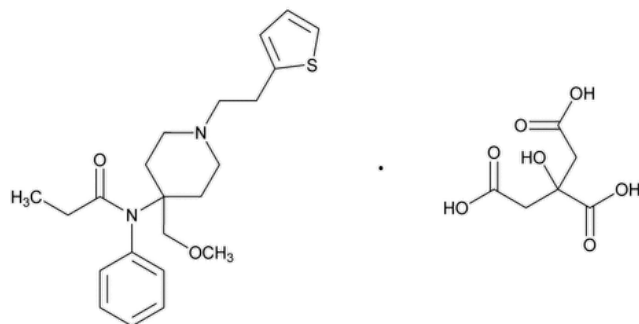


Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-F12C26D6-889C-4472-9BC8-1A115D635C86_4_en-US
DOI: https://doi.org/10.31003/USPNF_M78650_04_01
DOI Ref: d9msl

© 2025 USPC
Do not distribute

Sufentanil Citrate



$C_{22}H_{30}N_2O_2S \cdot C_6H_8O_7$ 578.67

Propanamide, N-[4-(methoxymethyl)-1-[2-(thienyl)ethyl]-4-piperidinyl]-N-phenyl-, 2-hydroxy-1,2,3-propanetricarboxylate (1:1);
N-[4-(Methoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide citrate (1:1) CAS RN®: 60561-17-3; UNII: S9ZFX8403R.

DEFINITION

Sufentanil Citrate contains NLT 98.0% and NMT 102.0% of sufentanil citrate ($C_{22}H_{30}N_2O_2S \cdot C_6H_8O_7$), calculated on the dried basis.

[CAUTION—Handle Sufentanil Citrate with great care because it is a potent opioid analgesic. Great care should be taken to prevent inhaling particles of Sufentanil Citrate and exposing the skin to it.]

IDENTIFICATION

Change to read:

- A. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)

Change to read:

- B. ▲ [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.

Acceptance criteria: Meets the requirements

- C. [IDENTIFICATION TESTS—GENERAL, Citrate \(191\)](#).

Sample solution: Dissolve 500 mg in 5 mL of water.

Analysis: Render the *Sample solution* alkaline with 1 N sodium hydroxide, and extract with three 5-mL portions of methylene chloride.

Acceptance criteria: The aqueous layer meets the requirements.

- D. 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 *Mobile phase*

Sample solution: 0.075 mg/mL of Sufentanil Citrate in *Mobile phase*

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 0.73%

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 Sufentanil Citrate 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 = concentration of Sufentanil Citrate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• ORGANIC IMPURITIES

Mobile phase: Proceed as directed in the Assay.

Blank: 0.664 mg/mL of citric acid in *Mobile phase*

Sample solution: 0.75 mg/mL of Sufentanil Citrate in *Mobile phase*

Chromatographic system: Proceed as directed in the Assay.

Analysis

Samples: *Blank* and *Sample solution*

Calculate the percentage of each impurity, disregarding any peaks corresponding to those found in the *Blank*, in the portion of Sufentanil Citrate taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity

r_T = sum of the responses of all of the peaks

Acceptance criteria

Individual impurity: NMT 0.5%

Total impurities: NMT 1.0%

SPECIFIC TESTS

• [Loss on Drying \(731\)](#)

Analysis: Dry a sample under vacuum at 60° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

• **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	Documentary Standards Support	SM22020 Small Molecules 2

Topic/Question	Contact	Expert Committee
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 39(2)

Current DocID: GUID-F12C26D6-889C-4472-9BC8-1A115D635C86_4_en-US

DOI: https://doi.org/10.31003/USPNF_M78650_04_01

DOI ref: [d9msl](#)

OFFICIAL