
[Protamine Monographs](#)

Type of Posting: Notice of Intent to Revise

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Expert Committee: Biologics and Biotechnology—Blood and Blood Products

In accordance with the Rules and Procedures of the Council of Experts, the USP Biologics and Biotechnology Blood and Blood Products Expert Committee (BB–BBP EC) intends to revise three Protamine monographs (Protamine Sulfate, Protamine Sulfate Injection and Protamine Sulfate for Injection) by introducing a new potency assay. The revised Assay replaces the current sheep plasma clotting assay and is supported by a new reference standard (RS), USP Heparin Sodium for Assays RS.

It is anticipated that the proposed revisions will be published in Pharmacopeial Forum 36(3) [May–Jun 2010] as Proposed Interim Revision Announcements. The comment period for this revision ends on **July 15, 2010**. In the absence of any adverse comments, the revisions will be published as final in Pharmacopeial Forum 36(5) [Sep–Oct 2010] with an official date of **1 October 2010**.

Should you have questions, please contact Anita Szajek, Ph.D., Scientific Liaison to the Biologics and Biotechnology Blood and Blood Products Expert Committee (301-816-8325 or AEY@usp.org).