



Isotretinoin Capsules

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Expert Committee	Small Molecules 3

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Isotretinoin Capsules monograph. The purpose of this revision is to add *Dissolution Test 7* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). Existing references to reagents have been updated for consistency with the reagent entry.

- *Dissolution Test 7* was validated using the Hypersil BDS C18 brand of column with L1 packing. The typical retention time for isotretinoin is about 5.8 min.

The Isotretinoin Capsules Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Brice Wagner, Documentary Standards Scientist (301-998-6832 or brice.wagner@usp.org).