

Clonidine Hydrochloride Extended-Release Tablets

Type of Posting	Revision Bulletin
Posting Date	30-Apr-2021
Official Date	1-May-2021
Expert Committee	Small Molecules 2

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 2 Expert Committee has revised the Clonidine Hydrochloride Extended-Release Tablets monograph. The purpose for the revision is to add *Dissolution Tests 2, 3, 4, and 5* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). Labeling information has been incorporated to support the inclusion of the *Dissolution Tests*. The revision also necessitates a change in the table numbering in the test for *Organic Impurities*.

- *Dissolution Test 2* was validated using the Zorbax RX-C8 brand of column with L7 packing. The typical retention time for clonidine is about 5.2 min.
- *Dissolution Test 3* was validated using the Supelcosil LC-8-DB brand of column with L7 packing. The typical retention time for clonidine is about 6.4–7.8 min.
- *Dissolution Test 4* was validated using the YMC-Pack Pro C18 brand of column with L1 packing. The typical retention time for clonidine is about 5.7 min.
- *Dissolution Test 5* was validated using the Luna SCX brand of column with L9 packing. The typical retention time for clonidine is about 3.5 min.

The Clonidine Hydrochloride Extended-Release Tablets Revision Bulletin supersedes the version to become official on May 1, 2021.

Should you have any questions, please contact Morgan Puderbaugh, Staff Scientist (301-998-6833 or mxp@usp.org).