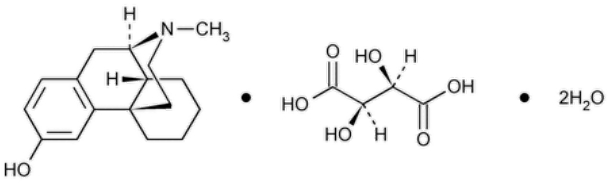
Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-AC96290B-E6A1-418D-A3C7-CD1562F6390D_2_en-US
DOI: https://doi.org/10.31003/USPNF_M44930_02_01
DOI Ref: ebo30

Levorphanol Tartrate



$C_{17}H_{23}NO \cdot C_4H_6O_6 \cdot 2H_2O$ 443.49

Morphinan-3-ol, 17-methyl-, [*R*-(*R**,*R**)]-2,3-dihydroxy butanedioate (1:1) (salt), dihydrate.

17-Methylmorphinan-3-ol, tartrate (1:1) (salt) dihydrate CAS RN®: 5985-38-6.

Anhydrous 407.47 CAS RN®: 125-72-4.

» Levorphanol Tartrate contains not less than 99.0 percent and not more than 101.0 percent of $C_{17}H_{23}NO \cdot C_4H_6O_6$, calculated on the anhydrous basis.

Packaging and storage—Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

USP Reference standards ⟨11⟩—

USP Levorphanol Tartrate RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) —Obtain the test specimen as follows. Dissolve 50 mg in 25 mL of water in a 125-mL separator. Add 2 mL of 6 N ammonium hydroxide, extract with 25 mL of chloroform, and filter the chloroform extract through a layer of 4 g of granular anhydrous sodium sulfate supported on glass wool into a 125-mL conical flask. Evaporate the chloroform extract on a steam bath with the aid of a stream of nitrogen to dryness. Dissolve the residue in 1 mL of acetone, and evaporate to dryness. Dry in vacuum at 90° for 1 hour. Proceed as directed with the dried levorphanol so obtained and a similar preparation of USP Levorphanol Tartrate RS.

Change to read:

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

Solution: 130 µg per mL.

Medium: 0.1 N hydrochloric acid.

Absorptivities at 279 nm, calculated on the anhydrous basis, do not differ by more than 3.0%.

Specific rotation ⟨781S⟩**:** between −14.7° and −16.3°.

Test solution: 30 mg per mL, in water. Heat on a water bath or sonicate to dissolve 750 mg in 20 mL of water in a 25-mL volumetric flask, dilute with water to volume, and mix.

Water Determination, *Method I* ⟨921⟩ **:** between 7.0% and 9.0%.

Residue on ignition ⟨281⟩**:** not more than 0.1%.

Ordinary impurities ⟨466⟩—

Test solution: water.

Standard solution: water.

Eluant: a mixture of hexanes, dehydrated alcohol, and ammonium hydroxide (80:25:1).

Visualization: 17; then view immediately under short-wavelength UV light.

Assay—Dissolve about 900 mg of sample, accurately weighed, in 85 mL of glacial acetic acid, warming slightly if necessary. Titrate with 0.1 N perchloric acid VS and determine the endpoint potentiometrically. Perform a blank determination and make any nececssary corrections. Each mL of 0.1 N perchloric acid consumed by the sample is equivalent to 40.75 mg of $C_{17}H_{23}NO \cdot C_4H_6O_6$.

Topic/Question	Contact	Expert Committee
LEVORPHANOL TARTRATE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(5)

Current DocID: GUID-AC96290B-E6A1-418D-A3C7-CD1562F6390D_2_en-US

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