED SESSION]**
- 4:00 p.m. **16. PDG Update** Dr. Moore  
Expected Outcome: Update and inform the EC on recent meeting  
a. PDG F2F Strasbourg Meeting (Oct 2 – 3)
- 4:30 p.m. **17. Indication of Harmonization Review** Dr. Liu  
Expected Outcome: Update and inform the EC  
a. Background  
b. Results from the USP Summer Intern
- 5:00 p.m. **Adjourn – Day 1, Transportation to Hotel**
- 6:00 p.m. **Transportation departs from Hotel to Restaurant**
- 6:30 p.m. **Dinner at:**  
Nick's Chop House  
700 King Farm Blvd  
Rockville, MD 20850

**Day 2**  
**Thursday, October 18, 2018**



**[CLOSED TO ALL OBSERVERS]**

- 8:30 a.m. **18. Expert Panel Updates**  
Expected Outcome: Update and inform the EC on progress
- a. **Glycerin**
  - b. **Talc Methods**
- 9:00 a.m. **19. E-66 Myristyl Myristate**  
Expected Outcomes: Discuss lab report and draft proposal
- a. ID by IR lab report
  - b. Draft proposal
  - c. Potential direct Assay method (similar to Cetyl Esters Wax)
- 9:25 a.m. **20. E-60 Sodium Lauryl Sulfate**
- Expected Outcomes: Discuss USP lab preliminary method development and questions about impurity quantitation limit
- a. Assay/Impurity
- 9:45 a.m. **21. E-33/34/35 Saccharin/Saccharin Na/Saccharin Ca**
- Expected Outcomes: Discuss PF 44(2) comments and lab project
- a. Assay – public comments
  - b. Impurity – USP lab work
- 10:10 a.m. **22. E-45 Sucrose**
- Expected Outcomes: Update EC on the SC discussion
- a. Assay/Impurity - Response to PDG
- 10:30 a.m. **Break**
- 10:45 a.m. **23. E-69 Calcium Silicate**
- Expected Outcome: Review and finalize draft proposal
- a. Draft proposal
  - b. pH information
- 11:05 a.m. **24. E-67 Sodium Cetyl Sulfate**
- Expected Outcome: Review PDG comments
- a. JP proposal
- 11:20 a.m. **25. E-65 Isostearyl Alcohol**
- Expected Outcome: SC update to EC
- a. JP proposal
- [END CLOSED SESSION]**
- 11:30 a.m. **26. General Chapters Revision Update**
- Expected Outcome: Update and inform the EC
- a. General Chapter <11> *USP Reference Standards*



12:00 p.m.	<b>Lunch</b>	
1:00 p.m.	<b>27. Element Specific Chapter Discussion</b> Expected Outcome: Update and inform the EC	Dr. Holloway/Dr. Serr/Dr. Wu
1:45 p.m.	<b>28. Excipient Impurities Update</b> Expected Outcome: Discuss and seek feedback from EC a. Survey results/comments b. How to update General Notices 5.60.10 <i>Other Impurities in USP and NF Articles</i>	Dr. Holloway
	<b>[CLOSED TO ALL OBSERVERS]</b>	
2:05 p.m.	<b>29. E-28/E-29 Petrolatum/White</b> Expected Outcome: Respond to EP and JP comments a. Stage 2, Version 2 Proposal	Dr. Liu/Mr. Yasika
2:15 p.m.	<b>30. E-36/E-37 Silicon Dioxide/Colloidal</b> Expected Outcome: Discuss next steps a. Round Robin Study	Dr. Liu/Mr. Bluj
	<b>[END CLOSED SESSION]</b>	
2:30 p.m.	<b>31. Japanese Pharmacopeia Updates</b> Expected Outcome: Update from the JP	Dr. Takeda
2:45 p.m.	<b>32. Meeting Wrap-Up</b>	Dr. Houck
3:00 p.m.	<b>Adjourn</b>	