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Morphine Sulfate Injection

DEFINITION

Morphine Sulfate Injection is a sterile solution of Morphine Sulfate in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of morphine sulfate pentahydrate $[(C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O]$. Injection intended for intramuscular or intravenous administration may contain sodium chloride as a tonicity-adjusting agent, and suitable antioxidants and antimicrobial agents. Injection intended for intrathecal or epidural use may contain sodium chloride as a tonicity-adjusting agent, but contains no other added substances.

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.
- **B.** [IDENTIFICATION TESTS\(191\)—GENERAL, Sulfate](#): It meets the requirements of test A.

ASSAY

PROCEDURE

Mobile phase: Dissolve 0.73 g of sodium 1-heptanesulfonate in 720 mL of water, and add 280 mL of methanol and 10 mL of glacial acetic acid.

System suitability solution: 0.24 mg/mL of [USP Morphine Sulfate RS](#) and 0.15 mg/mL of phenol in *Mobile phase*

Standard solution: 0.24 mg/mL of [USP Morphine Sulfate RS](#) (on the anhydrous basis) in *Mobile phase*. [NOTE—Prepare a fresh solution daily.]

Sample solution: Nominally 0.24 mg/mL of morphine sulfate from the Injection in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 284 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 25 µL

System suitability

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

[NOTE—The relative retention times for phenol and morphine are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between phenol and morphine sulfate, *System suitability solution*

Tailing factor: NMT 2.0 for the morphine sulfate peak, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of morphine sulfate pentahydrate $[(C_{17}H_{19}NO_3)_2 \cdot H_2SO_4 \cdot 5H_2O]$ in each mL 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 Morphine Sulfate RS](#) in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of morphine sulfate pentahydrate, 758.83

M_{r2} = molecular weight of anhydrous morphine sulfate, 668.77

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** (791): 2.5–6.5
- **BACTERIAL ENDOTOXINS TEST** (85): It contains NMT 17.0 USP Endotoxin Units/mg of morphine sulfate. If labeled for intrathecal use, it contains NMT 14.29 USP Endotoxin Units/mg of morphine sulfate.
- **PARTICULATE MATTER IN INJECTIONS** (788): Meets the requirements under small-volume injections
- **OTHER REQUIREMENTS:** It meets the requirements under [Injections and Implanted Drug Products](#) (1).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light. Preserve Injection labeled “Preservative-free” in single-dose containers.
- **LABELING:** It meets the requirements for [Labeling](#) (7), [Labels and Labeling for Injectable Products](#). Label it also to state that the Injection is not to be used if its color is darker than pale yellow, if it is discolored in any other way, or if it contains a precipitate. Injection containing no antioxidant or antimicrobial agents prominently bears on its label the words “Preservative-free” and includes in its labeling its routes of administration and the statement that it is not to be heat-sterilized. Injection containing antioxidant or antimicrobial agents includes in its labeling its routes of administration and the statement that it is not for intrathecal or epidural use.
- **USP REFERENCE STANDARDS** (11).
[USP Morphine Sulfate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MORPHINE SULFATE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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