

Cidofovir

Type of Posting: Notice of Intent to Revise

Posting Date: 04-Mar-2019

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 Cidofovir monograph. The Expert committee proposes to revise the following:

1. Delete the Residue on Ignition test based on the comments received with supporting data indicating that the test is not suitable for phosphoric compounds.
2. Revise the test for Organic impurities to include additional impurities to be consistent with FDA approval.

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

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