# Orlistat

**Type of Posting:** Notice of Intent to Revise

**Posting Date:** 22–Mar–2013

**Targeted Official Date:** Interim Revision Announcement, 01–Nov–2013

**Expert Committee:** Monographs—Small Molecules 2

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 2 Expert Committee intends to revise the Orlistat monograph as follows:

- Revise Identification test A, from Infrared Absorption <197M> to Infrared Absorption <197K> to avoid the interference of mineral oil
- Revise flow rate and split ratio in Limit of Orlistat Related Compound B test
- Revise the calculation of the percentage of orlistat related compound B in Limit of Orlistat Related Compound B test to correct for the concentration difference between the Sample solution and the Spiked sample solution
- Delete orlistat related compound D from System suitability solution in Organic Impurities, because orlistat related compound D is quantified by Orlistat Related Compound D test and the remaining requirements are adequate to evaluate system suitability for Organic Impurities
- Correct the particle size from 50µm to 5µm for the Guard column in the Limit of Orlistat Related Compound E test based on the initial validation report.
- Correct the General Chapter number for the Specific Rotation test
- Add the relevant chemical formula and molecular weight to the USP Reference Standards <11> section to be consistent with the current USP style

Minor editorial changes also will be made to be consistent with the current USP style. It is anticipated that the revision will be published as a Proposed Interim Revision Announcement in PF 39(3) [May–Jun 2013] pursuant to section 7.02 of the Rules and Procedures.

Should you have any questions, please contact Hui-Zhi (Hillary) Cai, Ph.D (301-230-3379, hzc@usp.org) Scientific Liaison to the Monographs—Small Molecules 2 Expert Committee.