



## Fludrocortisone Acetate Tablets

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In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 5 Expert Committee has revised the Fludrocortisone Acetate Tablets monograph. The purpose for the revision is to add *Dissolution Test 2* to accommodate FDA-approved drug products with different dissolution conditions than the existing dissolution test(s). Labeling Information has been incorporated to support the inclusion of Dissolution Test. The revision also necessitates a change in the table numbering in the test(s) for Organic Impurities.

- *Dissolution Test 2* was validated using the Zorbax Eclipse XDB-C8 brand of column with L7 packing. The typical retention time for fludrocortisone acetate is about 2 min.

The Fludrocortisone Acetate Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Jasmine Lawrence, Scientist IV +1 (301) 230-6363 or [jasmine.lawrence@usp.org](mailto:jasmine.lawrence@usp.org).