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

ENQUIRY REF. No.	KAPL/QAD/020/0253/25-26
DATE	21.05.2025
DUE DATE	27.05.2025 till 1:00 PM

Dear Sir,

Please submit your lowest and competitive offer in a SEALED ENVOLOPE, DULY SUPERSCRIBING OUR ABOVE ENQUIRY REF. NO., DATE and DUE DATE on it. Mentioned other details of F.O.R terms, Taxes, Credit period, Delivery offered, Name of the Make, Detailed Specification etc., for the below Supply or Service

Sl No	Item Code	Item Description	Uom	Qty
01	QFD023	ATLANTIS SILICA HILIC COLUMN,100Å,5µM,4.6MM X25 CM	NOS.	01

Please ensure that your offer reaches us on or before Due Date by courier OR Speed post or by Hand in sealed cover to below office address or email to purenp@kaplindia.com:

M/s. Karnataka Antibiotics and Pharmaceuticals Limited
Plot No.37, Arka The Business Centre, NTTF Main Road, Peenya Industrial Area
2nd Phase, Bengaluru-560058 Ph. No.080-23571590

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. SPECTIONS ATTACHED : 3 PAGE

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

MAKE: WATERS

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT
MOB: 9945317873

KARNATAKA ANTIBIOTICS AND PHARMACEUTICALS
LIMITED, BENGALURU
QUALITY CONTROL DEPARTMENT

User Requirement Specifications

Material Description: Atlantis Silica HILIC Column,100A°,5µm,4.6 mm X 25cm
URS Number: QC/URS/CL/001/2025

1.Description and Quantity

Material Description: Atlantis Silica HILIC Column,100A°,5µm,4.6 mm X 25cm
Item Code: :QFD023
Quantity/Box :1

2. User Specifications

#	Requirement	Specification
1	Brand Name	Atlantis Silica HILIC Column,100 A°,5µm.4.6 mm X 25 cm
2	Make	Waters
3	Brand	Atlantis
4	Part No.	186002033
5	Matrix active group	HILIC
6	Particle size	5µm
7	Surface Area (m/g)	300
8	Length	25cm
9	Internal Diameter(I.D)	4.6mm
10	Pore size	100 A°
11	Particel subsatnce	Silica
12	Particle shape	Spherical
13	External Construction materials	Stainless Steel
14	Endcapped	No
15	USP classification	L3
16	Separation mode	Hydrophilic Interaction(HILIC)
17	pH range	~~01-May~~ 1-5
18	Maximum pressure	6000 psi(415 Bar)
19	Age of column	Must be no more than 24 months old at the time of delivery

21/04/2025
Prepared by: E(NDS)-QC

21/04/2025
Checked by: AM(BSD)-QC

21/04/2025
Approved by: SM(NDC)-QC

levetiracetam is not less than 2.0 obtained with reference solution (a), the tailing factor for levetiracetam peak is not more than 2.0 and the relative standard deviation for replicate injections is not more than 10.0 per cent obtained with reference solution (b).

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to levetiracetam acid is not more than area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent), the area of any other secondary peak is not more than 0.33 the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent) and the sum of areas of all the secondary peaks is not more than 2 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.6 per cent).

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Solvent mixture. 20 volumes of *acetonitrile* and 80 volumes of *water*.

Test solution. Weigh and powder 20 tablets. Transfer a quantity of the powder containing about 40 mg of Levetiracetam in 100-ml volumetric flask and add about 80 ml of solvent mixture and disperse with aid the aid of ultrasound for about 10 minutes, cool and dilute to volume with solvent mixture and filter.

Reference solution. A solution containing 0.04 per cent w/v of *levetiracetam IPRS* in the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (4 µm),
- mobile phase: a mixture of 92 volumes of a buffer solution prepared by dissolving 1.4 g of *monobasic potassium phosphate* and 0.6 g of *sodium 1-haptanesulphonate* in 1000 ml of *water* and adjusted to pH 2.8 with *ortho phosphoric acid* and 8 volumes of *acetonitrile*,
- flow rate: 2 ml per minute,
- spectrophotometer set at 220 nm,
- injection volume: 10 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

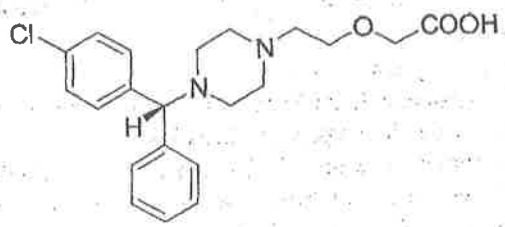
Inject the reference solution and the test solution.

Calculate the content of $C_8H_{14}N_2O_2$ in the tablets.

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

Levocetirizine Hydrochloride

Levocetirizine Dihyrochloride



$C_{21}H_{25}N_2O_3Cl,2HCl$ Mol. Wt. 461.8

Levocetirizine Hydrochloride is (*R*)-2-[2-[4-[(4-chloro-phenyl) phenylmethyl]piperazin-1-yl]ethoxy]acetic acid dihydrochloride.

Levocetirizine Hydrochloride contains not less than 98.0 per cent and not more than 102.0 per cent of $C_{21}H_{25}N_2O_3Cl,2HCl$ calculated on the dried basis.

Category. Antihistaminic.

Description. A white or almost white powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *levocetirizine dihydrochloride IPRS* or with the reference spectrum of levocetirizine dihydrochloride.

B. When examined in the range 200 nm and 350 nm (2.4.7), a 0.001 per cent w/v solution in *methanol* shows an absorption maximum at about 230 nm.

Tests

Specific optical rotation (2.4.22). +10° to +14°, determined in a 1 per cent w/v solution in *carbon dioxide-free water* at 365 nm.

Heavy metals (2.3.13). Dissolve the residue obtained in the test for sulphated ash in 20 ml *water*. 12 ml of the solution complies with limit test for heavy metals, Method D (20 ppm).

Enantiomeric purity. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 12.5 mg of the substance under examination in 1 ml of *ethanol (95 per cent)* and dilute to 25 ml with the mobile phase, filter.

Reference solution. Dissolve 12.5 mg of the *racemic cetirizine dihydrochloride IPRS* in 1 ml of *ethanol (95 per cent)* and dilute to 25 ml with the mobile phase.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm packed with chiral Pak AD-H (5 µm),

- mobile phase: a mixture of 70 volumes of *n-hexane*, 15 volumes of *isopropyl alcohol*, 15 volumes of *ethanol (95 per cent)*, 0.2 volume of *trifluoro acetic acid* and 0.01 volume of *diethylamine*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 230 nm,
- injection volume: 10 µl.

Inject the reference solution and the test solution.

The relative retention time of levocetirizine isomer is about 2 with respect to levocetirizine peak.

Calculate the chiral purity of levocetirizine dihydrochloride by area normalization method, the enantiomeric purity is not less than 98 per cent.

Related substances. Determine by liquid chromatography (2.4.14).

NOTE — Use the solutions within 16 hours.

Test solution. Dissolve 20 mg of the substance under examination in the mobile phase and dilute to 100.0 ml with the mobile phase, filter.

Reference solution (a). A solution containing 0.00002 per cent w/v, each of, *levocetirizine dihydrochloride IPRS*, *levocetirizine amide IPRS* and *chlorobenzhydryl piperazine IPRS* in the mobile phase.

Reference solution (b). A solution containing 0.02 per cent w/v of *levocetirizine dihydrochloride IPRS* and 0.00002 per cent w/v, each of, *levocetirizine amide IPRS* and *chlorobenzhydryl piperazine IPRS* in the mobile phase.

Chromatographic system

- a stainless steel column 25 cm × 4.6 mm packed with silica gel (5 µm),
- mobile phase: a mixture of 93 volumes of *acetonitrile*, 6.6 volumes of *water* and 0.4 volume of *1M sulphuric acid*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 230 nm,
- injection volume: 20 µl.

Name	Relative retention time
Levocetirizine	1.0
Chlorobenzhydryl piperazine[1]	1.4
Levocetirizine amide[2]	2.1

[1](R)-1-[(4-chlorophenyl)phenylmethyl]piperazine,

[2](R)-2-(2-{4-[(4-chlorophenyl)phenylmethyl]piperazin-1-yl}ethoxy) acetamide.

Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to chlorobenzhydryl piperzine and levocetirizine is not less than 3.0, the tailing factor for levocetirizine peak is not more than 2.0 in the chromatogram obtained with reference solution (b) and the relative standard deviation for replicate injections for levocetirizine is not more than 5.0 per cent in the chromatogram obtained with reference solution (a).

Inject reference solution (a) and the test solution. Run the chromatogram 3 times the retention time of levocetirizine peak. The area of any peak corresponding to chlorobenzhydryl piperzine or levocetirizine amide is not more than twice the area of the peak due to chlorobenzhydryl piperzine or levocetirizine amide in the chromatogram obtained with reference solution (a) (0.2 per cent), the area of any other secondary peak is not more than the area of the peak due to levocetirizine in the chromatogram obtained with reference solution (a) (0.1 per cent) and the sum of areas of all the secondary peaks is not more than 5 times the area of the peak due to levocetirizine in the chromatogram obtained with reference solution (a) (0.5 per cent).

Sulphated ash (2.3.18). Not more than 0.2 per cent, determined on 2 g.

Loss on drying (2.4.19). Not more than 1.0 per cent, determined on 1 g by drying in an oven at 100° at a pressure not exceeding 0.7 kPa.

Assay. Dissolve 0.1 g in 70 ml of a mixture of 30 ml of *water* and 70 ml of *acetone*. Titrate with *0.1 M sodium hydroxide* upto the second point of inflection. Determine the end-point potentiometrically (2.4.25). Carry out a blank titration.

1 ml of *0.1 M sodium hydroxide* is equivalent to 0.01539 g of $C_{21}H_{25}N_2O_3Cl,2HCl$.

Storage. Store protected from moisture.

Levocetirizine Tablets

Levocetirizine Dihydrochloride Tablets

Levocetirizine Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of levocetirizine hydrochloride, $C_{21}H_{25}N_2O_3Cl,2HCl$.

Usual strength. 5 mg.

Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests

Dissolution (2.5.2).

Apparatus No. 2 (Paddle),

Medium. 900 ml of *phosphate buffer pH 6.8*,