

Levocetirizine Dihydrochloride

Type of Posting: Notice of Intent to Revise

Posting Date: 30-Dec-2016

Targeted Official Date: 01-Sep-2017, Interim Revision Announcement

Expert Committee: Chemical Medicines Monographs 5

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 Medicine Monographs 5 Expert Committee intends to revise the Levocetirizine Dihydrochloride monograph.

Based on comments received, the Expert Committee proposes to replace the liquid chromatographic procedure in the test for *Enantiomeric Purity* with a different liquid chromatographic procedure to improve the reproducibility and robustness of the analysis.

It is anticipated that the proposed revision will be published as an Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 43(2) [Mar.–Apr. 2017] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on May 31, 2017. In the absence of any adverse comments, the proposed IRA will become official on September 01, 2017.

Should you have questions, please contact Mary P. Koleck, Ph.D., Scientific Liaison to the Chemical Medicines Monograph 5 Expert Committee (mpk@usp.org or 301-230-7420).