

Clarithromycin Tablets

Type of Posting: Notice of Intent to Revise

Posting Date: 17–Apr–2015; updated 26–Jun–2015*

Targeted Official Date: 01–Aug–2015, Revision Bulletin

Expert Committee: Monographs —Small Molecules 1

In accordance with section 7.05 (c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the Monographs—Small Molecules 1 Expert Committee intends to revise the test for Organic Impurities in the Clarithromycin Tablets monograph to:

1. Update the System suitability solution and Sample solution to clarify that the standard or sample is dissolved first in acetonitrile and diluted to volume with water to align with the preparation of the Standard stock solution.
2. Include a reporting threshold and information about peaks to be disregarded.
3. Include the typical retention time for the clarithromycin peak.

It is anticipated that the proposed revision will be published as a Revision Bulletin on July 31, 2015 and become official on August 1, 2015, pursuant to section 7.02 of the Rules and Procedures.

Should you have any questions, please contact Ahalya Wise, Scientific Liaison to the Monographs —Small Molecules 1 (301-816-8161 or aww@usp.org).

* Notice was updated on June 26, 2015 to include specific targeted official date and publication. Additional details on the proposed revisions were also provided.