Dicolofenac Sodium and Misoprostol Delayed-Release Tablets

Type of Posting: Notice of Intent to Revise
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Targeted Official Date: Interim Revision Announcement 01-Mar-2018
Expert Committee: Chemical Medicines Monographs 3

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 USP Chemical Medicines Monographs 3 Expert Committee intends to revise the Dicolofenac Sodium and Misoprostol Delayed-Release Tablets monograph.

The purpose of this revision is to update the Organic Impurities test as follows to accommodate products approved by FDA:

- Widen the specifications for B-type misoprostol from NMT 0.5% to NMT 0.7% and for A-type misoprostol from NMT 1.0% to NMT to 3.5%.
- Add limit for total misoprostol related impurities of NMT 6.2%
- Add limit for total diclofenac related impurities of NMT 1.0%.
- Delete the total impurities limit of NMT 3.0% for combined misoprostol and diclofenac impurities.

It is anticipated that the revision will be published as a Proposed Interim Revision Announcement in PF 43(5) [Sept. 1, 2017] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on November 30, 2017

Should you have any questions, please contact Andrea Carney**,** Associate Scientific Liaison to the USP Chemical Medicines Monographs 3 Expert Committee (301–816–8155 or afc@usp.org).