Selenious Acid Injection

DEFINITION

Change to read:

Selenious Acid Injection is a sterile solution in Water for Injection of Selenious Acid or of selenium dissolved in nitric acid. It contains •NLT 90.0% and NMT 110.0%• (RB 1-Jun-2012) of the labeled amount of selenium (Se).

IDENTIFICATION

- **A.** The *Sample solution*, prepared as directed in the *Assay*, exhibits an absorption maximum at about 196 nm, when tested as directed in the *Assay*.

ASSAY

Change to read:

- **PROCEDURE**

[**CAUTION—**Selenium is toxic; handle it with care.]

Standard stock solution: 1000 µg/mL of selenium, prepared as follows. Dissolve about 1 g of metallic selenium in a minimum volume of nitric acid. Evaporate to dryness, add 2 mL of water, and evaporate to dryness. Repeat the addition of water and the evaporation to dryness three times. Dissolve the residue in 3 N hydrochloric acid, transfer to a 1000-mL volumetric flask, dilute with 3 N hydrochloric acid to volume, and mix.

Standard solution A: 30 µg/mL of selenium from the *Standard stock solution* diluted with water

Standard solution B: 40 µg/mL of selenium from the *Standard stock solution* diluted with water

Standard solution C: 50 µg/mL of selenium from the *Standard stock solution* diluted with water

Sample solution: 40 µg/mL of selenium from Injection diluted with water

Instrumental conditions

(See *Spectrophotometry and Light-Scattering* ⟨851⟩.)

Mode: Atomic absorption spectrophotometer

Lamp: Selenium electrodeless discharge

Flame: Air–acetylene

Analytical wavelength: Selenium emission line at 196 nm

Blank: Water

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Sample solution*

Plot the absorbances of the *Standard solutions* versus concentration, in µg/mL, of selenium, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, C_S, in µg/mL, of selenium in the *Sample solution*.

Calculate the percentage of the labeled amount of selenium (Se) in the portion of Injection taken:

$$\text{Result} = (C_S/C_U) \times 100$$

C_S = concentration of selenium in the *Sample solution* determined from the calibration graph, µg/mL

C_U = nominal concentration of selenium in the *Sample solution*, µg/mL

Acceptance criteria: •90.0%–110.0%• (RB 1-Jun-2012)

SPECIFIC TESTS

- **pH** ⟨**791**⟩**:** 1.8–2.4
- **PARTICULATE MATTER IN INJECTIONS** ⟨**788**⟩**:** Meets the requirements for small-volume injections
- **BACTERIAL ENDOTOXINS TEST** ⟨**85**⟩**:** NMT 3.5 USP Endotoxin Units/µg of selenium
- **OTHER REQUIREMENTS:** Meets the requirements in *Injections* ⟨1⟩

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose or in multiple-dose containers, preferably of Type I or Type II glass.
- **LABELING:** Label the Injection to indicate that it is to be diluted to the appropriate strength with Sterile Water for Injection or other suitable fluid before administration.
- **USP REFERENCE STANDARDS** ⟨**11**⟩

  USP Endotoxin RS