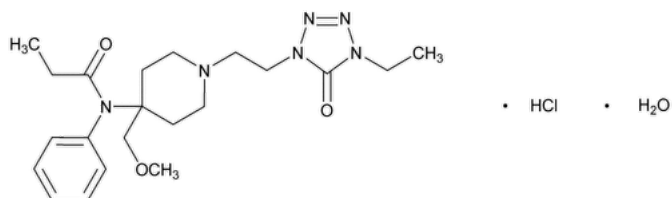


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Alfentanil Hydrochloride



$C_{21}H_{32}N_6O_3 \cdot HCl \cdot H_2O$ 470.99

$C_{21}H_{32}N_6O_3 \cdot HCl$ 452.98

Propanamide, *N*-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1*H*-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-piperidyl]-*N*-phenyl, monohydrochloride, monohydrate;

N-[1-[2-(4-Ethyl-5-oxo-2-tetrazolin-1-yl)-ethyl]-4-(methoxymethyl)-4-piperidyl]propionanilide monohydrochloride monohydrate CAS RN[®]: 70879-28-6; UNII: 11S92G0TIW.

Anhydrous CAS RN[®]: 69049-06-5; UNII: 333JT17A2M.

DEFINITION

Alfentanil Hydrochloride contains NLT 98.0% and NMT 102.0% of alfentanil hydrochloride ($C_{21}H_{32}N_6O_3 \cdot HCl$), calculated on the anhydrous basis.

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

IDENTIFICATION

Change to read:

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

Sample solution: 0.54 mg/mL of Alfentanil Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 235 nm

Column: 4.0-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 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

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

C_u = concentration of Alfentanil Hydrochloride in the *Sample solution* (mg/mL)

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **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 *Mobile phase*

Sample solution: 0.54 mg/mL of Alfentanil Hydrochloride in *Mobile phase*

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 0.73%

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Alfentanil Hydrochloride taken:

Result = $(r_u/r_T) \times 100$

r_u = peak response for each impurity

r_T = sum of all the peak responses

Acceptance criteria

Any single impurity: NMT 0.5%

Total impurities: NMT 1.0%

SPECIFIC TESTS

• [WATER DETERMINATION, Method I \(921\)](#): NMT 4.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers, 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 HYDROCHLORIDE	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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