Ketorolac Tromethamine Tablets

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Expert Committee: Monographs—Small Molecules 2

Reason for Revision: Compliance

In accordance with the Rules and Procedures of the 2010–2015 Council of Experts, the Monographs—Small Molecules 2 Expert Committee has revised the Ketorolac Tromethamine Tablets monograph. The purpose for the revision is to widen the limit from NMT 0.5% to NMT 0.8% for ketorolac related compound C for a drug product approved by the FDA.

Additionally, minor editorial changes have been made to update the monograph to current USP style.

The Ketorolac Tromethamine Tablets Revision Bulletin supersedes the currently official monograph. The Revision Bulletin will be incorporated in the Second Supplement to USP 38–NF 33.

Should you have any questions, please contact Hillary Cai, Scientific Liaison (301-230-3379 or hzc@usp.org).

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