

## Prasugrel Tablets

<b>Type of Posting</b>	Revision Bulletin
<b>Posting Date</b>	28-May-2021
<b>Official Date</b>	1-Aug-2021
<b>Expert Committee</b>	Small Molecules 2

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 2 Expert Committee has revised the Prasugrel 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(s). Labeling information has been incorporated to support the inclusion of *Dissolution Test 2*.

- *Dissolution Test 2* was validated using the Peerless Basic C18 brand of column with L1 packing. The typical retention time for prasugrel is about 3.4 min.

The Prasugrel Tablets Revision Bulletin supersedes the version which is scheduled to become official on August 1, 2021. Please note that Section 3.10 of *USP–NF General Notices* discusses Early Adoption. For questions regarding compliance, please consult your relevant regulatory authority.

Should you have any questions, please contact Donald Min, Staff Scientist (301-230-7457 or [ddm@usp.org](mailto:ddm@usp.org)).