Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Jul-2020
Document Type: USP Monographs
DocId: GUID-A6904614-E8E7-4325-8C15-95B0DD8FCD5E_4_en-US
DOI: https://doi.org/10.31003/USPNF_M6410_04_01
DOI Ref: h7ye4

Atropine Sulfate Injection

DEFINITION

Atropine Sulfate Injection is a sterile solution of Atropine Sulfate in Water for Injection. It contains NLT 93.0% and NMT 107.0% of the labeled amount of atropine sulfate monohydrate $[(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4 \cdot H_2O]$.

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**

Buffer: Dissolve 4.1 g of anhydrous sodium acetate and 2.9 mL of glacial acetic acid in 1 L of water.

Mobile phase: Transfer 5.1 g of tetrabutylammonium hydrogen sulfate to a 1-L volumetric flask. Add 50 mL of acetonitrile, and dilute with *Buffer* to volume. Adjust with 5 N sodium hydroxide to a pH of 5.5.

System suitability solution: 0.5 µg/mL of *p*-hydroxybenzoic acid and 64 µg/mL of USP Atropine Sulfate RS in water

Standard solution: 80 µg/mL of USP Atropine Sulfate RS

Sample solution: Nominally equivalent to 80 µg/mL of atropine sulfate in water, from a volume of the Injection containing an amount equivalent to 2 mg of atropine sulfate

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 30-cm × 3.9-mm; packing L1

Flow rate: 2 mL/min

Injection volume: 100 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times of atropine and *p*-hydroxybenzoic acid are 1.0 and 1.6, respectively.]

Suitability requirements

Resolution: NLT 2.2 between *p*-hydroxybenzoic acid and atropine, *System suitability solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of atropine sulfate monohydrate $[(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4 \cdot H_2O]$ in the portion of the Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Atropine Sulfate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of atropine sulfate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of atropine sulfate monohydrate, ▲694.84▲ (ERR 1-Jul-2020)

M_{r2} = molecular weight of anhydrous atropine sulfate, ▲676.82▲ (ERR 1-Jul-2020)

Acceptance criteria: 93.0%–107.0%

SPECIFIC TESTS

• **pH ⟨791⟩:** 3.0–6.5

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 55.6 USP Endotoxin Units/mg of atropine sulfate

• **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass. Store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Atropine Sulfate RS

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

Topic/Question	Contact	Expert Committee
ATROPINE SULFATE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 42(4)

Current DocID: GUID-A6904614-E8E7-4325-8C15-95B0DD8FCD5E_4_en-US

DOI: https://doi.org/10.31003/USPNF_M6410_04_01

DOI ref: h7ye4