Almotriptan Malate

Type of Posting: Notice of Intent to Revise

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Expert Committee: Chemical Medicines Monographs 4

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Chemical Medicines Monographs 4 Expert Committee intends to revise the Almotriptan Malate monograph.

Comments with supporting data were received that indicate the injection mode within the test for the *Limit of Almotriptan Related Compound D and N-Dimer* is not suitable and that the acceptance criteria for *Total Impurities* within the test for *Organic Impurities* is not consistent with approved specifications. The Expert Committee proposes to revise the Almotriptan Malate monograph as follows:

- Remove the use of USP Almotriptan Related Compound C RS in the System suitability solution, replace the reference to almotriptan related compound C with a reference to almotriptan in the Resolution requirement, and to clarify that almotriptan may not fully separate from almotriptan related compound C in the test for the *Limit of Almotriptan Related Compound D and N-Dimer*.
- Add a capillary rinsing procedure and update the instrumental conditions in the test for the *Limit of Almotriptan Related Compound D and N-Dimer*. The use of electrokinetic injection will be replaced with pressure injection.
- Widen the acceptance criteria for *Total impurities* in the test for *Organic Impurities* from NMT 0.7% to NMT 1.0%.
- Update the monograph to current USP style.

It is anticipated that the proposed revision proposal will be published as an Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 40(6) [Nov.–Dec. 2016] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on Jan. 31, 2017. In the absence of any adverse comments the proposed IRA will become official on May 1, 2017.

Should you have any questions, please contact Heather Joyce, Ph.D., Senior Scientific Liaison to the Chemical Medicines Monographs 4 Expert Committee (301–998-6792 or hrj@usp.org).

**In the previous version of this notice, posted on July 8, 2016, USP had indicated that Chemical Medicines Monographs 4 was considering revisions to the test for the Limit of Almotriptan Related Compound D and N-Dimer within the Almotriptan Malate monograph. The purpose of this revised notice is to add the intention to widen the acceptance criteria for Total Impurities within the test for Organic Impurities.*