

Azithromycin for Oral Suspension

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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 Azithromycin for Oral Suspension 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 Xbridge C18 brand of column with L1 packing. The typical retention time for azithromycin is about 3.5 min.

The Azithromycin for Oral Suspension 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).