Doxycycline Hyclate Capsules and Doxycycline Hyclate Tablets

Type of Posting: Notice of Intent to Revise

Posting Date: 10-Apr-2017

Targeted Official Date: 01-May-2017, Revision Bulletin

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 Doxycycline Hyclate Capsules and Doxycycline Hyclate Tablets monographs.

Based on comments received, the Expert Committee proposes to widen the limit for 4-epidoxycycline in the test for Organic Impurities from NMT 0.5% to 1.0% to accommodate a sponsor's FDA-approved specification.

It is anticipated that a Revision Bulletin for Doxycycline Hyclate Capsules and Doxycycline Hyclate Tablets will be posted on April 28, 2017 and become official on May 1, 2017.

Should you have any questions, please contact Praveen Pabba (301-816-8540 or pkp@usp.org).