Loperamide Hydrochloride Oral Solution

Type of Posting: Notice of Intent to Revise

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Expert Committee: Monographs—Small Molecules 3

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 3 Expert Committee intends to revise the Loperamide Hydrochloride Oral Solution monograph. The purpose of the revision is to address possible interference of the excipient matrix in the Oral Solution with the infrared absorption Identification test. It is proposed to revise the Acceptance criteria and include the list of the characteristic loperamide bands to be present in the spectra. The preparation of the Sample is also modified in order to accommodate different formulations.

Several minor changes and clarifications are also proposed in the Assay. The concentration of phosphoric acid used for pH adjustment of the Mobile phase is clarified, and the description of the chromatographic column is revised, to address the comments that chromatographic columns with the dimensions currently specified are no longer available.

It is anticipated that the revision will be published as a Proposed Interim Revision Announcement in Pharmacopeial Forum 39(6) [Nov.–Dec. 2013] pursuant to section 7.02 of the Rules and Procedures.

Should you have any questions, please contact Elena Gonikberg, Ph.D, Director, Chemical Medicines, (301-816-8251 or eg@usp.org).