

Calcitonin Salmon Monographs

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Expert Committee: Monographs—Biologics & Biotechnology 1

In accordance with section 7.05(c) the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the Monographs—Biologics & Biotechnology 1 Expert Committee intends to revise the Calcitonin salmon monographs to reflect the released USP reference standards. The proposed revisions are:

1. Assay

Current monograph instructions:

A. Standard preparation: Transfer about 10.0 mg of USP Calcitonin Salmon RS, accurately weighed, into a 10-mL volumetric flask, dissolve in and dilute with Solution A to volume

B. 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

Proposed revised wording:

A. Standard solution: 1.0 mg/mL, USP Calcitonin Salmon RS in Solution A.

B. 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 monograph instructions:

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.

Proposed revised wording:

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.

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).