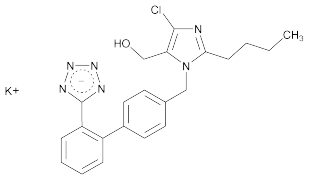
Losartan Potassium



$C_{22}H_{22}ClKN_6O$ 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 [124750-99-8].

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

Change to read:

• **A. INFRARED ABSORPTION** ⟨197M⟩ •**OR** ⟨197K⟩:●(RB 1-Jan-2012)
Meets the requirements

• **B. ULTRAVIOLET ABSORPTION** ⟨197U⟩
Sample solution: 10 µg/mL in methanol
Acceptance criteria: Meets the requirements

• **C. IDENTIFICATION TESTS—GENERAL,** *Potassium* ⟨191⟩**:**
Meets the requirements

ASSAY

• **PROCEDURE**
Solution A: 0.1% solution of phosphoric acid in water
Solution B: Acetonitrile
Mobile phase: *Solution B* and *Solution A* (2:3)
Standard solution: 0.25 mg/mL of USP Losartan Potassium RS in methanol
Sample solution: 0.25 mg/mL of Losartan Potassium in methanol
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 254 nm
Column: 4.0-mm × 25-cm; packing L1
Column temperature: 35°
Flow rate: 1 mL/min
Injection volume: 10 µL
System suitability
Sample: *Standard solution*
Suitability requirements
Column efficiency: NLT 5600 theoretical plates
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 area from the *Sample solution*
r_S = peak area from the *Standard solution*
C_S = concentration of USP Losartan Potassium RS in the *Standard solution* (mg/mL)
C_U = concentration of the *Sample solution* (mg/mL)

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

IMPURITIES

• **HEAVY METALS,** *Method II* ⟨**231**⟩**:** NMT 10 ppm

• **ORGANIC IMPURITIES**
Solution A: 0.1% solution of phosphoric acid in water
Solution B: Acetonitrile
System suitability solution: 0.3 mg/mL of USP Losartan Potassium RS and 2 µg/mL of triphenylmethanol in methanol
Sample solution: 0.3 mg/mL of Losartan Potassium in methanol
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

Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 220 nm
Column: 4.0-mm × 25-cm; packing L1
Flow rate: 1 mL/min
Injection volume: 10 µL
System suitability
Sample: *System suitability solution*
[NOTE—The relative retention times for losartan and triphenylmethanol are 1.0 and 1.9, respectively. The typical retention time for triphenylmethanol is 20 min.]
Suitability requirements
Tailing factor: NMT 1.6
Analysis
Sample: *Sample solution*
Calculate the percentage of each impurity in the portion of losartan potassium ($C_{22}H_{22}ClKN_6O$) taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity
r_T = sum of the responses for all peaks

Acceptance criteria
Individual impurities: NMT 0.2%
Total impurities: NMT 0.5%

SPECIFIC TESTS

Change to read:

• **WATER DETERMINATION,** *Method I* ⟨**921**⟩**:** NMT 0.5%. •If labeled as an amorphous form, NMT 5.0%.●(RB 1-Jan-2012)

ADDITIONAL REQUIREMENTS

Add the following:

•• **LABELING:** Where it is an amorphous form, the label so indicates.● (RB 1-Jan-2012)

• **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at controlled room temperature.

• **USP REFERENCE STANDARDS** ⟨**11**⟩
USP Losartan Potassium RS