



Promethazine Hydrochloride Oral Solution

Type of Posting	Revision Bulletin
Posting Date	27-Oct-2023
Official Date	1-Nov-2023
Expert Committee	Small Molecules 5

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 5 Expert Committee has revised the Promethazine Hydrochloride Oral Solution. The purpose of this revision is to widen the *Acceptance criteria* for promethazine sulfoxide in the test for *Organic Impurities* from NMT 1.0% to NMT 2.5% to accommodate FDA-approved drug products with different limits.

The Promethazine Hydrochloride Oral Solution Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or yanyin.yang@usp.org).