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

ENQUIRY REF. No.	KAPL/QAD/020/1990
DATE	06/12/2024
DUE DATE	10/12/2024 (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	QSPHPL476	15CMX3.9MM,C18,5U SYMMETRY C18	NOS	02

1)Please ensure that your offer reaches us on or before Due Date by courier OR speed post Or you can also mail us to our email: purenp@kaplindia.com
2) Please send your quotation mentioning item code

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 :
6. ATTACHED PAGES :

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

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

6/12

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT
MOB:9945317873

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtered solution, suitably diluted with the dissolution medium if necessary, at the maximum at about 239 nm (2.4.7). Calculate the content of $C_{20}H_{25}ClN_2O_5$ in the medium from the absorbance obtained from a solution of known concentration of *amlodipine besilate IPRS* in the same medium.

Q. Not less than 75 per cent of the stated amount of $C_{20}H_{25}ClN_2O_5$.

Related substances. Determine by liquid chromatography (2.4.14).

Test solution (a). Weigh and powder 20 tablets. Disperse a quantity of the powder containing 50 mg amlodipine, dissolve in the mobile phase, dilute to 50.0 ml with the mobile phase and centrifuge.

Test solution (b). Dilute 5.0 ml of test solution (a) to 100.0 ml with the mobile phase.

Reference solution (a). A solution of *amlodipine besilate IPRS* containing 0.005 per cent w/v of amlodipine in the mobile phase.

Reference solution (b). Dilute 5.0 ml of test solution (a) to 100.0 ml with the mobile phase. Dilute 5.0 ml of the solution to 50.0 ml with the mobile phase.

Reference solution (c). Dissolve 5 mg of *amlodipine besilate IPRS* in 5 ml of strong *hydrogen peroxide solution*. Heat at 70° for 45 minutes and centrifuge.

Chromatographic system

- a stainless steel column 15 cm x 3.9 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 15 volumes of *acetonitrile*, 35 volumes of *methanol* and 50 volumes of a solution prepared by dissolving 7.0 ml of *triethylamine* in 1000 ml of *water*, adjusted to pH 3.0 with *phosphoric acid*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 237 nm,
- injection volume: 10 µl.

The relative retention time between amlodipine and amlodipine impurity D (3-ethyl 5-methyl 2-[(2-aminoethoxy) methyl]-4-(2-chlorophenyl)-6-methylpyridine-3,5-dicarboxylate) is about 0.5.

Inject reference solution (c). The test is not valid unless the resolution between the peaks corresponding to amlodipine and impurity D is at least 4.5.

Inject test solution (a) and reference solution (b). Continue the chromatography for 3 times the retention time of amlodipine. The area of any peak corresponding to amlodipine impurity D multiplied by 2 is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent). The sum of the areas of all the other secondary peaks is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent). Ignore any peak due to benzene sulphonate (relative retention about 0.2) and any peak with an area 0.1 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 Related substances with the following modification.

Test solution. Disperse one tablet in the mobile phase and dilute with the mobile phase to obtain a solution containing 0.005 per cent w/v of Amlodipine. Filter through a glass fibre filter paper.

Inject reference solution (a) and the test solution.

Calculate the content of $C_{20}H_{25}ClN_2O_5$ in the tablet.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14) as described under Related substances.

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

Calculate the content of $C_{20}H_{25}ClN_2O_5$ in the tablets.

Storage. Store protected from moisture.

Labelling. The label states the strength in terms of the equivalent amount of amlodipine.

Amlodipine and Atenolol Tablets

Amlodipine Besylate and Atenolol Tablets; Amlodipine Besilate and Atenolol Tablets.

Amlodipine and Atenolol Tablets contain amlodipine besylate equivalent to not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of amlodipine, $C_{20}H_{25}ClN_2O_5$ and atenolol, $C_{14}H_{22}N_2O_3$.

Usual strengths. Amlodipine, 2.5 mg and Atenolol, 25 mg; Amlodipine, 2.5 mg and Atenolol, 50 mg; Amlodipine, 5 mg and Atenolol, 50 mg.

Identification

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

Tests

Dissolution (2.5.2).

Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.01 M hydrochloric acid*.

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

User Requirement specifications

Material Description : HPLC COLUMN 15 cm x 3.9mm, C18, 5u

URS Number: QC/URS/012/1024

1. Description and Quantity:

Material Description	15cm x 3.9mm, C18, 5u
Item code	QSPHPL476
Quantity/ Box	2

2. User Specifications:

#	Requirement	Specification
1	Brand Name	15cm x 3.9mm,5u, C18 bonded to porous silica
2	Make	WATERS
3	Brand	Symmetry C18
4	Cat. Number	WAT046980
5	Matrix active group	Silica
6	Particle size	5u
7	Length (mm)	150
8	Internal Diameter (I.D.)	3.9 mm
9	Particle type	Base-Deactivated Silica
10	Particle Shape	Spherical
11	External Construction Materials	Stainless Steel
12	Endcapped	Yes
13	USP Classification	L1
14	Separation Mode	Reverse phase
15	P^H Range	2-8
16	Maximum Pressure	6000 psi (410 Bar)
17	Pore Size	100 °A