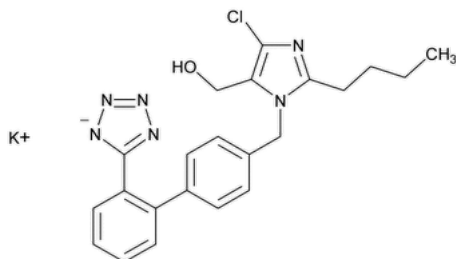


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Losartan Potassium

Change to read:



$C_{22}H_{22}ClKN_6O$ 461.00

1*H*-Imidazole-5-methanol, 2-butyl-4-chloro-1-[[2'-(1*H*-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]-, monopotassium salt;

2-Butyl-4-chloro-1-[*p*-(*o*-1*H*-tetrazol-5-ylphenyl)benzyl]imidazole-5-methanol, monopotassium salt;

▲Potassium 5-[4'-[(2-butyl-4-chloro-5-hydroxymethyl-1*H*-imidazol-1-yl)methyl]biphenyl-2-yl]tetrazol-1-ide.▲ (USP 1-Aug-2021) CAS RN®: 124750-99-8; UNII: 3ST302B24A.

DEFINITION

Losartan Potassium contains NLT 98.5% and NMT 101.0% of losartan potassium ($C_{22}H_{22}ClKN_6O$), calculated on the anhydrous, solvent-free basis.

IDENTIFICATION

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS <197>](#), [Infrared Spectroscopy](#):** 197M or 197K

Meets the requirements

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-Aug-2021)

- **C. [IDENTIFICATION TESTS—GENERAL <191>](#), [Chemical Identification Tests](#), [Potassium](#):** Meets the requirements

ASSAY

Change to read:

• PROCEDURE

Solution A: 0.1% [phosphoric acid](#) in [water](#)

Solution B: [Acetonitrile](#)

Mobile phase: *Solution B* and *Solution A* (40:60)

▲**Diluent:** [Methanol](#) and [water](#) (40:60)▲ (USP 1-Aug-2021)

Standard solution: 0.25 mg/mL of [USP Losartan Potassium RS](#) in ▲*Diluent*▲ (USP 1-Aug-2021)

Sample solution: 0.25 mg/mL of Losartan Potassium in ▲*Diluent*▲ (USP 1-Aug-2021)

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.0-mm × 25-cm; ▲5-μm▲ (USP 1-Aug-2021) packing [L1](#)

Column temperature: 35°

Flow rate: 1 mL/min

Injection volume: 10 μL

▲**Run time:** NLT 3 times the retention time of losartan▲ (USP 1-Aug-2021)

System suitability

Sample: *Standard solution*

Suitability requirements▲▲ (USP 1-Aug-2021)

Tailing factor: NMT 1.4

Relative standard deviation: NMT 0.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of losartan potassium ($C_{22}H_{22}ClKN_6O$) in the portion of Losartan Potassium taken:

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

r_U = peak response ▲ of losartan ▲ (USP 1-Aug-2021) from the *Sample solution*

r_S = peak response ▲ of losartan ▲ (USP 1-Aug-2021) from the *Standard solution*

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

C_U = concentration of ▲ Losartan Potassium in ▲ (USP 1-Aug-2021) the *Sample solution* (mg/mL)

Acceptance criteria: 98.5%–101.0% on the anhydrous, solvent-free basis

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

▲ **Solution A** and **Solution B:** Prepare as directed in the Assay. ▲ (USP 1-Aug-2021)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
25	10	90
35	10	90
45	75	25
50	75	25

System suitability solution: 0.3 mg/mL of [USP Losartan Potassium RS](#) and 2 µg/mL of triphenylmethanol in [methanol](#)

▲ **Standard solution:** 0.3 µg/mL of [USP Losartan Potassium RS](#) in [methanol](#)

Sensitivity solution: 0.15 µg/mL of [USP Losartan Potassium RS](#) in [methanol](#) from the *Standard solution* ▲ (USP 1-Aug-2021)

Sample solution: 0.3 mg/mL of Losartan Potassium in [methanol](#)

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.0-mm × 25-cm; ▲ 5-µm ▲ (USP 1-Aug-2021) packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution*, ▲ *Standard solution*, and *Sensitivity solution* ▲ (USP 1-Aug-2021)

[NOTE—The relative retention times for losartan and triphenylmethanol are 1.0 and 1.9, respectively. ▲ (USP 1-Aug-2021)]

Suitability requirements

Tailing factor: NMT 1.6, *System suitability solution*

▲ **Relative standard deviation:** NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution* ▲ (USP 1-Aug-2021)

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Losartan Potassium ($C_{22}H_{22}ClKN_6O$) taken: