Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-E65A0680-E638-43D6-AFCF-8B38941921A6_4_en-US
DOI: https://doi.org/10.31003/USPNF_M78656_04_01
DOI Ref: ris74

Sufentanil Citrate Injection

DEFINITION

Sufentanil Citrate Injection is a sterile solution of Sufentanil Citrate in Water for Injection. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of sufentanil citrate ($C_{22}H_{30}N_2O_2S \cdot C_6H_8O_7$).

[**Caution—**Handle Sufentanil Citrate Injection with great care, because it is a potent opioid analgesic.]

IDENTIFICATION

Change to read:

- **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)

Sample solution: 50 µg/mL

Medium: Use *Mobile phase* prepared as directed in the *Assay*. [Note—For samples that do not require dilution to achieve 50 µg/mL, use Water for Injection as the medium for the *Standard solution*.]

Acceptance criteria: Meets the requirements

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

ASSAY

- **Procedure**

Mobile phase: Methanol, acetonitrile, and 0.13 M ammonium acetate (45:24:31). Adjust with glacial acetic acid or ammonium hydroxide to a pH of 7.2.

Standard solution: 0.075 mg/mL of USP Sufentanil Citrate RS in water

Sample solution: Use Sufentanil Citrate Injection.

Chromatographic system

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

Mode: LC

Detector: UV 228 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sufentanil citrate ($C_{22}H_{30}N_2O_2S \cdot C_6H_8O_7$) in the portion of Injection taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 6.25 USP Endotoxin Units/mL
- **pH ⟨791⟩:** 3.5–6.0
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections
- **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.
- **USP Reference Standards ⟨11⟩**
  USP Sufentanil Citrate RS

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

Topic/Question	Contact	Expert Committee
SUFENTANIL CITRATE 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:
Pharmacopeial Forum: Volume No. PF 30(6)

Current DocID: GUID-E65A0680-E638-43D6-AFCF-8B38941921A6_4_en-US
DOI: https://doi.org/10.31003/USPNF_M78656_04_01
DOI ref: ris74