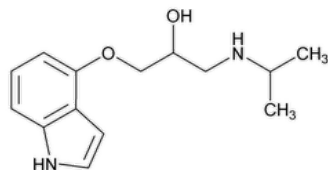


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Pindolol



$C_{14}H_{20}N_2O_2$

248.33

2-Propanol, 1-(1*H*-indol-4-yloxy)-3-(1-methylethyl)amino-;

1-(Indol-4-yloxy)-3-(isopropylamino)-2-propanol CAS RN[®]: 13523-86-9; UNII: BJ4HF6IU1D.

DEFINITION

Pindolol contains NLT 98.5% and NMT 101.0% of pindolol ($C_{14}H_{20}N_2O_2$), calculated on the dried basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197A or 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

• PROCEDURE

Mobile phase: [Acetonitrile](#) and 0.05 M [sodium acetate](#), previously adjusted with [glacial acetic acid](#) to a pH of 5.0 (350:650)

System suitability solution: 0.005 mg/mL each of [USP Pindolol RS](#) and [USP Indole RS](#) in *Mobile phase*

Standard stock solution: 1 mg/mL of [USP Pindolol RS](#) in *Mobile phase* prepared as follows. To a suitable amount of [USP Pindolol RS](#) add *Mobile phase* to fill about 90% of the total volume, and sonicate for about 5 min to dissolve. ▲Dilute with *Mobile phase* to volume.▲ (ERR 1-May-2023)

Standard solution: 0.1 mg/mL of [USP Pindolol RS](#) from *Standard stock solution* in *Mobile phase*

Sample stock solution: 1 mg/mL of Pindolol in *Mobile phase* prepared as follows. To a suitable amount of Pindolol add *Mobile phase* to fill about 90% of the total volume, and sonicate for about 5 min to dissolve. Dilute with *Mobile phase* to volume.

Sample solution: 0.1 mg/mL of Pindolol from *Sample stock solution* in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 219 nm

Column: 4.6-mm × 15-cm; 3-μm packing [L10](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

Run time: NLT 2 times the retention time for pindolol

System suitability

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

[NOTE—The relative retention times for indole and pindolol are 0.5 and 1.0, respectively.]

Suitability requirements

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

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pindolol ($C_{14}H_{20}N_2O_2$) in the portion of Pindolol 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 = concentration of Pindolol in the *Sample solution* (mg/mL)

Acceptance criteria: 98.5%–101.0% on the dried basis

IMPURITIES

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

• 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*. [NOTE—Sonication may be needed to aid in the dissolution.]

Standard solution: 0.003 mg/mL of [USP Pindolol RS](#) and 0.005 mg/mL of [USP 4-Hydroxyindole RS](#) in *Mobile phase*. [Note—Sonication may be needed to aid in the dissolution.]

Sensitivity solution: 0.5 µg/mL of [USP Pindolol RS](#) from *Standard solution* in *Mobile phase*

Sample solution: Use the *Sample stock solution*, prepared as directed in the Assay.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 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 the retention time of the pindolol peak

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% for 4-hydroxyindole and pindolol, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the specified impurity, 4-hydroxyindole, in the portion of Pindolol taken:

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

r_U = peak response of 4-hydroxyindole from the *Sample solution*

r_S = peak response of 4-hydroxyindole from the *Standard solution*

C_S = concentration of [USP 4-Hydroxyindole RS](#) in the *Standard solution* (mg/mL)

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

Calculate the percentage of any individual unspecified impurity in the portion of Pindolol taken:

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

r_U = peak response of each unspecified impurity 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 = concentration of Pindolol in the *Sample solution* (mg/mL)

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
4-Hydroxyindole	0.6	0.15
Indole ^a	0.7	—
Pindolol	1.0	—
Any individual unspecified impurity	—	0.10
Total impurities	—	0.6

^a For resolution measurement only. It is not to be reported or included in the total impurities.

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP 4-Hydroxyindole RS](#)

1*H*-Indol-4-ol.

C_8H_7NO 133.15

[USP Indole RS](#)

Indole.

C_8H_7N 117.15

[USP Pindolol RS](#)

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

Topic/Question	Contact	Expert Committee
PINDOLOL	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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