

Amantadine Hydrochloride Tablets

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Expert Committee	Small Molecules 1

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 1 Expert Committee has revised the Amantadine Hydrochloride Tablets 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. *Labeling* information has been incorporated to support the inclusion of *Dissolution Test 2*. In this revision, the concentration of the *Standard solution* in the existing *Dissolution Test 1* is corrected and clarity is provided on the preparation of the *Standard solution*. The revision also necessitates a change in the table numbering in the *Organic Impurities* section.

- *Dissolution Test 2* was validated using the DB-1 brand of column with phase G1. The typical retention time for amantadine is about 4.5 min.

The Amantadine Hydrochloride Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact V. Durga Prasad, Associate Scientific Liaison (+91-40-4448-8723 or durgaprasad.v@usp.org).