



Excipient Monographs 1 Expert Committee (EM 1 EC) Meeting
Thursday – Friday, November 30 – December 1, 2017
Bache and Woods Rooms
USP Headquarters, Rockville, Maryland

Agenda-Draft

Goals and Objectives of the Meeting

- Review USP Staff Roles and Responsibilities
Review and Update EM1 FY 18 Work Plan
Review USP-NF Standard Setting Process Monograph Up-to-Date
Monograph Updates – New in Development
Monograph Updates – Request for Revision and Monographs Targeted for or Already in PF
Visiting Scientist Program Updates
EC Status Updates
EC Cross-Cutting Updates

Attendees

Attendee list provided on the day of the meeting

Day 1

Thursday, November 30, 2017

CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS

- 8:30 a.m. 1. Procedural Matters and Standard of Conduct (Informational)
a. Call Meeting to Order
b. Establish Quorum
c. Identification of Observers and Confidential Information
d. Conflicts of Interest
Dr. Munson

END OF CLOSED SESSION

- 8:45 a.m. 2. Opening and Procedural Matters (Informational & Decision-making)
a. Meetings Center Announcements
b. Welcome
c. Introductions
d. Approval of Previous Meeting Minutes (Sep 20, Oct 18)
e. Approval of the Agenda
Ms. Hawkins
Dr. Munson
All
Dr. Munson
Dr. Munson

9:00 a.m. 3. Review USP Staff Roles and Responsibilities
USP Staff

9:10 a.m. 4. Review and Update EM1 Work Plan
a. FY18 Work Plan prioritization
Ms. Sheehan/Dr. Wang

9:40 a.m. 5. Review USP-NF Standard Setting Process
a. Review Reference Standards and RS Candidate
Dr. Reddy/Ms. Macarthy

Evaluation Package (RSCEP)

- b. Review Balloting Responsibilities

10:30 a.m. **Break**

10:45 a.m. **6. Monograph Updates – New in Development** Scientific Liaisons

- a. Polypropylene Glycol 11 Stearyl Ether
Expected Outcome: Update EC on project
- b. Methyl Acrylate, Methyl Methacrylate and Methacrylic Acid (7:3:1) Copolymer 280000 Dispersion
Expected Outcome: Update EC on project
- c. Guanidine Hydrochloride
Expected Outcome: Discussion of comments; EC recommendations for the final monograph text

12:00 p.m. **Lunch (Group Photo)**

1:00 p.m. **7. Monograph Updates – Request for Revision and Monographs Targeted for or already in PF** Dr. Wang/Dr. Holloway

- a. Polysorbate 20
Expected Outcome: Review and discuss monograph package
- b. Lauroyl Polyoxylglycerides
Expected Outcome: Update EC on project
- c. Triethyl Citrate
Expected Outcome: Review and discuss lab data and reports; EC input on the revision proposal.

2:30 p.m. **Break**

2:45 p.m. **8. Monograph Updates – Request for Revision and Monographs Targeted for or already in PF (Continued)** Scientific Liaisons

- a. Galactose
Expected Outcome: Update EC on the lab work; need EC input on the future modernization and inclusion of plant-derived galactose in the monograph.

3:45 p.m. **9. Visiting Scientist Program Updates** Scientific Liaisons and EC members

- a. Polyvinyl Alcohol

4:30 p.m. **10. Monograph Updates – Inorganic Excipients** Dr. Holloway/Dr. Zhang

- a. Update on Raman Feasibility

5:00 p.m. **Adjourn for the Day**

5:15 p.m. **Transportation Departs for Hotel**

6:10 p.m. **Bus Departs from Outside the Hotel Lobby for Dinner**

6:30 p.m. **Dinner at:**

Mon Ami Gabi
7239 Woodmont Ave
Bethesda, MD 20814

Day 2

Friday, December 1, 2017

- 8:30 a.m. **11. EC Status Update** All
- a. Current State
 - I. Monograph Up-to-Date strategy and streamlining the process
 - II. Increasing Member Involvement/Communication
 - III. Projects for Monographs Containing Multiple Grades and Modernization Pathway
 - b. Future State
 - i. Excipient Needs for 2020-2025 CoE Revision Cycle
 - ii. Excipients at risk of adulteration – Identification – Feedback from EC members to help prioritize work
- 9:45 a.m. **Break**
- 10:00 a.m. **12. EC Cross-Cutting Updates** Dr. Holloway
- a. Excipient Impurities Joint Subcommittee (EM1 & EM2) – Discuss Stimuli article
- 11:00 a.m. **13. EC Status Update (Continued – If necessary)** All
- 12:00 p.m. **Lunch**
- 1:00 p.m. **14. EC Cross-Cutting Updates (Continued)** Dr. Wang
- a. Excipient Nomenclature Joint Subcommittee
 - I. Glyceryl Monocaprylocaprate – Comment on the proposed nomenclature
 - II. USP-NF List of Excipients for Inclusion in UNII
 - III. Excipient Nomenclature Guideline – Request for volunteers to write sections
 - b. Element Specific Tests in Excipient Monographs
 - c. <1059> *Excipient Performance* Expert Panel Dr. Holloway/Dr. Zhang
- 2:45 p.m. **15. Meeting Wrap-Up and Action Items** Mr. Lew
- 3:00 p.m. **Adjourn**



3:15 p.m. **Transportation Departs for Hotel/Airport**