कर्नाटका एन्टिबायोटिक्स एण्ड फार्मास्युटिकल्स लिमिटेड
(भारत सरकार का उद्यम)
KARNATAKA ANTIBIOTICS &
PHARMACEUTICALS LIMITED
(A Government of India Enterprise)

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|---|---|
| ENQUIRY REF. No. | KAPL/QAD/020/0963 |
| DATE | 31/07/2024 |
| DUE DATE | 05/08/2024 (13.00HRS) |

Dear Sir,

Please submit your lowest and competitive offer in a SEALED ENVELOPE, DULY SUPERSCRIBING OUR ABOVE ENQUIRY REF. NO., DATE and DUE DATE on it/ OR MAIL, with other details of F.O.R terms, Taxes, Credit period, Delivery offered, Name of the Make, Detailed Specification etc., for below mentioned material/s

| SL. NO. | ITEM CODE | ITEM DESCRIPTION | UOM | QTY |
|---|---|---|---|---|
| 01 | QSPHPL424 | HPLC COLUMN 25CM X 4.0MM, C18,5µ (NUCLEOSIL C18) | NOS | 02 |

OTHER TERMS:

1. F.O.R TERMS : DOOR DELIVERY
2. GST % : PLEASE SPECIFY
3. PACKING & FORWARDING CHARGES : NOT APPLICABLE
4. CREDIT PERIOD : 30 DAYS
5. DELIVERY OFFERED :

NOTE: IN CASE YOU ARE NOT QUOTING PLEASE SEND THE REGRET LETTER.

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT

the peak in the chromatogram obtained with the reference solution.

**Related substances**. Change to:

**Related substances**. Determine by liquid chromatography (2.4.14).

*Test solution*. Dissolve 30 mg of the substance under examination in *methanol* and dilute to 100.0 ml with *methanol*.

*Reference solution (a)*. A 0.00003 per cent w/v solution of *losartan potassium IPRS* in *methanol*.

*Reference solution (b)*. A solution containing 0.03 per cent w/v of *losartan potassium IPRS* and 0.0002 per cent w/v of *triphenylmethanol* in *methanol*.

*Reference solution (c)*. Dilute 5.0 ml of reference solution (a) to 10.0 ml in *methanol*.

Chromatographic system

- a stainless steel column 25 cm x 4.0 mm, packed with octadecylsilane bonded to porous silica (5µm) (Such as Nucleosil C18),
- mobile phase: A. 0.1 per cent v/v solution of *orthophosphoric acid* in *water*,
  B. *acetonitrile*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 220 nm,
- injection volume: 10 µl.

| Time (in min.) | Mobile phase A (per cent v/v) | Mobile phase B (per cent v/v) |
|---|---|---|
| 0 | 75 | 25 |
| 25 | 10 | 90 |
| 35 | 10 | 90 |
| 45 | 75 | 25 |
| 50 | 75 | 25 |

The relative retention time with reference to losartan, for triphenylmethanol is about 1.9.

Inject reference solution (a), (b) and (c). The test is not valid unless the tailing factor is not more than 1.6 in the chromatogram obtained with reference solution (b), the relative standard deviation for replicate injections is not more than 5.0 per cent in the chromatogram obtained with reference solution (a) and the signal-to-noise ratio is not less than 10 in the chromatogram obtained with reference solution (c).

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (0.2 per cent) and the sum of the areas of all the secondary peaks is not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

**Assay**. Change to:

**Assay**. Determine by liquid chromatography (2.4.14).

*Solvent mixture*. 40 volumes of *methanol* and 60 volumes of *water*.

*Test solution*. Dissolve 25 mg of the substance under examination in the solvent mixture and dilute to 100.0 ml with the solvent mixture.

*Reference solution*. A 0.025 per cent w/v solution of *losartan potassium IPRS* in the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm x 4.0 mm, packed with octadecylsilane bonded to porous silica (5µm),
- column temperature: 35°,
- mobile phase: a mixture of 60 volumes of 0.1 per cent v/v of *orthophosphoric acid* and 40 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 10 µl.

Run the chromatogram at least 3 times the retention time of the principal peak.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 1.6 and the relative standard deviation for replicate injections is not more than 0.5 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{22}H_{22}ClKN_6O$.

## Losartan Tablets. Page 2792

### Identification

Change to: In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (b).

**Related substances**. Change to:

**Related substances**. Determine by liquid chromatography (2.4.14).

*Test solution*. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 25 mg of Losartan Potassium in 50 ml of mobile phase A, with the aid of ultrasound with intermittent shaking and dilute to 100.0 ml with the mobile phase A and filter.

*Reference solution (a)*. Transfer 12 mg of *losartan potassium IPRS* to a 50-ml volumetric flask, add 5 ml of *water*, 5 ml of

chromatogram obtained with reference solution (b), the tailing factor is not more than 1.8 and the relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution.

Calculate the content of $C_{11}H_{12}N_2S$ in the tablets.

## Lindane Lotion

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Gamma Benzene Hexachloride Lotion

Lindane Lotion is Lindane in a suitable aqueous vehicle.

Lindane Lotion contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of lindane ($\gamma$-$C_6H_6Cl_6$).

