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Losartan Potassium Tablets

DEFINITION

Losartan Potassium Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of losartan potassium ($C_{22}H_{22}ClKN_6O$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• **PROCEDURE**

Buffer: 1.25 mg/mL of monobasic potassium phosphate and 1.5 mg/mL of dibasic sodium phosphate in water. The resulting pH is approximately 7.0. Pass the solution through a PTFE or equivalent filter of 0.45-µm pore size, and degas before use.

Solution A: Acetonitrile and *Buffer* (15:85)

Solution B: Use acetonitrile.

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
10	40	60
11	80	20
15	80	20

System suitability stock solution: Dissolve 12 mg of [USP Losartan Potassium RS](#) in a 50-mL volumetric flask, first using 5 mL of water, followed by 5 mL of 0.1 N hydrochloric acid. Place the flask in a 105° oven for 1–2 h, and allow to cool to room temperature. Pipet 5 mL of 0.1 N sodium hydroxide into the flask, and dilute with water to volume. Adjust with either 0.1 N hydrochloric acid or 0.1 N sodium hydroxide to a pH of 6.0. [NOTE—The resulting solution contains the 1*H*-dimer and 2*H*-dimer, and the resulting solution may be cloudy.]

System suitability solution: Add 3 mL of acetonitrile to 7 mL of *System suitability stock solution* to clear the cloudy solution, and mix well.

Standard solution: 0.25 mg/mL of [USP Losartan Potassium RS](#) in *Solution A*. Pass through a PTFE or equivalent filter of 0.45-µm pore size.

Sample stock solution: Transfer 10 Tablets to a 500-mL volumetric flask, add *Solution A* to fill the flask to about 50% of the final volume, and sonicate with intermittent shaking for 15 min. Sonicate for an additional 10 min. Dilute with *Solution A* to volume, and mix well.

Sample solution: 0.25 mg/mL of losartan potassium in *Solution A* from the *Sample stock solution*. Mix well. Pass an aliquot of the solution through a PTFE filter of 0.45-µm pore size, and use the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 250 nm

Column: 3.9-mm × 15-cm; 5-µm packing L7

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for the losartan, 1*H*-dimer, and 2*H*-dimer peaks; *System suitability solution*

Resolution: NLT 2.0 between the 1*H*-dimer and 2*H*-dimer, *System suitability solution*

Column efficiency: NLT 3000 theoretical plates, *Standard solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of the labeled amount of losartan potassium ($C_{22}H_{22}ClKN_6O$) in the portion of Tablets taken:

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

 r_U = peak response of losartan from the *Sample solution* r_S = peak response of losartan from the *Standard solution* C_S = concentration of [USP Losartan Potassium RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of losartan potassium in the *Sample solution* (mg/mL)**Acceptance criteria:** 95.0%–105.0%**PERFORMANCE TESTS**• [DISSOLUTION \(711\)](#)**Test 1****Medium:** Water; 900 mL, deaerated**Apparatus 2:** 50 rpm**Time:** 30 min**Standard solution:** ($L/1000$) mg/mL of [USP Losartan Potassium RS](#) in *Medium*, where L is the Tablet label claim, in mg**Sample solution:** Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.**Analysis:** Determine the amount of losartan potassium ($C_{22}H_{22}ClKN_6O$) dissolved by using one of the following procedures:**Instrumental conditions****Analytical wavelength:** Maximum absorbance at about 256 nm**Path length:** See [Table 2](#) or make the appropriate dilution of the solutions with *Medium* to be within the linearity range of the spectrophotometer.**Table 2**

Tablet Strength (mg/Tablet)	Cell Size (cm)
25	1.0
50	0.5
100	0.2

Blank: *Medium*Calculate the percentage of the labeled amount of losartan potassium ($C_{22}H_{22}ClKN_6O$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S/L) \times V \times 100$$

 A_U = absorbance of the *Sample solution* A_S = absorbance of the *Standard solution* C_S = concentration of [USP Losartan Potassium RS](#) in the *Standard solution* (mg/mL) L = label claim (mg/Tablet) V = volume of *Medium*, 900 mL**Chromatographic procedure****Solution A:** 0.1% v/v phosphoric acid in water**Mobile phase:** Acetonitrile and *Solution A* (40:60)**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 254 nm**Column:** 4.0-mm $\times$ 25-cm; 5- μ m packing L1**Column temperature:** 35°**Flow rate:** 1 mL/min