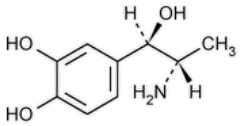
Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-E42F1930-F4E7-44DE-820C-7F23C06813CD_3_en-US
DOI: https://doi.org/10.31003/USPNF_M44810_03_01
DOI Ref: 40a93

Levonordefrin



$C_9H_{13}NO_3$ 183.20

1,2-Benzenediol, 4-(2-amino-1-hydroxypropyl)-, [*R*-(*R**,*S**)]-.

(-)-α-(1-Aminoethyl)-3,4-dihydroxybenzyl alcohol CAS RN®: 18829-78-2; 829-74-3; UNII: V008L6478D.

» Levonordefrin, dried in vacuum at 60° for 15 hours, contains not less than 98.0 percent and not more than 102.0 percent of $C_9H_{13}NO_3$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Levonordefrin RS

Change to read:

Identification—

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020)

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ (ERR 1-May-2020)

Solution: 25 µg per mL.

Medium: 0.1 N hydrochloric acid.

Specific rotation ⟨781S⟩: between −28° and −31°.

Test solution: 50 mg, previously dried, per mL, in 0.3 N hydrochloric acid.

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 15 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩: not more than 0.2%.

Chromatographic purity—

Standard solutions—Dissolve an accurately weighed quantity of USP Levonordefrin RS in a mixture of methanol and glacial acetic acid (96:4) to obtain a Standard stock solution having a known concentration of 5 mg per mL. Dilute this solution quantitatively with a mixture of methanol and glacial acetic acid (96:4) to obtain *Standard solutions*, designated below by letter, having the following compositions:

Standard solution	Dilution	Concentration (µg RS per mL)	Percentage (%, for comparison with test specimen)
A	(1 in 10)	500	1.0
B	(1 in 20)	250	0.5
C	(1 in 50)	100	0.2
D	(1 in 100)	50	0.1

Test solution—Dissolve an accurately weighed quantity of Levonordefrin in a mixture of methanol and glacial acetic acid (96:4) to obtain a solution containing 50 mg per mL.

Procedure— Apply separately 5 µL of the *Test solution* and 5 µL of each *Standard solution* to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with 0.25-mm layer of chromatographic silica gel mixture. Position the plate in a chromatographic chamber, and develop the chromatograms in a solvent system consisting of a mixture of *n*-butyl alcohol, water, and glacial acetic acid (70:20:10) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate in warm, circulating air. Examine the plate under short-wavelength UV light. Expose the plate to iodine vapors, and examine again. Compare the intensities, observed by both visualizations, of any secondary spots observed in the chromatogram of the *Test solution* with those of the principal spots in the chromatograms of the *Standard solutions:* the sum of the intensities of secondary spots obtained from the *Test solution* corresponds to not more than 1.0% of related compounds, with no single impurity corresponding to more than 0.5%.

Assay—Transfer about 350 mg of Levonordefrin, previously dried and accurately weighed, to a small flask, dissolve in 50 mL of glacial acetic acid, heating, if necessary, add 1 drop of crystal violet TS, and titrate with 0.1 N perchloric acid VS to a green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 18.32 mg of $C_9H_{13}NO_3$.

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

Topic/Question	Contact	Expert Committee
LEVONORDEFRIN	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-E42F1930-F4E7-44DE-820C-7F23C06813CD_3_en-US
DOI: https://doi.org/10.31003/USPNF_M44810_03_01
DOI ref: 40a93