
[Insulin, Insulin Injection, Insulin Zinc Suspension, Extended Insulin Zinc Suspension, Isophane Insulin Suspension, Prompt Insulin Zinc Suspension, and <121> Insulin Assays](#)

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Expert Committee: Biologics Monographs 1 - Peptides Expert Committee

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 Biologics 1 – Peptides Expert Committee intends to revise the Insulin, Insulin Injection, Insulin Zinc Suspension, Extended Insulin Zinc Suspension, Isophane Insulin Suspension, Prompt Insulin Zinc Suspension monographs and General Chapter <121> *Insulin Assays*.

Due to unavailability of suitable bovine insulin reference material and the absence of approved manufacturers of therapeutic bovine insulin or mixtures of bovine and porcine insulin in the USA, USP intends to revise the above listed monographs to remove requirements associated with bovine insulin and the use of the USP Insulin Beef Reference Standard. The only use of bovine insulin in non-bovine products is as a standard for identification for porcine insulin, where the Insulin Pork RS and Insulin Beef RS are mixed together and used for peak identification. Since bovine and porcine insulin peaks are well resolved in the Assay, the Insulin Beef RS is not necessary for identification of insulin pork. Furthermore, a second identification test, Peptide Mapping, is used in the drug substance monograph and can easily distinguish insulin beef vs insulin pork. An accelerated revision is being implemented in order to provide regulatory relief to manufacturers of Insulin Pork.

It is anticipated that these revisions will be published as a Revision Bulletin on March 29, 2019 and become official on April 1, 2019.

Should you have any questions, please contact Diane McCarthy, PhD, Scientific Liaison (301–692-3637 or diane.mccarthy@usp.org).
