Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-484F393F-85FF-4106-B209-22CD4629F65A_3_en-US
DOI: https://doi.org/10.31003/USPNF_M74778_03_01
DOI Ref: ace7z

Selenious Acid Injection

DEFINITION

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% 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

• **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 *Atomic Absorption Spectroscopy* ⟨852⟩.)

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%

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 and Implanted Drug Products* ⟨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.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
SELENIOUS ACID INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-484F393F-85FF-4106-B209-22CD4629F65A_3_en-US
Previous DocID: GUID-484F393F-85FF-4106-B209-22CD4629F65A_1_en-US
DOI: https://doi.org/10.31003/USPNF_M74778_03_01
DOI ref: ace7z