



Chemical Medicines Monographs 4 & 5 Joint Expert Committee Meeting
May 15–16, 2017
USP–U.S. Rockville, MD

Executive Summary

A quorum was present and Ms. Kim Huynh-Ba and Ms. Amy KarrenChairs, presided over the Chemical Medicines Monographs 4 & 5 Joint Expert Committee Meeting (CHM 4 & 5 EC) face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the CHM 4 & 5 ECs, grouped by topic.

1. **USP 41–NF 36 Ballot:** Attendees met with their respective ECs during a closed session to review the monographs on the 2017 ballot.
2. **System Suitability in Chromatographic Procedures:** USP staff discussed approaches to address inconsistencies of system suitability requirements across monographs. Attendees discussed method suitability and clarifying the limit for system suitability.
3. **General Chapter <197> Spectroscopic Identification Tests:** Attendees discussed the proposed revision for <197> that is targeted for publication in *PF* 43(6) [Nov.–Dec. 2017].
4. **Chemical Medicines Collaborative Group (CG):** Chairs and Vice-Chairs provided an update on topics discussed during CG meetings in 2017. Attendee discussion focused on alternate high-performance liquid chromatography (HPLC) columns, method validation with missing impurities, and removing the term “disregard limits” from monographs.
5. **Radioactive Drugs Expert Panel: EC member and** USP staff provided an update on the monograph review process and discussed a path forward to support existing monographs and potential future revisions.
6. **Monograph Proposal Review:** USP staff provided an overview of the major areas of recurring errata. Attendees identified opportunities for error mitigation in order to strengthen USP’s review process.
7. **Trending of Monograph Review Comments:** USP staff provided an overview of public comment trends that identified the frequently asked clarification questions. Attendees discussed various methods to increase the efficiency of the review process.