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Alfentanil Injection

DEFINITION

Alfentanil Injection is a sterile solution of Alfentanil Hydrochloride in Water for Injection. It contains an amount of Alfentanil Hydrochloride equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of alfentanil ($C_{21}H_{32}N_6O_3$).

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

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Standard solution: 0.54 mg/mL of USP Alfentanil Hydrochloride RS

Sample solution: 0.5 mg/mL of alfentanil in water

Chromatographic system

Application volume: 200 µL

Developing solvent system: Chloroform, methanol, and formic acid (85:10:5)

Visualizing agent: Dragendorff's reagent

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter.

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: Acetonitrile and 0.01 M tetrabutylammonium hydrogen sulfate (14:86)

Standard solution: 0.54 mg/mL of USP Alfentanil Hydrochloride RS in saline TS

Sample solution: Equivalent to 0.50 mg/mL of alfentanil from a suitable volume of Injection in saline TS

Chromatographic system

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

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 2 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 5400 theoretical plates

Tailing factor: NMT 1.3

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of alfentanil ($C_{21}H_{32}N_6O_3$) in the portion of 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 Alfentanil Hydrochloride RS in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of alfentanil, 416.52

M_{r2} = molecular weight of alfentanil hydrochloride, 452.98

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

Mobile phase: Acetonitrile and 0.01 M tetrabutylammonium hydrogen sulfate (14:86)

Standard solution: 0.54 mg/mL of USP Alfentanil Hydrochloride RS in saline TS

Sample solution: Equivalent to 0.50 mg/mL of alfentanil from a suitable volume of Injection in saline TS

Chromatographic system

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

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 2 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 5400 theoretical plates

Tailing factor: NMT 1.3

Relative standard deviation: NMT 1.0%

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Injection taken:

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

r_U = peak response of each impurity

r_T = sum of all of the peaks

Acceptance criteria: The sum of all impurities is NMT 2.0%.

SPECIFIC TESTS

• **pH ⟨791⟩:** 4.0–6.0

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 10 USP Endotoxin Units/mL

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

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Alfentanil Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
ALFENTANIL INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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