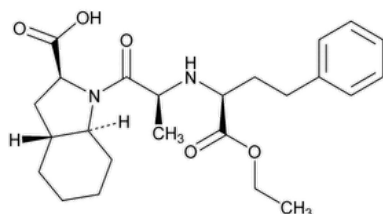


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Trandolapril



$C_{24}H_{34}N_2O_5$ 430.54

1*H*-Indole-2-carboxylic acid, octahydro *N*-[(2*S*)-1-ethoxy-1-oxo-4-phenylbutan-2-yl]-1-alanyl (2*S*,3*aR*,7*aS*);
 (2*S*,3*aR*,7*aS*)-1-[(*S*)-*N*-[(*S*)-1-Carboxy-3-phenylpropyl]alanyl]hexahydro-2-indolinecarboxylic acid, 1-ethyl ester CAS RN[®]: 87679-37-6.

DEFINITION

Trandolapril contains NLT 98.0% and NMT 102.0% of trandolapril ($C_{24}H_{34}N_2O_5$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020) or [\(197M\)](#)

Change to read:

- **B.** ▲ The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-May-2019)

ASSAY

Change to read:

• PROCEDURE

Buffer: 6.8 g/L of [monobasic potassium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

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

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

Standard solution: 0.002 mg/mL ▲ of [USP Trandolapril RS](#) ▲ (USP 1-May-2019) in *Mobile phase* from *Standard stock solution*

Sample stock solution: ▲ 0.1 ▲ (USP 1-May-2019) mg/mL of Trandolapril in *Mobile phase*

Sample solution: 0.002 mg/mL of Trandolapril in *Mobile phase* from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 100 μL

Run time: NLT 5.5 times the retention time of trandolapril

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT $\blacktriangle$ 0.73% $\blacktriangle$ (USP 1-May-2019)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of trandolapril ($C_{24}H_{34}N_2O_5$) in the portion of Trandolapril taken:

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

r_U = peak response $\blacktriangle$ of trandolapril $\blacktriangle$ (USP 1-May-2019) from the *Sample solution*

r_S = peak response $\blacktriangle$ of trandolapril $\blacktriangle$ (USP 1-May-2019) from the *Standard solution*

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

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

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

IMPURITIES

Change to read:

- $\blacktriangle$ (USP 1-MAY-2019) [RESIDUE ON IGNITION \(281\)](#).

Sample: 2.0 g

Acceptance criteria: NMT 0.1%

Change to read:

- $\blacktriangle$ ORGANIC IMPURITIES $\blacktriangle$ (USP 1-MAY-2019)

Buffer: 6.8 g/L of [monobasic potassium phosphate](#). Adjust with [phosphoric acid](#) to a pH of 2.5 ± 0.1 .

Solution A: [Acetonitrile](#) and *Buffer* (25:75), filtered and degassed

Solution B: [Acetonitrile](#) and *Buffer* (50:50), filtered and degassed

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
20	95	5
35	5	95
45	5	95
46	95	5
60	95	5

System suitability solution: 0.05 mg/mL each of [USP Trandolapril Related Compound C RS](#) and [USP Trandolapril Related Compound D RS](#) in *Solution A*

Standard solution: 0.0025 mg/mL of [USP Trandolapril RS](#) in *Solution A*

Sample solution: 2.5 mg/mL of Trandolapril in *Solution A*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm $\times$ 15-cm;

$\blacktriangle$ 3.5- μ m $\blacktriangle$ (USP 1-May-2019) packing [L1](#)

Column temperature: 40°