**Usual strength.** 1 per cent w/v.

### Identification

Wind a strip of 20-mesh copper gauze 1.5 cm wide and 5 cm long around the end of a copper wire. Heat the gauze in the nonluminous flame of a Bunsen burner until it glows without colouring the flame green. Allow the gauze to cool, and repeat the heating and cooling step several times until a thorough coating of oxide is formed. Apply a small amount of lotion to the cooled gauze, ignite, and allow to burn freely in the air. Hold the gauze in the outer edge of the burner flame at a height of 4 cm. A bright green colour is imparted to the flame.

### Tests

**pH**(2.4.24). 6.5 to 8.5.

**Other tests**. Comply with the tests stated under Lotion.

**Assay**. Determine by gas chromatography (2.4.13).

*Mobile phase.* A mixture of 6 volumes of *anhydrous ethyl ether* and 94 volumes of *hexane.*

*Internal standard solution.* A 0.1 per cent w/v solution of *n-docosane* in *methylene chloride.*

*Solid support.* 60 to 100 mesh magnesium silicate that has been heated previously at 300° for 2 hours.

*Test solution (a).* Place a pledget of cotton on a removable porous plate at the base of a 2.5 cm × 20 cm chromatographic tube fitted with a polytef stopcock. Add 50 ml of the solvent mixture and 10 g of solid support, and stir the mixture to expel air bubbles. Add 1.5 g of *anhydrous sodium sulphate* to the tube, and elute until the surface of the liquid is 4 cm above the solid support, discarding the eluate. Transfer a quantity of lotion containing 10 mg of Lindane to a 150-ml beaker, and add 10 g of solid support. Mix with a spatula, adding *hexane* as necessary to produce a homogeneous mixture, and continue stirring until a free-flowing powder is produced. Transfer this mixture to the chromatographic tube with the aid of three 5 ml portions of the solvent mixture, and elute the tube with 225 ml of the solvent mixture at a flow rate of 2 to 3 ml per minutes, collecting the eluate in a 250-ml beaker. Remove the chromatographic tube, add 5.0 ml of internal standard solution to the eluate, and evaporate with the aid of gentle heat and a current of dry air to 5 ml.

*Test solution (b).* Transfer test solution (a) to a graduated centrifuge tube with the aid of 1 ml of *methylene chloride*, and evaporate with the aid of gentle heat and dry air to 3 ml (Avoid evaporating to dryness). If the mixture is inadvertently evaporated to dryness, discard it, and begin another test solution (b).

*Reference solution (a).* A 0.2 per cent w/v solution of *lindane IPRS* in *methylene chloride.*

*Reference solution (b).* Transfer 5.0 ml of reference solution (a) to a graduated centrifuge tube and add 5.0 ml of internal standard solution, evaporate with the aid of gentle heat and dry air to 3 ml (Avoid evaporating to dryness).

Chromatographic system

- a glass or stainless steel column 1.8 m x 2 mm, packed with 3 per cent liquid phase (50 per cent of Phenyl- 50 per cent of methylpolysiloxane) on acid-washed, then water-washed until neutral, siliceous earth support (Such as OV-17),
- temperature:
  column. 195°,
  injection port and detector 250°,
- flame ionization detector,
- flow rate: 40 ml per minute, using nitrogen as the carrier gas,
- injection volume:1 µl.

Inject reference solution (b). The test is not valid unless the resolution between the peaks due to lindane and n-docosane is not less than 5.0, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 3.0.

Inject reference solution (b) and test solution (b).

Calculate the content of ($\gamma$-$C_6H_6Cl_6$) in the lotion.

**Storage**. Store protected from moisture, at a temperature not exceeding 30°.

## Losartan Potassium. Page 2791

**Identification**. B

Change **to**: B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to

## User Requirement specifications

**Material Description :** HPLC COLUMN 25cm x 4.0mm, C18, 5u

**URS Number**: QC/URS/007/0724

### 1. Description and Quantity:

| | |
|---|---|
| Material Description | 25cm x 4.0mm, C18, 5u |
| Item code | QSPHPL424 |
| Quantity/ Box | 2 |

### 2. User Specifications:

| # | Requirement | Specification |
|---|---|---|
| 1 | Brand Name | 25cm x 4.0mm, C18, 5u (Nucleosil C18) |
| 2 | Make | Macherey-Nagel |
| 3 | Brand | NUCLEOSIL |
| 4 | Cat. Number | 720014.40 |
| 5 | Matrix active group | Silica |
| 6 | Particle size | 5u |
| 7 | Length (mm) | 250 |
| 8 | Internal Diameter (I.D.) | 4.0 mm |
| 9 | Particle type | Fully porous particles |
| 10 | Particle Shape | Spherical |
| 11 | External Construction Materials | Stainless Steel |
| 12 | Endcapped | Yes |
| 13 | Endfitting Type | Nucleosil |
| 14 | USP Classification | L1 |
| 15 | Separation Mode | Reverse phase |
| 16 | $P^H$ Range | 2-8 |
| 17 | Maximum Pressure | 5800 psi (400 Bar) |
| 18 | Pore Size | 100 °A |