

Formoterol Fumarate

Type of Posting: Notice of Intent to Revise

Posting Date: 22-Feb-2019

Targeted Official Date: 01-Nov-2019, Interim Revision Announcement

Expert Committee: Monographs-Chemical Medicines 4

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 Monographs–Chemical Medicines 4 Expert Committee intends to revise the Formoterol Fumarate monograph.

The Expert Committee proposes to revise the test for *Organic Impurities*, system suitability solution preparation instructions by eliminating the use of the USP Formoterol Fumarate System Suitability Mixture (CI) Reference Standard. The proposed preparation instructions instead specify the use of separate reference standards for formoterol fumarate and formoterol related compounds A, C, and D. Formoterol related compounds E, F, G and H, which were formerly constituents of the system suitability mixture and were used for the purpose of retention time reference, are no longer required; these compounds, when present in the sample chromatogram, will be identified on the basis of their retention times relative to that of the formoterol peak. The proposed change will help to ensure the continuity of supply for the required reference materials. Additionally, elimination of formoterol related compound G, a DEA Scheduled (Class I) compound, from the System suitability solution will improve accessibility of the reference material. Corresponding changes to the test for *Organic Impurities* system suitability requirements have been proposed to support the use of the new individual reference standards. Additional changes to improve the flexibility of the monograph and to align it with current USP style are also proposed.

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement (IRA) in *Pharmaceutical Forum* 45(3) [May–Jun. 2019] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on July 31, 2019. In the absence of any adverse comments the proposed IRA will become official on November 1, 2019.

Should you have any questions, please contact Nicholas Garito, Scientific Liaison (301–816–8321 or njg@usp.org).

CN-19-029-00