



## Dutasteride and Tamsulosin Hydrochloride Capsules

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In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Dutasteride and Tamsulosin Hydrochloride Capsules monograph. The purpose of this revision is to add *Dissolution Test 2* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). Existing references to reagents and reagent names have been updated for consistency with official reagent entry names. This revision also necessitates a change in the table numbering.

- *Dissolution Test 2* was validated using the XBridge C18 brand of column with L1 packing. The typical retention time for dutasteride is about 9 min. The typical retention time for tamsulosin is about 2 min.

The Dutasteride and Tamsulosin Hydrochloride Capsules 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](mailto:yanyin.yang@usp.org)).