

Vasopressin

Type of Posting: Notice of Intent to Revise

Posting Date: 31-Mar-2011

Expert Committee: Monograph Development—Biologics & Biotechnology 1

In accordance with section 7.05 (c) of the 2010-2015 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Monographs—Biologics & Biotechnology 1 Expert Committee intends to revise the Vasopressin monograph based on comments received.

The revision will focus on the assay acceptance criteria that are currently set at not less than 95.0 percent and not more than 102.0 percent Vasopressin. USP's Monographs—Biologics & Biotechnology 1 Expert Committee is looking for input from Vasopressin manufacturers on the acceptance criteria based on batch data of actual Vasopressin API lots. Information should be submitted to Tom A. Sigambris at the contact information given below.

It is anticipated that the proposed revision will be published as an Interim Revision Announcement (IRA) at a date yet to be determined, pursuant to section 7.02 of the Rules and Procedures.

Should you have any questions, please contact Tom A. Sigambris (301-998-6789 or tzs@usp.org).