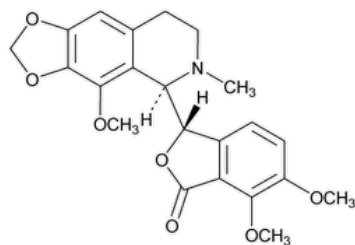


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Noscapine



$C_{22}H_{23}NO_7$

413.42

1(3*H*)-Isobenzofuranone, 6,7-dimethoxy-3-(5,6,7,8-tetrahydro-4-methoxy-6-methyl-1,3-dioxolo[4,5-*g*]isoquinolin-5-yl), [*S*-(*R**,*S**)]-;

Narcotine CAS RN®: 128-62-1; UNII: 8V32U4AOQU.

DEFINITION

Noscapine contains NLT 99.0% and NMT 100.5% of noscapine ($C_{22}H_{23}NO_7$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- A. [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#) : 197K.▲ (CN 1-May-2020) Do not dry specimens.

Change to read:

- B. [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U](#)▲ (CN 1-MAY-2020)

Solution: 60 µg/mL

Medium: Methanol

Acceptance criteria: Meets the requirements

- C.

Analysis: Place about 100 mg in a small porcelain dish, add a few drops of sulfuric acid, and stir.

Acceptance criteria: A greenish yellow solution is produced, and on warming it becomes red and then turns violet.

ASSAY

• PROCEDURE

Sample solution: Dissolve about 1.5 g of Noscapine in 25 mL of glacial acetic acid.

Analysis: Add 25 mL of dioxane and 5 drops of crystal violet TS to the *Sample solution*, and titrate with 0.1 N perchloric acid VS to a blue endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 41.34 mg of noscapine ($C_{22}H_{23}NO_7$).

Acceptance criteria: 99.0%–100.5% on the anhydrous basis

IMPURITIES

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

- [CHLORIDE AND SULFATE, Chloride \(221\)](#): A 700-mg portion shows no more chloride than corresponds to 0.20 mL of 0.020 N hydrochloric acid (0.02%).

- **LIMIT OF MORPHINE**

Sample solution: Dissolve 100 mg in 10 mL of 0.1 N hydrochloric acid.

Analysis: To 1.0 mL of the *Sample solution* add 5.0 mL of diluted ferricyanide reagent (prepared by dissolving 0.50 g of potassium ferricyanide in 50 mL of water, adding 0.50 mL of ferric chloride TS, and diluting 5.0 mL of the resulting solution to 25.0 mL).

Acceptance criteria: No blue or dark green color develops within 1 min.

- [ORDINARY IMPURITIES \(466\)](#).

Standard solution: Chloroform

Test solution: Chloroform

Eluant: Ethyl acetate and ether (80:20)

Visualization: 17; then examine the plate immediately.

Acceptance criteria: The sum of the intensities of all secondary spots of the *Test solution* corresponds to NMT 1.0%.

SPECIFIC TESTS

- **MELTING RANGE OR TEMPERATURE** (741): 174°–176°

- **OPTICAL ROTATION, Specific Rotation** (781S).

Sample solution: 20 mg/mL in 0.1 N hydrochloric acid

Acceptance criteria: +42° to +48°

- **WATER DETERMINATION, Method I** (921): NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

- **USP REFERENCE STANDARDS** (11).

[USP Noscapine RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
NOSCAPINE	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:

Pharmacopeial Forum: Volume No. Information currently unavailable

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