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Levorphanol Tartrate Tablets

DEFINITION

Levorphanol Tartrate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of levorphanol tartrate ($C_{17}H_{23}NO \cdot C_4H_6O_6 \cdot 2H_2O$).

IDENTIFICATION

• **A.**

Sample: Nominally equivalent to about 1 mg of levorphanol tartrate from a number of finely powdered Tablets

Analysis: To the *Sample*, add 1 mL of water, 1 drop of 3 N hydrochloric acid, and 2 drops of ferric chloride TS, and heat to boiling. To the hot solution, add 1 mL of potassium ferricyanide solution (1 in 200).

Acceptance criteria: A bluish color develops.

•**B.**

Sample solution: Powder a number of Tablets, equivalent to about 60 mg of levorphanol tartrate, and transfer the mixture to a small separator. Add 10 mL of water, dissolve as much of the powder as possible, add about 400 mg of sodium bicarbonate, and extract with a 50-mL portion of chloroform. Evaporate the filtered chloroform extract on a steam bath to a small volume, and dilute with chloroform to 10 mL.

Analysis: Determine the angular rotation of the *Sample solution* (see *Optical Rotation* ⟨781⟩).

Acceptance criteria: The *Sample solution* is levorotatory.

ASSAY

• **Procedure**

Sample solution: Weigh and finely powder Tablets (NLT 20). Transfer an amount nominally equivalent to about 40 mg of levorphanol tartrate to a 125-mL separator. Add 20 mL of water and sufficient sodium bicarbonate to render the suspension alkaline to litmus. Add an additional 100 mg of sodium bicarbonate, and extract the levorphanol with five 20-mL portions of a mixture of 3 volumes of ether and 1 volume of chloroform. Pass the combined extracts through a layer of about 10 g of granular sodium sulfate, anhydrous into a 500-mL conical flask, and evaporate to a volume of about 30 mL.

Titrimetric system

Mode: Direct titration

Titrant: 0.01 N perchloric acid in dioxane VS

End point detection: Visual

Analysis: To the *Sample solution*, add about 50 mL of chloroform and 1 drop of methyl red TS, methanolic. Titrate with the *Titrant* to a red endpoint. Perform a blank determination, and make any necessary correction. Each milliliter of 0.01 N perchloric acid is equivalent to 4.435 mg of levorphanol tartrate ($C_{17}H_{23}NO \cdot C_4H_6O_6 \cdot 2H_2O$).

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Water; 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: A known concentration of USP Levorphanol Tartrate RS in *Medium*

Sample solution: Pass a portion of the solution under test through a filter and suitably dilute with water.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 279 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of levorphanol tartrate ($C_{17}H_{23}NO \cdot C_4H_6O_6 \cdot 2H_2O$) dissolved by comparing the UV absorbances between the *Standard solution* and *Sample solution*.

Tolerances: NLT 75% (*Q*) of the labeled amount of levorphanol tartrate ($C_{17}H_{23}NO \cdot C_4H_6O_6 \cdot 2H_2O$) is dissolved.

Change to read:

• **Uniformity of Dosage Units** ⟨905⟩**:** ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Diluent: 0.1 N hydrochloric acid

Standard solution: USP Levorphanol Tartrate RS in *Diluent* having a known concentration of about 80 µg/mL of anhydrous levorphanol tartrate

Sample solution: Nominally about 80 ▲µg▲ (ERR 1-Aug-2023) /mL of levorphanol tartrate in *Diluent* prepared as follows. Transfer 1 Tablet to a glass-stoppered flask, add 25.0 mL of *Diluent*, and allow the Tablet to disintegrate. Shake well, filter through a small filter paper, and discard the first portion of the filtrate. Dilute a portion of the filtrate quantitatively and stepwise, if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 279 nm

Blank: *Diluent*

Cell: 1 cm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of levorphanol tartrate ($C_{17}H_{23}NO \cdot C_4H_6O_6 \cdot 2H_2O$) in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Levorphanol Tartrate RS, on the anhydrous basis, in the *Standard solution* (µg/mL)

C_U = nominal concentration of levorphanol tartrate in the *Sample solution* (µg/mL)

M_{r1} = molecular weight of the hydrated form of levorphanol tartrate, 443.49

M_{r2} = molecular weight of the anhydrous form of levorphanol tartrate, 407.47

▲▲ (CN 1-Aug-2023)

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩
  USP Levorphanol Tartrate RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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