

Clindamycin Phosphate

Type of Posting: Notice of Intent to Revise

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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 Clindamycin Phosphate monograph.

The current procedures for *Assay* and *Organic Impurities* require the use of USP Clindamycin Phosphate RS to evaluate resolution between clindamycin phosphate and 7-epiclindamycin phosphate. To address issues with availability of a suitable reference material, USP plans to revise the monograph to add a USP Clindamycin Phosphate System Suitability RS and a *System suitability solution* to be used to evaluate resolution between clindamycin phosphate and 7-epiclindamycin phosphate. The new *System suitability solution* will contain clindamycin phosphate at the same concentration as in the current *Standard solution* and will not significantly change the procedures that are currently in use.

The Expert Committee proposes to revise the Clindamycin Phosphate monograph via Revision Bulletin in the near future with appropriate timing of the release of the USP Clindamycin Phosphate System Suitability RS.

Should you have any questions, please contact Morgan Puderbaugh, Senior Scientific Liaison to the USP Chemical Medicines Monographs 1 Expert Committee (301-816-8373 or mxp@usp.org).