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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:**

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