

Doxorubicin Hydrochloride Injection

Type of Posting: Notice of Intent to Revise

Posting Date: 26-Feb-2016

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 Chemical Medicines Monographs 1 Expert Committee intends to revise the Doxorubicin Hydrochloride Injection monograph.

The Expert Committee proposes to revise the test for Organic Impurities to widen the limits for specified and unspecified impurities to be consistent with FDA approved acceptance criteria.

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

Should you have any questions, please contact Slavica Shane, Scientific Liaison to the Chemical Medicines Monographs 1 Expert Committee (301-230-3384 or sis@usp.org).