
Fentanyl

Type of Posting: Revision Bulletin: POSTPONEMENT

Posting Date: 28–Jan–2011

Official Date: 01–Feb–2011

Expert Committee: Monographs—Small Molecules 2

In accordance with the Rules and Procedures of the 2010–2015 Council of Experts, the Monographs—Small Molecules 2 Expert Committee intends to indefinitely postpone the Organic Impurities section of the Fentanyl monograph. The purpose for the postponement is to provide adequate time to evaluate and resolve potential impurity limit compliance issues that were recently brought to USP's attention. Also, there is a correction to the preparation of the System suitability solution in the Assay.

The Fentanyl Revision Bulletin supersedes the Organic Impurities section that was published in the Second Supplement to *USP 33–NF 28* Reissue. Please note that the other sections of the monograph (Definition, Identification, Assay, Specific Tests, Additional Requirements and the tests for Residue on Ignition and Heavy Metals in the Impurities section) are not affected by this postponement and will become official as scheduled on February 01, 2011.

Should you have any questions, please contact Clydewyn M. Anthony, Ph.D. (301-816-8139 or cma@usp.org).

- [Download the Fentanyl Revision Bulletin](#)