

Ketoconazole

Type of Posting: Notice of Intent to Revise

Posting Date: 17-Nov-2017

Targeted Official Date: To be determined

Expert Committee: Chemical Medicines 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 USP Chemical Medicines Monographs 1 Expert Committee intends to revise the test for Organic Impurities in the Ketoconazole monograph to accommodate the FDA approved limit for a specified impurity that is wider than the unspecified impurity limit.

The process for and timing of the revision will be determined following additional consideration by the Expert Committee and USP staff.

Should you have any questions, please contact Shankari Shivaprasad, Ph.D., Senior Scientific Liaison to the USP Chemical Medicines Monographs 1 Expert Committee (301–230–7426 or sns@usp.org).