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

ENQUIRY REF. No.	KAPL/QAD/020/2265
DATE	23.01.2025
DUE DATE	27/01/2025 (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	QSPHPL174	HPLC COLUMN 250MMX4.6MM,5 MIC,SILICA(SI)	NOS	02
02	QSPHPL105	30CMX3.9MM C18 5 MICRON HPLC COLUMN	NOS	02

Please ensure that your offer reaches us on or before Due Date by courier OR Speed post or By hand in sealed cover only to below office address:

M/s. Karnataka Anitibiotics 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. DELIVERY OFFERED : 06
6. ATTACHMENTS

NOTE:

1).IF YOU ARE NOT PARTICIPATING IN THE TENDER PLEASE SEND A REGRET LETTER .

2).VENDER HAS TO QUOTE AS PER OUR TENDER IN YOUR COMPANY LETTER HEAD.

3).QUOTATION MUST BE SUBMITTED IN TWO SEALED COVERS (TECHNICAL&COMMERCIAL /PRICE BID)SEPARATELY AND IN ONE ENVELOP OR ELSE YOUR PROPOSAL WILL NOT BE CONSIDERED.

IF YOU NEED ANY CLARIFICATION , PLEASE CONTACT US.

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED
23/1/25
YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT
MOB:9945317873

Cetirizine Tablets

Cetirizine Hydrochloride Tablets

Cetirizine Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of cetirizine hydrochloride, $C_{21}H_{25}ClN_2O_3,2HCl$.

Usual strengths. 10 mg; 20 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 *0.1 M hydrochloric acid,*
Speed and time. 100 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtrate, suitably diluted with the dissolution medium if necessary, at the maximum at about 230 nm (2.4.7). Calculate the content of $C_{21}H_{25}ClN_2O_3,2HCl$ in the medium from the absorbance obtained from a solution of known concentration of *cetirizine hydrochloride IPRS* in the same medium.

Q. Not less than 75 per cent of the stated amount of $C_{21}H_{25}ClN_2O_3,2HCl$.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 20 mg of Cetirizine Hydrochloride, add 50 ml of the mobile phase, mix and dilute to 100 ml with the mobile phase.

Reference solution (a). A solution containing 0.02 per cent w/v, each of, *cetirizine hydrochloride IPRS* and *(RS)-1-[(4-chlorophenyl)phenylmethyl]piperazine IPRS (cetirizine impurity A)* in the mobile phase. Dilute 1.0 ml of the solution to 100.0 ml with the mobile phase.

Reference solution (b). Dilute 1.0 ml of the test solution to 100.0 ml with the mobile phase.

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

Inject reference solution (a). The test is not valid unless the resolution between the peaks due to cetirizine and cetirizine impurity A is not less than 2.0 and the tailing factor is not more than 2.0 for cetirizine peak.

Inject reference solution (b) and the test solution. Run the chromatogram 3 times the retention time of cetirizine. In the chromatogram obtained with the test solution the area of any impurity peak is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent) and the sum of the areas of all such peaks is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent). Ignore any peak with an area 0.05 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Uniformity of content. Complies with the test stated under Tablets.

Determine by liquid chromatography (2.4.14), as described under Assay, using the following solution as the test solution.

Test solution. Disperse 1 tablet in the mobile phase, mix and dilute to 100.0 ml with the mobile phase, filter. Dilute 5.0 ml of the solution to 10.0 ml with mobile phase.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing about 25 mg of Cetirizine Hydrochloride, add the mobile phase, mix and dilute to 50.0 ml with the mobile phase, filter. Dilute 1.0 ml of the solution to 10.0 ml with mobile phase.

Reference solution. A 0.05 per cent w/v solution of *cetirizine hydrochloride IPRS* in the mobile phase. Dilute 1.0 ml of the solution to 10.0 ml with the mobile phase.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane chemically bonded to porous silica (5 µm),
- mobile phase: dissolve 0.19 g of *heptane sulphonic acid sodium salt* in 300 ml *water* add 700 ml *acetonitrile* and mix. Adjust pH to 3.2 with *0.05 M sulphuric acid,* filter,
- flow rate: 1.2 ml per minute,
- spectrophotometer set at 230 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, 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 $C_{21}H_{25}ClN_2O_3,2HCl$ in the tablets.

