

Clarithromycin Extended-Release 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 Clarithromycin Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Test* 6 to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). The revision also necessitates a change in the table numbering in the test for *Organic Impurities*.

• *Dissolution Test 6* was validated using the Hypersil BDS C18 brand of column with L1 packing. The typical retention time for clarithromycin is about 3.6 min.

The Clarithromycin Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact V. Durga Prasad, Senior Scientist II (91-40-4448-8723 or durgaprasad.v@usp.org).