Propofol Injectable Emulsion

Type of Posting: Notice of Intent to Revise

Posting Date: 28–Jan–2011

Targeted Official Date: Interim Revision Announcement, 01–Nov–2011

Expert Committee: Monographs—Small Molecules 4

In accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Monographs—Small Molecules 4 Expert Committee intends to revise the preparation of solutions used in the Organic impurities Procedure 2 test in the Propofol Injectable Emulsion monograph. The purpose of the revision is to remove USP Propofol RS as a component of the existing Standard solution because there is no analytical value to including this reference standard in the Standard solution. The proposed revision will include changing the name of the existing Standard solution to System suitability solution, and adding a new Standard solution that is comprised of only USP Propofol Related Compound A RS and USP Propofol Related Compound B RS. No changes to the Chromatographic system, System suitability requirements, analyte concentrations, diluent composition, or acceptance criteria are planned.

It is anticipated that the revision will be published as a Proposed Interim Revision Announcement in PF 37(3) [May–June 2011] pursuant to section 7.02 of the Rules and Procedures.

Should you have questions, please contact Mary Waddell, Scientific Liaison to the Expert Committee (301-816-8124 or msw@usp.org).