
Olanzapine Tablets

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Expert Committee: Monographs—Small Molecules 4

In accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Monographs—Small Molecules 4 Expert Committee intends to revise the Olanzapine Tablets monograph to widen the limit of olanzapine related compound B under Organic Impurities, pending final FDA approval for tentatively approved Abbreviated New Drug Application (ANDA) holders. A Note will also be included under Assay and Organic Impurities that a few drops of acetonitrile may be added to the Standard and Sample solutions prior to final dilution, to reduce foaming.

It is anticipated that the revision will be published as a Revision Bulletin pursuant to section 7.02 of the Rules and Procedures.

Should you have questions, please contact Mr. Hari Ramanathan, Associate Scientific Liaison to the Monographs—Small Molecules 4 Expert Committee (301-816-8313 or hr@usp.org).