Calcitonin Salmon

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Expert Committee: Monographs—Biologics & Biotechnology 1

Reason for Revision: Compliance

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 Monographs—Biologics & Biotechnology 1 Expert Committee has revised the Calcitonin Salmon monograph based on comments received:

Revisions are needed to the Calcitonin Salmon monograph, drug substance, in order to reflect the newly released USP calcitonin reference standards and to revise General Chapter <61> and <62> requirements.

The monograph is updated in three sections:

1. **Assay**

   Current text:
   
   “System suitability solution: “Dissolve the contents of a vial of USP Calcitonin Salmon Related Compound A RS in 0.4 mL of Solution A, add 0.1 mL of the Standard preparation, and mix.”

   Revised text:
   
   “System suitability solution: Prepare a solution in Solution A containing about 0.2 mg/mL of USP Calcitonin Salmon Related Compound A RS and 0.2 mg/mL of USP Calcitonin Salmon RS.”

2. **Related peptides and other related substances (Test 2)**

   Current text:
   
   “Resolution solution: Dissolve a suitable quantity of USP Calcitonin Salmon RS to obtain a solution containing 1 mg per mL of water. Combine equal volumes of this solution with USP Calcitonin Salmon Related Compound B RS. To 1 mL of this mixture add 100 µL of pH 3.0 Citrate buffer.”

   Revised text:
   
   “Resolution solution: Prepare a solution in water containing about 0.5 mg/mL of each, USP Calcitonin Salmon RS and USP Calcitonin Salmon Related Compound B RS. To 1 mL of this solution add 100 µL of pH 3.0 Citrate buffer.”

3. **Acceptance criteria under chapter Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>**

   Current text:
   
   “The total aerobic microbial count is NMT 102 cfu/g and the total combined molds and yeasts count is NMT 102 cfu/g. It meets the requirements of the tests for absence of Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella species, and Escherichia coli.”
Change:
The bolded text will be removed because it is not the requirement in the submission and approval of the drug substance. Specific organism limits are contained in the calcitonin salmon dosage forms monographs.

This Calcitonin Salmon Revision Bulletin supersedes the currently official USP calcitonin salmon monograph. The Revision Bulletin will be incorporated in USP 36–NF 31.

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

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