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Pindolol Tablets

DEFINITION
Pindolol Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of pindolol ($C_{14}H_{20}N_2O_2$).

IDENTIFICATION
- **A.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The retention time of pindolol of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
Change to read:
- **Procedure**

Solution A: 6 mg/mL of ammonium carbonate in water

Mobile phase: Acetonitrile, methanol, and *Solution A* (19:19:2)

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

System suitability solution: 0.2 mg/mL of USP Nortriptyline Hydrochloride RS in *Standard solution*

Sample solution: Transfer a portion of the powdered Tablets (NLT 20 Tablets), nominally equivalent to 20 mg of pindolol, to a 100-mL volumetric flask, add 4 mL of water, and sonicate for 2 min, with occasional shaking to disperse the powder. Add 30 mL of *Mobile phase*, sonicate for 15 min, and allow to cool. Dilute with *Mobile phase* to volume, and filter. Use the clear filtrate as the *Sample solution*.

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

Mode: LC

Detector: UV 254 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing L16

Flow rate: 3 mL/min

Injection volume: 10 µL

Run time: NLT 2 times the retention time of the ▲nortriptyline▲ (ERR 1-Jan-2021) peak

System suitability

Samples: *Standard solution* and *System suitability solution*

[Note—The relative retention times for pindolol and nortriptyline are 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between pindolol and nortriptyline, *System suitability solution*

Relative standard deviation: NMT 2.0% of pindolol, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pindolol ($C_{14}H_{20}N_2O_2$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid; 500 mL

Apparatus 2: 50 rpm

Time: 15 min

Mobile phase and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard stock solution: 0.002*J* mg/mL of USP Pindolol RS in *Medium*. [Note—*J* is the labeled quantity, in milligrams, of pindolol in each Tablet.]

Standard solution: *Mobile phase* and *Standard stock solution* (1:1)

System suitability solution: 0.005 mg/mL of USP Nortriptyline Hydrochloride RS in *Standard solution*

Sample solution: Filter a portion of the solution under test. Mix equal volumes of the filtrate and of *Mobile phase*.

Analysis:

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pindolol ($C_{14}H_{20}N_2O_2$) dissolved:

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

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

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

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

V = volume of the *Medium*, 500 mL

L = label claim (mg/Tablet)

D = dilution factor for the *Sample solution*

Tolerances: NLT 80% (*Q*) of the labeled amount of pindolol ($C_{14}H_{20}N_2O_2$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

Solution A: 0.05 M sodium acetate. Adjust with glacial acetic acid to a pH of 5.0.

Mobile phase: Acetonitrile and *Solution A* (50:50)

System suitability solution: 0.003 mg/mL of USP Pindolol RS and 0.005 mg/mL of USP Indole RS in *Mobile phase*

Standard solution: 0.003 mg/mL of USP Pindolol RS in *Mobile phase*

Sensitivity solution: 1.0 µg/mL of USP Pindolol RS from *Standard solution* in *Mobile phase*

Sample solution: Nominally 1 mg/mL of pindolol in *Mobile phase* prepared as follows. Transfer a portion of the powdered Tablets (NLT 25), equivalent to 100 mg of pindolol, to a 100-mL volumetric flask. Add 90 mL of *Mobile phase* and sonicate for 5 min. Dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: 264 nm

Column: 4.6-mm × 15-cm; 3-µm packing L10

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: NLT 3 times of the retention time of pindolol

System suitability

Samples: *System suitability solution, Standard solution,* and *Sensitivity solution*

[Note—See *Table 1* for the relative retention times.]

Suitability requirements

Resolution: NLT 7 between indole and pindolol, *System suitability solution*

Relative standard deviation: NMT 2%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of each unspecified degradation product from the *Sample solution*

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

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

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

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Indole[a]	0.7	—
Pindolol	1.0	—
Any individual unspecified degradation product	—	0.2
Total degradation products	—	1.0

[a] For peak identification and resolution measurement.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, protected from light. Store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Indole RS

Indole.

C_8H_7N 117.15

USP Nortriptyline Hydrochloride RS

USP Pindolol RS

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

Topic/Question	Contact	Expert Committee
PINDOLOL TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

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