Losartan Potassium

C₂₂H₂₂ClKN₆O

1H-imidazole-5-methanol, 2-butyl-4-chloro-1-[2’-(1H-tetrazol-5-yl)[1′,1′-biphenyl]-4-yl]methyl], monopotassium salt;
2-Butyl-4-chloro-1-[(o-1H-tetrazol-5-yl)phenyl]benzyl]imidazole-5-methanol, monopotassium salt [124750-99-8].

DEFINITION
Losartan Potassium contains NLT 98.5% and NMT 101.0% of losartan potassium (C₂₂H₂₂ClKN₆O), calculated on the anhydrous, solvent-free basis.

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
  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 (C₂₂H₂₂ClKN₆O) in the portion of Losartan Potassium taken:
  
  \[
  \text{Result} = \left( \frac{r_U}{r_T} \right) \times \left( \frac{C_S}{C_U} \right) \times 100
  \]
  
  \( r_U \) = 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>
<thead>
<tr>
<th>Time (min)</th>
<th>Solution A (%)</th>
<th>Solution B (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>75</td>
<td>25</td>
</tr>
<tr>
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<td>25</td>
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</tbody>
</table>

  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
  Suitability requirements
  Column efficiency: NLT 6000 theoretical plates
  Tailing factor: NMT 1.4
  Relative standard deviation: NMT 0.5%

SPECIFIC TESTS

• **WATER DETERMINATION, Method I (921):** NMT 0.5%. If labeled as an amorphous form, NMT 5.0%.

ADDITIONAL REQUIREMENTS

Add the following:

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

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

- **USP Reference Standards** (11)
  USP Losartan Potassium RS