

[Insulin Glargine](#)

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Expert Committee: Biologics Monographs 1—Peptides

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 Monographs 1—Peptides intends to revise the Insulin Glargine.

Based on the comments with supporting data received, the Expert Committee proposes to revise the Insulin Glargine. The purpose for the revision is to include a dried basis form of the drug substance to the monograph in addition to the anhydrous form to accommodate the product recently approved by the FDA with different conditions. The changes addressing this specification are listed below.

- Revise the *Definition* to include the dried basis form for the drug substance when other volatile solvents in addition to water are present.
- Revise the *Assay* acceptance criteria to include the dried basis.
- Add the *Loss on drying* test including a Note of “This test is recommended when the drug substance contains water and other volatile solvents” and the limit of NMT 10.0% to the section of *Specific Tests*.
- Add a Note of “This test is recommended when the drug substance predominantly contains water” to *Water determination* to distinguish this specification from *Loss on drying*.
- The revision also requires the addition of “Where it is a dried basis, the label so indicates” to the *Labeling* section.

In addition, a definition for the activity units of *Staphylococcus aureus* V8 protease is included in Peptide Mapping for a clarification.

The Expert Committee also intends to revise the titles of the *Impurities* and *Related Proteins* sections to *Product-Related Substances and Impurities* and *Product-Related Substances respectively*. Subsequently, the term “related substance” was replaced with the term “related protein.”

It is anticipated that the proposed revision will be published as an Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 42(3) [May–Jun. 2016] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on July, 31, 2016. In the absence of any adverse comments the proposed IRA will become official on November 1, 2016.

Should you have any questions, please contact Edith Chang (301–816–8392 or yec@usp.org).