



## Esomeprazole Magnesium Delayed-Released Capsules

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| <b>Expert Committee</b> | Small Molecules 3 |

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Esomeprazole Magnesium Delayed-Release Capsules monograph. The purpose of this revision is to add *Dissolution Test 5* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). Additionally, existing references to reagents have been updated for consistency with the reagent entry.

- *Dissolution Test 5* was validated using the Inertsil C8 brand of column with L7 packing. The typical retention time for esomeprazole is about 6 min.

The Esomeprazole Magnesium Delayed-Release Capsules Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Jasmine Lawrence, Scientist IV (301-230-6363 or [jasmine.lawrence@usp.org](mailto:jasmine.lawrence@usp.org)).