

Penicillamine Capsules

Type of Posting	Revision Bulletin
Posting Date	28-Jul-2023
Official Date	1-Aug-2023
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 Penicillamine 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. Labeling Information has been incorporated to support the inclusion of *Dissolution Test 2*.

• *Dissolution Test 2* was validated using the Atlantis dC18 brand of column with L1 packing. The typical retention time for penicillamine is about 3.5 min.

The Penicillamine Capsules 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 <u>durgaprasad.v@usp.org</u>).