
Revisions to Selected Insulin Family Monographs

Type of Posting: Notice of Intent to Revise

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Targeted Official Date: 01–Jan–2019, Interim Revision Announcement

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 Aspart Injection, Insulin Lispro, Insulin Lispro Injection, Insulin Zinc Suspension, Isophane Insulin Suspension, Isophane Insulin Human Suspension, Human Insulin Isophane Suspension, and Human Insulin Injection monographs.

Based on comments received, USP intends to revise the above listed monographs to provide more flexibility in selection of methods for determination of zinc in insulin drug substances and drug products. The Expert Committee proposes to revise the above listed monographs to reference <591> *Zinc Determination* instead of <591> *Zinc Determination, Dithizone Method*.

It is anticipated that the proposed revision will be published as an Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 44(4) [Jul.–Aug. 2018] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on September 30, 2018. In the absence of any adverse comments the proposed IRA will become official on January 1, 2019.

Should you have any questions, please contact Diane McCarthy, Scientific Liaison to the Biologics Monographs 1–Peptides Expert Committee (301–692-3637 or diane.mccarthy@usp.org).