



General Chapters Physical Analysis Expert Committee (GC-PA EC)
Thursday, September 14, 2017
8:30 a.m. – 4:00 p.m.
USP-U.S., Rockville
Draft Agenda

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 Expert Committee on activities involving the different Subcommittees, and introduce new topics for discussion according to the work plan.

Attendees - list to be provided at the meeting

Breakfast for Volunteers at the Hotel

8:00 a.m. Depart from hotel lobby by RMA Shuttle to USP-Rockville

CLOSED TO ALL OBSERVERS AND GOVERNMENT LIAISONS

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

END OF CLOSED SESSION

8:45 a.m. **2. Opening and Procedural Matters**
(Informational & Decision-making)
a. Meetings Center Announcements Ms. Hawkins
b. Welcome Dr. He
c. Introductions All
d. Minutes of the Previous Meeting Dr. He
e. Approval of the Agenda Dr. He
f. Procedural Announcements Mr. Freebern

9:00 a.m. **3. Ballots** (Informational) Dr. He
a. Chapters on the Oct. 9 - 23 Ballot for *USP 41-NF 36 1st Supplement*
i. None
b. Reference Standards Dr. Yang
i. *USP Vanillin Melting Point Standard RS (May 22–28)*
ii. *USP Phenyl Salicylate Melting Point Standard RS (July 10–16)*
iii. *Theophylline Melting Point Standard RS (coming soon)*

9:10 a.m. **4. Subcommittee / Expert Panel / Chapter Updates**
(Discussion and Decision-making)
a. Solutions Dr. Templeton, Mr. Hernández-Cardoso
i. <631> *Color and Achromicity*

- ii. <781> *Optical Rotation*
- iii. <841> *Specific Gravity*
- iv. <1061> *Color – Instrumental Determination*
- v. <1236> *Determination of Thermodynamic Solubility (new)*

b. Powders Dr. Sun, Dr. Liu, Mr. Hernández-Cardoso

- i. <281> *Residue on Ignition*
- ii. <616> *Bulk Density and Tapped Density of Powders*
- iii. <699> *Density of Solids*
- iv. <731> *Loss on Drying*
- v. <733> *Loss on Ignition*
- vi. <1174> *Powder Flow*

c. Crystal / Microscopy Dr. Hubert, Dr. Biba, Mr. Hernández-Cardoso

- i. <741> *Melting Range or Temperature*
- ii. <776> *Optical Microscopy*
- iii. <891> *Thermal Analysis*
- iv. <941> *Characterization of Crystalline and Partially Crystalline Solids by X-Ray Powder Diffraction (XRPD)*

10:30 a.m. Break

11:00 a.m. **4. Subcommittee / Expert Panel / Chapter Updates** (continued)

d. Rheology Dr. Block, Dr. Wang, Mr. Hernández-Cardoso

- i. <651> *Congealing Temperature*
- ii. <784> *Dropping Temperature*
- iii. <915> *Measurement of Structural Strength of Semisolids by Penetrometry*
- iv. <1912> *Determination of Consistency in Semisolids (new)*

e. Particles Drs. Meury, Biba

- i. <429> *Light Diffraction Measurement of Particle Size*
- ii. <430> *Particle Size Analysis by Dynamic Light Scattering*
- iii. <1xxx> *Image Analysis of Particles*
- iv. <1xxx> *Zeta Potential* (with light-scattering Expert Panel)

12:00 p.m. Lunch

1:00 p.m. **4. Subcommittee / Expert Panel / Chapter Updates** (continued)

f. Osmolality and Osmolarity-Expert Panel Drs. Coffey, Marques

- i. <785> *Osmolality and Osmolarity*

g. Updates on Joint Subcommittees

- i. Physical Stability (PA EC) Dr. Hancock, Mr. Hernández-Cardoso
- ii. Analytical Methodologies based on Light Scattering Phenomena Expert Panel (CA EC) Dr. Biba
- iii. Quality Standards for Pharmaceutical Continuous Manufacturing Expert Panel (CA EC) Dr. Biba
- iv. Nanotechnology (CA EC and DF EC) Drs. Block, Welfare, Scoggins, Zaidi

2:20 p.m.	5. Harmonization Topics (Informational)	Dr. He
2:30 p.m.	6. Updated Work Plan Review for Year 3 and Subcommittee Rosters (Decision-making)	Dr. He
3:00 p.m.	Break	
3:30 p.m.	7. Upcoming Events HPLC 2018 meeting	Dr. Marques
3:40 p.m.	8. Action Items	Ms. Palmer
3:50 p.m.	9. Meeting Summary	Dr. He
4:00 p.m.	Adjourn	