
Fentanyl

Type of Posting: Notice of Intent to Revise

Posting Date: 26–Apr–2019

Targeted Official Date: TBD

Expert Committee: Monographs-Chemical Medicines 2

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Chemical Medicines Monographs 2 Expert Committee intends to revise the Fentanyl monograph.

Proposed revisions to the Fentanyl monograph were published for public notice and comment in *Pharmaceutical Forum* 44(1) [Jan.–Mar. 2018]. The proposed *Organic Impurities* test is intended to replace the one which is postponed in the currently official Fentanyl monograph. In the interim, USP wishes to clarify that the postponed *Organic Impurities* test in the currently official USP Fentanyl monograph does not need to be performed to demonstrate conformance to monograph specifications.

The comment period for the *PF* 44(1) revision proposal ended on March 31, 2018. The Chemical Medicines Monographs 2 Expert Committee is currently evaluating the comments received and planning for a future ballot. The ballot results will be published on our website (<https://www.uspnf.com/official-text/proposal-statuscommentary>).

Should you have any questions, please contact Wei Yang, Scientific Liaison to the Chemical Medicines Monograph 2 Expert Committee at (301–816–8338 or wiy@usp.org).

