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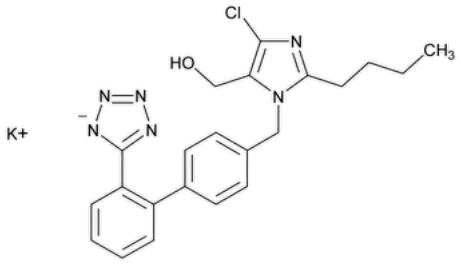
Losartan Potassium

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:

Result = $(r_U/r_T) \times 100$

r_U = peak response for each impurity

r_T = sum of the responses for all peaks

Acceptance criteria: ▲The reporting threshold is 0.05%.▲ (USP 1-Aug-2021)

Individual impurities: NMT 0.2%

Total impurities: NMT 0.5%

SPECIFIC TESTS

• **Water Determination** ⟨921⟩, *Method I*: NMT 0.5%. If labeled as an amorphous form, NMT 5.0%.

ADDITIONAL REQUIREMENTS

• **Labeling:** Where it is an amorphous form, the label so indicates.

• **Packaging and Storage:** Preserve in well-closed containers. Store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Losartan Potassium RS

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

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

Chromatographic Database Information: Chromatographic Database

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