Sorafenib Tablets

Type of Posting	Revision Bulletin
Posting Date	26-May-2023
Official Date	1-Jun-2023
Expert Committee	Small Molecules 3

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Sorafenib Tablets monograph. The purpose of this revision is to add *Dissolution Test 3* 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 *Dissolution Test 3.*

- *Dissolution Test 3* was validated using the Eclipse XDB C18 brand of column with L1 packing. The typical retention time for sorafenib is about 4 min.

The Sorafenib Tablets Revision Bulletin supersedes the currently official monograph.

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