Calcitonin Salmon Injection

DEFINITION

Calcitonin Salmon Injection is a sterile solution of Calcitonin Salmon in a suitable diluent. Each mL of Calcitonin Salmon Injection possesses an activity of NLT 80% and NMT 120% of that stated on the label.

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **PROCEDURE**

Solution A: Dissolve 3.26 g of tetramethylammonium hydroxide pentahydrate in 900 mL of water, add 100 mL of acetonitrile, and mix. Adjust with phosphoric acid to a pH of 2.5, pass through a filter of 0.5-µm or finer pore size, and degas.

Solution B: Dissolve 1.45 g of tetramethylammonium hydroxide pentahydrate in 400 mL of water, add 600 mL of acetonitrile, and mix. Adjust with phosphoric acid to a pH of 2.5, pass through a filter of 0.5-µm or finer pore size, and degas.

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	72	28
30	48	52
32	72	28
55	72	28

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.• (IRA 1-Jan-2015) Take 0.1 mL of this solution, add 0.9 mL of *Solution A*, and mix.

Standard stock solution: 1.0 mg/mL of USP Calcitonin Salmon RS in *Solution A*

Standard solution: 0.1 mg/mL of USP Calcitonin Salmon RS from *Standard stock solution* diluted with *Solution A*

Sample solution: Use the solution from an undiluted Injection vial.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; packing L1

Column temperature: 65°

Flow rate: 1 mL/min

Injection volume: 200 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for calcitonin salmon and calcitonin salmon related compound A are 1.0 and 1.15, respectively.]

Suitability requirements

Resolution: NLT 3 between calcitonin salmon and calcitonin salmon related compound A

Tailing factor: NMT 2.5

Relative standard deviation: NMT 3%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the potency, in USP Calcitonin Salmon Units/mL, in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times C_S$$

r_U = peak area from the *Sample solution*
r_S = peak area from the *Standard solution*
C_S = concentration of USP Calcitonin Salmon RS in the *Standard solution* (USP Calcitonin Salmon Units/mL)

Acceptance criteria: 80%–120%

SPECIFIC TESTS

• **BACTERIAL ENDOTOXINS TEST** ⟨**85**⟩**:** NMT 0.625 USP Endotoxin Units/USP Calcitonin Salmon Unit
• **STERILITY TESTS** ⟨**71**⟩**:** Meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*
• **PARTICULATE MATTER IN INJECTIONS** ⟨**788**⟩**:** Meets the requirements for small-volume injections
• **pH** ⟨**791**⟩**:** 3.9–4.5
• **INJECTIONS** ⟨**1**⟩**:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass. Avoid freezing. Store in a refrigerator.
• **LABELING:** Label it to indicate the activity in USP Calcitonin Salmon Units/mL. The labeling states that the material is synthetic. Label it to state that it is to be stored in a refrigerator, and that freezing is to be avoided.
• **USP REFERENCE STANDARDS** ⟨**11**⟩
USP Calcitonin Salmon RS
USP Calcitonin Salmon Related Compound A RS
N-Acetyl-cys[1]-calcitonin.
$C_{146}H_{243}N_{44}O_{49}S_2$ 3463
USP Endotoxin RS