Hydroxyurea Capsules

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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 Hydroxyurea 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. Existing references to reagents and reagent names have been updated for consistency with official reagent entry names. *Labeling* information has been incorporated to support the inclusion of *Dissolution Test 2*.

In the *Acceptance criteria* for *Identification A*, the term "*wavelengths*" has been updated to "*wavenumbers*", as it is the preferred terminology for infrared spectroscopy comparisons.

• *Dissolution Test 2* was validated using the Inertsil ODS-3 brand of column with L1 packing. The typical retention time for hydroxyurea is about 5 min.

Additionally minor editorial changes have been made to update the monograph to current *USP* style.

The Hydroxyurea Capsules Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or yanyin.yang@usp.org).