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

ENQUIRY REF. No.	KAPL/QAD/020/1354
DATE	16/09/2024
DUE DATE	19/09/2024(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	QSPHPL428	HPLC COLUMN 30CM X3.9MM,10MIC,C18 BONDED TO SILICA	NOS	02

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.

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 : PLEASE SPECIFY

NOTE: IN CASE YOU ARE NOT QUOTING PLEASE SEND THE REGRET LETTER.
NOTE: PLEASE MENTION OUR CODE IN YOUR QUOATION

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT

User Requirement specifications

Material Description : HPLC COLUMN 30 cm x 3.9mm, C18, 10u

URS Number: QC/URS/010/0924

1. Description and Quantity:

Material Description	30cm x 3.9mm, C18, 10u
Item code	QSPHPL428
Quantity/ Box	2

2. User Specifications:

#	Requirement	Specification
1	Brand Name	30cm x 3.9mm,10u C18 bonded to porous silica
2	Matrix active group	Silica
3	Particle size	10u
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

sulphonic acid sodium salt and 0.5 g of *sodium chloride* in 900 ml of *water*, adjusted to pH 3.8 with *0.06 M orthophosphoric acid* and dilute to 1000 ml with *water* and 10 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 218 nm,
- injection volume: 10 µl.

Name	Relative retention time
Metformin related compound B[1]	0.86
Metformin (Retention time: about 10 minutes)	1.0
Metformin related compound C[2]	2.1-2.3

[1]1-Methylbiguanide hydrochloride,

[2]*N,N*-Dimethyl-[1,3,5]triazine-2,4,6-triamine.

NOTE — Metformin related compound C can have a variable retention time. The composition of the mobile phase may be changed to 5:95, if it elutes at a relative retention time of less than 2.1.

Inject reference solution (b). The test is not valid unless the resolution between the peaks due to metformin related compound B and metformin is not less than 1.5, the tailing factor is not more than 2.0 for metformin peak and the relative standard deviation for replicate injections is not more than 1.5 per cent for metformin peak and not more than 10 per cent for each of the peaks due to metformin related compound B and metformin related compound C.

Inject reference solution (a) and the test solution.

Calculate the content of $C_4H_{11}N_5,HCl$.

Metformin Tablets. Page 2878

Identification. B

Change **to**: B. 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 (a).

Assay. Change **to**:

Assay. Determine by liquid chromatography (2.4.14).

Solution A. 1.25 per cent v/v solution of *acetonitrile* in *water*.

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 100 mg of Metformin Hydrochloride, in 200 ml of 10 per cent v/v of *acetonitrile* in *water* with the aid of ultrasound with intermittent shaking and dilute to 500.0 ml with the same solvent. Dilute 25.0 ml of the solution to 200.0 ml with *water*.

Reference solution (a). A 0.0025 per cent w/v solution of *metformin hydrochloride IPRS* in solution A.

Reference solution (b). A solution containing 0.00125 per cent w/v, each of, *metformin related compound B IPRS* and *metformin related compound C IPRS* in solution A. Dilute 1.0 ml of the solution to 100.0 ml with reference solution (a).

Chromatographic system
- a stainless steel column 30 cm x 3.9 mm, packed with octadecylsilane bonded to porous silica (10 µm),
- mobile phase: a mixture of 90 volumes of a buffer solution prepared by dissolving 0.5 g of *1-heptane sulphonic acid sodium salt* and 0.5 g of *sodium chloride* in 900 ml of *water*, adjusted to pH 3.8 with *0.06 M orthophosphoric acid* and dilute to 1000 ml with *water* and 10 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 218 nm,
- injection volume: 10 µl.

Name	Relative retention time
Metformin related compound B[1]	0.86
Metformin (Retention time: about 10 minutes)	1.0
Metformin related compound C[2]	2.1-2.3

[1]1-Methylbiguanide hydrochloride,

[2]*N,N*-Dimethyl-[1,3,5]triazine-2,4,6-triamine.

NOTE — Metformin related compound C can have a variable retention time. The composition of the Mobile phase may be changed to 5:95, if it elutes at a relative retention time of less than 2.1.

Inject reference solution (b). The test is not valid unless the resolution between the peaks due to metformin related compound B and metformin is not less than 1.5, the tailing factor is not more than 2.0 for metformin peak and the relative standard deviation for replicate injections is not more than 1.5 per cent for metformin peak and not more than 10 per cent for each of the peaks due to metformin related compound B and metformin related compound C.

Inject reference solution (a) and the test solution.

Calculate the content of $C_4H_{11}N_5,HCl$.

Methylparaben. Page 2897

Change **to**:

Methylparaben

Methyl Hydroxybenzoate

This monograph has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia.

Portions of the IP text that and are not part of the PDG harmonized text, are marked with symbols (♦♦).