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

QUALITY CONTROL DEPARTMENT		KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED (A Government of India Enterprise)

User Requirement specifications

Material Description : HPLC COLUMN 25 cm x 4.6mm, 5u, Silica gel

URS Number: QC/URS/017/0125

1. Description and Quantity:

Material Description	25cm x 4.6mm, 5u , Silica gel
Item code	QSPHPL174
Quantity/ Box	2

2. User Specifications:

#	Requirement	Specification
1	Brand Name	25cm x 4.6mm, 5u, Packed with silicagel.
2	Matrix active group	Silica
3	Particle size	5u
4	Length (mm)	250
5	Internal Diameter (I.D.)	4.6 mm
6	Particle type	Silica gel
7	Particle Shape	Spherical
8	External Construction Materials	Stainless Steel
9	Endcapped	Yes
10	USP Classification	L3
11	Separation Mode	Reverse phase
12	P^H Range	2-8
13	Maximum Pressure	6000 psi (410 Bar)
14	Pore Size	100 °A

- mobile phase: dissolve 1.1 g of *sodium 1-heptanesulphonate* and 0.71 g of *anhydrous dibasic sodium phosphate* in 700 ml of *water*. Add 2 ml of *dibutylamine*, and adjusted to pH 3.0 with *0.8 M orthophosphoric acid*, add 300 ml of *methanol*,
- flow rate: 0.6 ml per minute,
- spectrophotometer set at 226nm,
- injection volume: 50 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the tailing factor is not more than 2.0.

Inject the reference solution and the test solution. Run the chromatogram 6 times the retention time of the principal peak. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than 0.25 times the area of the principal peak in the chromatogram obtained with reference solution (0.25 per cent). The sum of areas of all the secondary peaks is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (0.5 per cent).

Chlorides (2.3.12). Dissolve 0.25 g in a mixture of 1 ml of *2 M nitric acid* and 15 ml of *water*. The solution complies with the limit test for chlorides without further addition of *2 M nitric acid* (0.1 per cent).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Loss on drying (2.4.19). Not more than 0.5 per cent, determined on 1.0 g by drying in an oven at 105°.

Assay. Dissolve 0.2 g in 80 ml of *anhydrous glacial acetic acid*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (2.4.25). Carry out a blank titration.

1 ml of *0.1 M perchloric acid* is equivalent to 0.02663 g of $C_{14}H_{22}N_2O_3$.

Atenolol Tablets

Atenolol Tablets contain not less than 92.5 per cent and not more than 107.5 per cent of the stated amount of atenolol, $C_{14}H_{22}N_2O_3$.

Usual strengths. 50 mg; 100 mg.

Identification

A. Heat a quantity of the powdered tablets containing about 0.1 g of Atenolol with 15 ml of *methanol* to 50°, shake for 5 minutes, filter (Whatman No. 42 paper is suitable) and evaporate the filtrate to dryness on a water-bath. Warm the residue with 10 ml of *0.1 M hydrochloric acid*, shake and filter. Add to the filtrate sufficient *1 M sodium hydroxide* to make it alkaline, extract with 10 ml of *chloroform*, dry by shaking with *anhydrous sodium sulphate*, filter, evaporate the filtrate to dryness on a water-bath and dry the residue at 105° for 1hour. The residue complies with the following test.

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

B. When examined in the range 230 nm to 360 nm (2.4.7), the solution obtained in the Assay shows absorption maxima at about 275 nm and 282 nm.

Tests

Dissolution (2.5.2).

Apparatus No. 2 (Paddle),
Medium. 900 ml of acetate buffer pH 4.6 prepared by mixing 45 volumes of *0.1M sodium acetate* and 55 volumes of *0.1M acetic acid*, adjusted to pH 4.6 with *dilute sodium hydroxide* or *dilute acetic acid*,
Speed and time. 50 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. Use the filtrate, dilute if necessary, with the mobile phase to obtain a solution containing 0.001 per cent w/v of Atenolol.

Reference solution. A 0.001 per cent w/v solution of *atenolol IPRS* in the mobile phase.

Chromatographic system
- a stainless steel column 30 cm × 3.9 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 70 volumes of a buffer solution prepared by dissolving 1.57 g *sodium1-heptanesulphonate* and 1.0 g of *anhydrous dibasic sodium phosphate* and 2.85 ml of *dibutylamine* in 700ml of *water*, adjusted to pH 3.0 with *0.8 M phosphoric acid*, diluted to 1000 ml with *water* and 30 volumes of *methanol*,
- flow rate: 0.6 ml per minute,
- spectrophotometer set at 226 nm,
- injection volume: 10 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 5000 theoretical plates, 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 $C_{14}H_{22}N_2O_3$ in the medium

Q. Not less than 80 per cent of the stated amount of $C_{14}H_{22}N_2O_3$.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Disperse a quantity of the powdered tablets containing 25 mg of Atenolol with 25 ml of the mobile phase and mix with the aid of ultrasound for 20 minutes, filter (Such as Whatman GF/C filter) and use the filtrate.

Reference solution (a). Dilute 1 volume of the test solution to 200 volumes with the mobile phase.

Reference solution (b). Dissolve 10 mg of *atenolol impurity standard IPRS* in 0.1 ml of *dimethyl sulphoxide* with the aid of gentle heat, dilute to 10 ml with the mobile phase and mix.

