
Cloxacillin Sodium Intramammary Infusion

Type of Posting Notice of Intent to Revise

Posting Date 23–Feb–2018

Targeted Official Date To be determined, In-Process Revision

Expert Committee Biologics 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 USP Biologics Monographs 4 Expert Committee intends to revise the Cloxacillin Sodium Intramammary Infusion monograph.

The Expert Committee proposes to revise the monograph's Assay test from a microbiological-based test to a chromatographic-based to align with the drug substance and related drug products. As described in the USP Cloxacillin Sodium RS Certificate, the RS is assigned a value using a mass balance approach. In addition, the title of the monograph may change to align with current nomenclature practices described in USP Chapter <1121> *Nomenclature*.

It is anticipated that the proposed revision will be published in the future once the laboratory work is complete as an In-process Revision in the *Pharmacopeial Forum* pursuant to section 7.02 of the Rules and Procedures.

Should you have any questions, please contact Julie Zhang, Scientific Liaison to the USP Biologics Monographs 4 Expert Committee (301–816–8350 or julie.zhang@usp.org).