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Nadolol Tablets

DEFINITION
Nadolol Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of nadolol ($C_{17}H_{27}NO_4$).

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Standard solution: 5 mg/mL of USP Nadolol RS in 0.1 N hydrochloric acid

Sample solution: Nominally 5 mg/mL of nadolol from powdered Tablets in 0.1 N hydrochloric acid. Stir for 30 min, using a magnetic stirrer, and place in an ultrasonic bath for an additional 30 min. Centrifuge, and use the supernatant.

Chromatographic system

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 100 µL

Developing solvent system: Acetone, chloroform, and 2 N ammonium hydroxide (80:10:10)

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Samples* as streaks. Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, allow the solvent to evaporate, and examine the chromatogram under short-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **Procedure**

Mobile phase: A mixture of 700 mL of methanol and 1300 mL of water containing 5.84 g of sodium chloride and 1.0 mL of 0.1 N hydrochloric acid

Standard solution: 0.2 mg/mL of USP Nadolol RS in *Mobile phase*

Sample solution: Equivalent to 0.2 mg/mL of nadolol from NLT 20 finely powdered Tablets in *Mobile phase*, prepared as follows. To a suitable amount of the powder in a suitable volumetric flask, add *Mobile phase* to fill 75% of the total volume. Place the flask in an ultrasonic bath for 15 min, shaking intermittently, and clarify the solution by filtration or centrifugation. Dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; packing L16

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 3

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of nadolol ($C_{17}H_{27}NO_4$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of nadolol from the *Sample solution*

r_S = peak response of nadolol from the *Standard solution*

C_S = concentration of USP Nadolol RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of nadolol in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm

Time: 50 min

Solution A: Dissolve 5.84 g of sodium chloride in 1440 mL of water.

Mobile phase: Methanol and *Solution A* (560:1440). Adjust with 0.1 N hydrochloric acid to a pH of 2.5.

Standard solution: USP Nadolol RS in *Medium*

Sample solution: Use filtered portions of the solution under test. Dilute with *Medium*, as necessary.

Chromatographic system and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Determine the percentage of the labeled amount of nadolol ($C_{17}H_{27}NO_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S/L) \times V \times D \times 100$$

r_U = peak response of nadolol from the *Sample solution*

r_S = peak response of nadolol from the *Standard solution*

C_S = concentration of USP Nadolol RS in the *Standard solution* (mg/mL)

L = label claim (mg/tablet)

V = volume of *Medium*, 900 mL

D = dilution factor used in preparation of the *Sample solution*

Acceptance criteria: NLT 80% (Q) of the labeled amount of nadolol ($C_{17}H_{27}NO_4$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards** ⟨11⟩

USP Nadolol RS

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

Topic/Question	Contact	Expert Committee
NADOLOL TABLETS	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

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