Iohexol

Type of Posting: Notice of Intent to Revise
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Expert Committee: Chemical Medicines Monographs 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 Chemical Medicines Monographs 4 Expert Committee intends to revise the Iohexol monograph.

The proposed revision will reinstate the statement “Exclude peaks with a relative retention time between 0.84 (relative to the endo?isomer of iohexol [first main peak]) and the endo?isomer of iohexol” that previously appeared in the official monograph through *Second Supplement* to *USP* 38-*NF* 33.

This statement was removed via an in-process revision published in *Pharmacopeial Forum (PF)* 41(1) [Jan-Feb 2015]. No comments were received during the public comment period. The party requesting the in-process revision indicated that the removal of the statement led to an unintended tightening of acceptance criteria for any individual impurity in iohexol, which created compliance challenges for the manufacturers. Reinstating the statement as it appeared in the USP prior to the in-process revision will allow the manufacturers to comply with the monograph requirements.

Should you have any questions, please contact Ravi Ravichandran, Principal Scientific Liaison to the Chemical Medicines Monographs 4 Expert Committee (301-816-8330 or rr@usp.org).