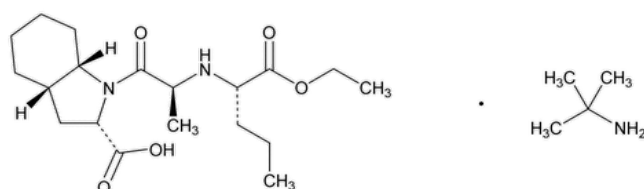


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Perindopril Erbumine

Change to read:



$C_{19}H_{32}N_2O_5 \cdot C_4H_{11}N$ ▲441.60▲ (USP 1-Aug-2022)

1*H*-Indole-2-carboxylic acid, 1-[2-[[1-(ethoxycarbonyl)butyl]amino]-1-oxopropyl]octahydro-, [2*S*-1[*R**(*R**)),2 α ,3 α ,7 α]], compound with 2-methyl-2-propanamine (1:1);
 (2*S*,3 α *S*,7 α *S*)-1-[(*S*)-*N*-[(*S*)-1-Carboxybutyl]alanyl]hexahydro-2-indolinecarboxylic acid, 1-ethyl ester, compound with *tert*-butylamine (1:1);
 ▲2-Methylpropan-2-amine (2*S*,3 α *S*,7 α *S*)-1-[(*S*)-1-ethoxy-1-oxopentan-2-yl]-[*L*-alanyl]octahydro-1*H*-indole-2-carboxylate▲ (USP 1-Aug-2022) CAS
 RN®: 107133-36-8; UNII: 1964X464OJ.

DEFINITION

Perindopril Erbumine contains NLT 98.0% and NMT 102.0% of perindopril erbumine ($C_{19}H_{32}N_2O_5 \cdot C_4H_{11}N$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of *System suitability solution 1*, as obtained in the test for *Limit of Perindopril Related Compound I*.

ASSAY

• PROCEDURE

Buffer: Dissolve 0.92 g of [sodium 1-heptanesulfonate](#) in 1 L of [water](#) and add 1 mL of [triethylamine](#). Adjust with a solution of [perchloric acid](#) and [water](#) (1:1) to a pH of 2.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (35:65)

Standard solution: 0.1 mg/mL of [USP Perindopril Erbumine RS](#) in *Buffer*. Initially add *Buffer* to about 60% of the flask volume, sonicate to dissolve, and dilute with *Buffer* to volume.

Sample solution: 0.1 mg/mL of Perindopril Erbumine in *Buffer*. Initially add *Buffer* to about 60% of the flask volume, sonicate to dissolve, and dilute with *Buffer* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5- μ m packing [L7](#)

Column temperature: 60°

Flow rate: 1 mL/min

Injection volume: 20 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of perindopril erbumine ($C_{19}H_{32}N_2O_5 \cdot C_4H_{11}N$) in the portion of Perindopril Erbumine taken:

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

r_U = peak area of perindopril from the *Sample solution*

r_S = peak area of perindopril from the *Standard solution*

C_S = concentration of [USP Perindopril Erbumine RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

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

Change to read:

- **ORGANIC IMPURITIES**

Solution A: Proceed as directed for the *Buffer* as described in the Assay.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
5	80	20
27	68	32
45	50	50
60	20	80
70	20	80
71	80	20
80	80	20

Diluent: *Solution B* and *Solution A* (20:80)

System suitability stock solution A: 0.03 mg/mL of [USP Imidazole RS](#) in *Diluent*

System suitability stock solution B: 0.03 mg/mL each of [USP Perindopril Erbumine RS](#), [USP Perindopril Related Compound B RS](#), [USP Perindopril Related Compound C RS](#), [USP Perindopril Related Compound D RS](#), and [USP Perindopril Related Compound F RS](#) in *Diluent*

System suitability solution: Transfer 5 mL each of *System suitability stock solution A* and *System suitability stock solution B* to a 50-mL volumetric flask and dilute with *Diluent* to volume. Pass through a suitable filter of 0.45-μm pore size, discard the first 3 mL of the filtrate, and use the clear filtrate.

Standard stock solution: 0.03 mg/mL of [USP Perindopril Erbumine RS](#) in *Diluent* prepared as follows. Dissolve a suitable quantity of [USP Perindopril Erbumine RS](#) in 80% of the total volume of *Diluent*, sonicate for about 5 min, and dilute with *Diluent* to volume.

Standard solution: 0.003 mg/mL of [USP Perindopril Erbumine RS](#) in *Diluent* from the *Standard stock solution*. Pass through a suitable filter of 0.45-μm pore size and discard the first 3 mL of the filtrate.

Sample solution: 3 mg/mL of Perindopril Erbumine in *Diluent* prepared as follows. Dissolve a suitable quantity of Perindopril Erbumine in 80% of the total volume of *Diluent*, sonicate for 5 min, and dilute with *Diluent* to volume. Pass through a suitable filter of 0.45-μm pore size and discard the first 3 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.0-mm × 25-cm; 4-μm packing [L7](#)

Column temperature: 60°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: System suitability solution

Suitability requirements

Tailing factor: NMT 1.5 for the perindopril peak

Relative standard deviation: NMT 5.0% for the perindopril peak

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of each impurity in the portion of Perindopril Erbumine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each impurity from the Sample solution

r_S = peak response of perindopril [▲] (USP 1-Aug-2022) from the Standard solution

C_S = concentration of [USP Perindopril Erbumine RS](#) in the Standard solution (mg/mL)

C_U = concentration of Perindopril Erbumine in the Sample solution (mg/mL)

F = relative response factor (see [Table 2](#))

Acceptance criteria: See [Table 2](#). [▲]The reporting threshold is 0.05%. [▲] (USP 1-Aug-2022)

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Imidazole ^a	0.08	—	—
Perindopril related compound B [▲] (USP 1-Aug-2022)	0.42	1.20	0.3
Perindopril related compound C [▲] (USP 1-Aug-2022)	0.74	0.96	0.1
Perindopril related compound D [▲] (USP 1-Aug-2022)	0.85	0.98	0.1
Perindopril erbumine	1.0	—	—
Isopropyl perindopril ^{▲b} (USP 1-Aug-2022)	1.22	1.00	0.40 (if present)
Perindopril related compound F [▲] (USP 1-Aug-2022)	1.38	0.85	0.2