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane chemically bonded to porous silica or ceramic microparticles (5 µm),
- mobile phase: dissolve 0.8 g of *sodium octanesulphonate* and 0.4 g of *tetrabutylammonium hydrogen sulphate* in 1000 ml of a mixture of 20 volumes of *tetrahydrofuran*, 180 volumes of *methanol* and 800 volumes of a 0.34 per cent w/v solution of *potassium dihydrogen phosphate* and adjusted to pH 3.0 with *orthophosphoric acid*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 226 nm,
- injection volume: 20 µl.

Inject reference solution (b). The test is not valid unless the chromatogram obtained with reference solution (b) resembles the reference chromatogram supplied with the atenolol impurity standard RS in that the peak due to bis-ether precedes and is separated from that due to tertiary amine, which is normally a doublet. If necessary, adjust the concentration of sodium octanesulphonate in the mobile phase; if its concentration is increased, the retention time of the tertiary amine is prolonged.

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to 4-(2-hydroxy-3-isopropylamino-propoxy)phenylacetic acid (blocker acid) is not more than the area of the peak in the chromatogram obtained with reference solution (a) (0.5 per cent) and the area of any peak corresponding to either tertiary amine or bis-ether is not more than half the area of the peak in the chromatogram obtained with reference solution (a) (0.25 per cent).

Other tests. Comply with the tests stated under Tablets.

Assay. Weigh and powder 20 tablets. Disperse a quantity of the powder containing about 0.2 g of Atenolol, transfer to a 500-ml volumetric flask using 300 ml of *methanol*, heat the resulting suspension to 60° and shake for 15 minutes. Cool, dilute to 500.0 ml with *methanol*, filter through a fine glass micro-fibre filter paper (Whatman GF/C) and dilute a suitable volume of the filtrate with sufficient *methanol* to produce a solution containing 0.01 per cent w/v of Atenolol. Measure the absorbance of the resulting solution at the maximum at about 275 nm (2.4.7). Calculate the content of $C_{14}H_{22}N_2O_3$ taking 53.7 as the value of the specific absorbance at 275 nm.

Atenolol and Chlorthalidone Tablets

Atenolol and Chlorthalidone Tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of atenolol, $C_{14}H_{22}N_2O_3$ and not less than 92.5 per cent and not more than 107.5 per cent of the stated amount of chlorthalidone, $C_{14}H_{11}ClN_2O_4S$.

Usual Strengths. Atenolol, 25 mg and Chlorthalidone, 6.25 mg; Atenolol, 50 mg and Chlorthalidone, 12.5 mg; Atenolol, 100 mg and Chlorthalidone, 25 mg.

Identification

A. Determine by thin layer chromatography (2.4.17), using the plate coated with *silica gel GF254*.

Mobile phase. A mixture of 30 volumes of *18 M ammonia* and 150 volumes of *butan-1-ol*.

Test solution. Remove any film coating from the tablets. Disperse a quantity of the powdered tablets containing 0.1 g of Atenolol with 10.0 ml of *methanol* for 15 minutes and filter.

Reference solution (a). A 1.0 per cent w/v solution of *atenolol IPRS* in *methanol*.

Reference solution (b). A 0.25 per cent w/v solution of *chlorthalidone IPRS* in *methanol*.

Apply to the plate 5 µl of each solution. Allow the mobile phase to rise 15 cm. After development, dry the plate in a current of warm air and examine under ultraviolet light at 254 nm. The two principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution (a) and reference solution (b).

B. In the Assay, the principal peaks in the chromatogram obtained with test solution correspond the principal peaks in the chromatograms obtained with reference solution (c).

Tests

Dissolution (2.5.2).

Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.01 M hydrochloric acid*,
Speed and time. 50 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Solvent mixture. 100 volumes of *acetonitrile* and 3.2 volumes of 1.8 M *sulphuric acid*.

QUALITY CONTROL DEPARTMENT		KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED (A Government of India Enterprise)

User Requirement specifications

Material Description : HPLC COLUMN 30 cm x 3.9mm, C18, 5u

URS Number: QC/URS/016/0125

1. Description and Quantity:

Material Description	30cm x 3.9mm, C18, 5u
Item code	QSPHPL105
Quantity/ Box	2

2. User Specifications:

#	Requirement	Specification
1	Brand Name	30cm x 3.9mm,5u C18 bonded to porous silica
2	Matrix active group	Silica
3	Particle size	5u
4	Length (mm)	300
5	Internal Diameter (I.D.)	3.9 mm
6	Particle type	Base-Deactivated Silica
7	Particle Shape	Spherical
8	External Construction Materials	Stainless Steel
9	Endcapped	Yes
10	USP Classification	L1
11	Separation Mode	Reverse phase
12	P^H Range	2-8
13	Maximum Pressure	6000 psi (410 Bar)
14	Pore Size	100 °A