

Promethazine Hydrochloride Oral Solution

Type of Posting: Notice of Intent to Revise

Posting Date: 18–Nov–2017

Targeted Official Date: Revision Bulletin, 01–Feb-2017

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 Promethazine Hydrochloride Oral Solution monograph.

Based on a comment received, the Expert Committee proposes to make the following change to the test of *Organic impurities*:

- The limit of promethazine sulfoxide will be widened from NMT 0.2% to NMT 1.0% to be consistent with FDA approved limits.

It is anticipated that the proposed revision will be published as a Revision Bulletin pursuant to section 7.02 of the Rules and Procedures. If approved by the Expert Committee the Revision Bulletin will be posted on January 27, 2017 and become official date on February 01, 2017.

Should you have questions, please contact Ren-Hwa Yeh, Ph.D., Scientific Liaison to the Chemical Medicines Monograph 5 Expert Committee at (rhy@usp.org or 301-816-6818).