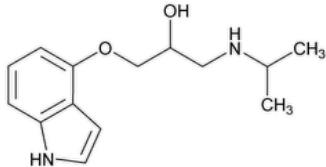


Status: Currently Official on 16-Feb-2025  
 Official Date: Official as of 01-May-2023  
 Document Type: USP Monographs  
 DocId: GUID-D87067C6-670E-4BD3-B46F-FF0169EFAA79\_6\_en-US  
 DOI: [https://doi.org/10.31003/USPNF\\_M65080\\_06\\_01](https://doi.org/10.31003/USPNF_M65080_06_01)  
 DOI Ref: 17quh

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## Pindolol



$C_{14}H_{20}N_2O_2$  248.33

2-Propanol, 1-(1*H*-indol-4-yl)oxy)-3-(1-methylethyl)amino-;  
 1-(Indol-4-yl)oxy)-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  $\mu$ g/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  $\times$  15-cm; 3- $\mu$ m packing [L10](#)

**Flow rate:** 1 mL/min

**Injection volume:** 10  $\mu$ L

**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 <sup>a</sup>	0.7	—
Pindolol	1.0	—
Any individual unspecified impurity	—	0.10
Total impurities	—	0.6

<sup>a</sup> 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](#)

1H-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	<a href="#">Documentary Standards Support</a>	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM22020 Small Molecules 2

**Chromatographic Database Information:** [Chromatographic Database](#)

#### Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 45(3)

**Current DocID:** [GUID-D87067C6-670E-4BD3-B46F-FF0169EFAA79\\_6\\_en-US](#)

**DOI:** [https://doi.org/10.31003/USPNF\\_M65080\\_06\\_01](https://doi.org/10.31003/USPNF_M65080_06_01)

**DOI ref:** [17quh](#)