

Octyldodecanol

Type of Posting: Notice of Intent to Revise

Posting Date: 26–Feb–2016; updated 29–Apr–2016*

Targeted Official Date: 01–Jan–2017, Interim Revision Announcement, TBD

Expert Committee: Excipient Monographs 1

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 Excipient Monographs 1 Expert Committee intends to revise the Octyldodecanol NF monograph.

Comments with supporting data were received which indicate that a flexible monograph approach should be used for octyldodecanol, due to different manufacturing processes. The Expert Committee intends to revise the current test for *Limit of Related Fatty Alcohols* to the *Organic Impurity Test 1: Limit of Related Fatty Alcohols*, and to introduce the *Organic Impurity Test 2* with different acceptance criteria for different impurities. In addition, an appropriate Note and *Labeling* requirement will be added correspondingly.

It is anticipated that the proposed revisions will be published as Interim Revision Announcements (IRA) in *Pharmacopeial Forum* 42(4) [Jul.–Aug. 2016] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on September 30, 2016. In the absence of any adverse comments the proposed IRAs will become official on January 1, 2017.

Should you have any questions, please contact Hong Wang, Scientific Liaison to the Excipient Monographs 1 Expert Committee (301–816–8351 or hw@usp.org).

*The notice was updated to specify that the proposed version will be published as an IRA in PF 42(4) [Jul.–Aug. 2016] with a targeted official date of January 1, 2016.