
Protamine Sulfate Injection

Type of Posting: Notice of Intent to Revise

Posting Date: 17–Apr–2015

Targeted Official Date: Revision Bulletin, 01–June–2015; Interim Revision Announcement, 01–Jan–2016

Expert Committee: Monographs—Biologics & Biotechnology 1

In accordance with section 7.05 (c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the Monographs—Biologics & Biotechnology 1 Expert Committee intends to revise the Protamine Sulfate Injection monograph based on comments received.

It is proposed to omit specification for the pH test in this monograph via a Revision Bulletin. The pH specification will later be proposed in an Interim Revision Announcement (IRA) to allow public comment on the proposed specification.

Pursuant to section 7.02 of the Rules and Procedures, it is anticipated that the Revision Bulletin will be published on USP's website on May 25, 2015 and become official June 1, 2015. It is also anticipated the new pH specification for the Protamine Sulfate Injection monograph will be published as a proposed Interim Revision Announcement in Pharmacopeial Forum 41(5) [Jul.–Aug. 2015] with a comment deadline of November 30, 2015.

Should you have questions, please contact Anita Szajek, Scientific Liaison to the Expert Committee (301-816-8325 or aeey@usp.org).