
Tramadol Hydrochloride

Type of Posting: Notice of Intent to Revise

Posting Date: 29–Jun–2012

Targeted Official Date: Interim Revision Announcement, 01–Mar–2013

Expert Committee: Monographs—Small Molecules 2

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 2 Expert Committee intends to revise the Tramadol Hydrochloride monograph as follows:

- Add Identification test C with the retention time agreement of the major peak as obtained in the Assay to strengthen the monograph.
- Revise the TLC Analysis for Procedure 1: Limit of Related Compound B under Organic Impurities to include a critical step and clarify the distance traveled by the solvent.
- Update the formatting of chemical names of USP Tramadol Related Compound A RS and USP Tramadol Related Compound B RS, and add the relevant chemical formula and molecular weight to be consistent with the current USP naming convention and style guide

It is anticipated that the revision will be published as a Proposed Interim Revision Announcement in PF 38(5) [Sept.–Oct. 2012] pursuant to section 7.02 of the Rules and Procedures.

Should you have any questions, please contact Hui-Zhi (Hillary) Cai, Ph.D. (301-230-3379, hzc@usp.org) or Clydewyn Anthony, Ph.D. (301-816-8139, cma@usp.org).

