Levodopa (LP)[1]
L-Dihydroxyphenylalanine

$C_9H_{11}NO_4$: 197.19

Levodopa (LP), when dried, contains not less than 99.0 percent and not more than 100.5 percent of Levodopa ($C_9H_{11}NO_4$). [by AJI TEST14]

Levodopa (LP), when dried, contains not less than 98.0 percent and not more than 102.0 percent of Levodopa ($C_9H_{11}NO_4$). [by HPLC[2]]

Description

White to slightly off-white, crystals or crystalline powder.
Freely soluble in formic acid and slightly soluble in water and practically insoluble in ethanol (95). Dissolves in 1 M hydrochloric acid.

Identification

(1) Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.
(2) The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay (HPLC).

Specifications

Item	Limit	Test
Specific rotation $[\alpha]_D^{25}$	-160 to -167°	[USP]
Appearance of solution	Passed test	[EP]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [1.0g, (4), ref: 1.0mL of Pb Std. (0.01mg/mL)]
Related substances	3-(3, 4, 6-Trihydroxyphenyl) alanine Not more than 0.10% L-Tyrosine Not more than 0.10% 3-Methoxytyrosine Not more than 0.20% L-Veratrylglycine Not more than 0.05% Unspecified impurities Not more than 0.05% Total Not more than 1.0%	[HPLC][3]
Enantiomeric purity	Not more than 0.50% of D-Dopa	[HPLC][4]

Specifications (cont'd)

Item	Limit	Test
Loss on drying	Not more than 0.50%	AJI TEST 11 [1g, at 105°C for 4 hours]
Residue on ignition (Sulfated)	Not more than 0.10%	AJI TEST 13 [1g, at 550°C to 650°C for 3 hours]
Assay	99.0 to 100.5%	AJI TEST 14 [Dried sample, 200mg, (1), 3mL of formic acid, 50mL of acetic acid (100), 0.1mol/L $HClO_4$ 1mL=19.72mg $C_9H_{11}NO_4$]
Assay (HPLC)	98.0 to 102.0%	[HPLC][5]
pH	4.5 to 7.0	AJI TEST 33 [0.10g in 10mL of H_2O, shaking for 15 minutes]
Particle size 180μm on 75μm on	 Not more than 20.0% 10.0 to 60.0%	AJI TEST 39 [Air jet sieve Method]

[1] This product, in terms of actual quality, conforms to USP and EP.

[2] Assay (HPLC) [HPLC]

Excluding the Test solution proceed as directed in USP.

Test solution-Dilute of the Test solution which prepared as directed in the Related substances to containing about 400μg per mL with Diluent.

[3] Related substances [HPLC]

Excluding the Test solution proceed as directed in USP.

Test solution-Transfer about 400mg of Levodopa, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with Diluent to volume, and mix.

Disregard limit: 0.03%

[4] Enantiomeric purity [HPLC]

(1) Analytical condition

Detector : UV detector (280nm)

Column : CROWNPAK CR (+) 4.0Φ × 150mm

Temperature : 25°C

Mobile phase : Add perchloric acid to water and adjust to pH1.5

Flow rate : 0.6 mL/min

Injection volume : 20μL

(2) Solution preparation

1) Test solution

Weigh accurately about 50mg (Amg) of Levodopa, add 50mL of mobile phase.

2) Standard solution

i) Primary stock solution

Weigh accurately about 5mg (Cmg) of D-Dopa standard, add 100mL of mobile phase.

ii) Standard solution

Exactly take 5mL of the Primary stock solution to 50mL with the mobile phase.

(3) Procedure

Separately inject equal volumes (20μL) of the Test solution and the Standard solution into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of D-Dopa in the portion of Levodopa taken by the formula:

$$\text{D-Dopa (\%)} = \frac{B \times C}{D \times A} \times 5$$

In which B is the peak area for D-Dopa in the Test solution, and D is the peak area for D-Dopa in the Standard solution.

Disregard limit: 0.03%

(4) Resolution

Exactly take 2.5mL of the Test solution and add the mobile phase to make 50mL.

Exactly take 3mL both of this solution and Primary stock solution and add the mobile phase to make 50mL.

Resolution between two chromatographic peaks is not less than 1.5.

[5] The same as footnote 2.

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