

Stearyl Alcohol

Type of Posting: Notice of Intent to Revise

Posting Date: 28-Feb-2020

Targeted Official Date: 01-Nov-2020, IRA

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 Stearyl Alcohol monograph.

Comments with supporting data were received which indicate that a flexible monograph approach should be used for Stearyl Alcohol, 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 introduce the *Organic Impurity Test 2: Limit of branched chain fatty alcohols, related linear fatty alcohols, related unsaturated alcohols and alkanes* 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 revision will be published as a proposed Interim Revision Announcement (IRA) in *Pharmacoepial Forum* 46(3) [May–Jun 2020] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on July 31, 2020. In the absence of any adverse comments the proposed IRA will become official on November 1, 2020.

Should you have any questions, please contact Santhi Kumar Saladi, Assistant Scientific Liaison to the Excipient Monographs 1 Expert Committee (+91-4044488721 or santhikumar.saladi@usp.org).

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