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

ENQUIRY REF. No.	KAPL/QAD/020/2264
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	QSPHPL415	HPLC COLUMN 15CMX4.6MM,ODS,5u(X-TERRA RP 18)	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 : QSPDRES
6. ATTACHMENT

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

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT
MOB:9945317873

Capsules. Page 1297

Soft Gelatin Capsules

Disintegration. Line 5

Change **from**: 60 minutes

to: 30 minutes

NOTE — This change shall be applicable for all soft gelatin capsules including any three or more components of vitamins, minerals, amino acids, fatty acids, trace elements etc.

Abacavir Sulphate. Page 1355

Specific optical rotation. Delete the requirement.

Insert before **Heavy metals**

Enantiomeric purity. Determine by liquid chromatography (2.4.14).

Solvent mixture. A 0.5 per cent v/v solution of *trifluoroacetic acid* in *methanol.*

Test solution. Dissolve 4 mg of the substance under examination in 3 ml of the solvent mixture, with the aid of ultrasound, add 3 ml of *2-propanol*, mix and dilute to 10.0 ml with *heptane.*

Reference solution. A solution containing 0.04 per cent w/v of *abacavir stereoisomers mixture IPRS* in the solvent mixture (30 per cent of the final volume) and disperse with the aid of ultrasound. Add *2-propanol* (30 per cent of the final volume), mix and dilute to volume with *heptane.*

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with amylose tris-3,5-dimethylphenylcarbamate coated to porous spherical silica particles (10 µm) (Such as Chiralpak AD),
- mobile phase: A. a mixture of 85 volumes of *heptane*, 15 volumes of *2-propanol* and 0.1 volume of *diethylamine*,
  B. a mixture of 50 volumes of *heptane* and 50 volumes of *2-propanol*,
- a gradient programme using the conditions given below,
- spectrophotometer set at 286 nm,
- injection volume: 20 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)	Flow rate (ml/min)
0	100	0	1.0
25	100	0	1.0
27	0	100	0.8
37	0	100	0.8
39	100	0	1.0
55	100	0	1.0

Name	Relative retention time
trans-abacavir[1]	0.8
Abacavir enantiomer	0.9
Abacavir	1.0

[1] {(1*R*,4*R*)-4-[2-Amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-cyclopent-2-enyl}methanol.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to *trans*-abacavir and abacavir enantiomer is not less than 1.0 and abacavir enantiomer and abacavir is not less than 1.5.

Inject the test solution. The area of any peak due to abacavir enantiomer is not more than 0.3 per cent, calculated by area normalization.

Water. Change **to**:

Water (2.3.43). Not more than 0.5 per cent, determined on 0.5 g.

Sulphated ash

Change **from**: 0.3 per cent.

to: 0.2 per cent.

Aceclofenac and Paracetamol Tablets N

Aceclofenac and Paracetamol Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of aceclofenac, $C_{16}H_{13}C_{12}NO_4$ and paracetamol, $C_8H_9NO_2$.

Usual strength. Aceclofenac 100 mg and Paracetamol 325 mg.

Identification

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

Tests

Dissolution (2.5.2).

Apparatus No. 2 (Paddle),

Medium. 900 ml of phosphate buffer pH 6.8, prepared by dissolving 6.8 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 6.8 with *dilute sodium hydroxide*,

Speed and time. 75 rpm and 45 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 dissolution medium.

Reference solution. Dissolve 11 mg of *aceclofenac IPRS* and 35 mg of *paracetamol IPRS* in 5 ml of *acetonitrile* and dilute to 100.0 ml with the dissolution medium.

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as X-Terra RP 18),
- mobile phase: A. a mixture of 90 volumes of *0.005 M disodium hydrogen phosphate*, adjusted to pH 8.0 with *dilute orthophosphoric acid*, 9 volumes of *acetonitrile* and 1 volume of *methanol*,

  B. a mixture of 90 volumes of *acetonitrile* and 10 volumes of *methanol*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 280 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	95	5
10	35	65
11	95	5
15	95	5

Inject the reference solution. The test is not valid unless the column efficiency is not less than 1500 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, for both the peaks.

Inject the reference solution and the test solution.

Calculate the content of $C_{16}H_{13}C_{12}NO_4$ and $C_8H_9NO_2$ in the medium.

Q. Not less than 70 per cent of the stated amount of $C_{16}H_{13}C_{12}NO_4$ and $C_8H_9NO_2$.

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. Equal volumes of *acetonitrile* and *water*.

Test solution. Disperse a quantity of the powdered tablets containing 325 mg of Paracetamol in the solvent mixture, with the aid of ultrasound for 10 minutes with intermittent shaking and dilute to 100.0 ml with the solvent mixture, filter.

Reference solution. A solution containing 0.01624 per cent w/v of *paracetamol IPRS* and 0.005 per cent w/v of *aceclofenac IPRS* in the solvent mixture. Dilute 1.0 ml of the solution to 10.0 ml with the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as Symmetry C18),
- column temperature: 40°,
- mobile phase: A. a buffer solution prepared by dissolving 1 g of *1-octane sulphonic acid sodium salt anhydrous* and 2 g of *sodium dihydrogen orthophosphate anhydrous* in 1000 ml of *water*, adjusted to pH 3.5 with *dilute orthophosphoric acid*,

  B. a mixture of 90 volumes of *acetonitrile* and 10 volumes of *water*,
- 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	95	5
3	95	5
8	80	20
42	20	80
50	20	80
52	95	5
60	95	5

Name	Relative retention time	Correction factor
Paracetamol	0.27	---
4-aminophenol	0.43	0.62
4-chloroacetanilide	0.69	1.52
Aceclofenac (Retention time: about 31 minutes)	1.0	---
Aceclofenac impurity A[1]	1.1	0.89

[1][2-[(2,6-dichlorophenyl)amino] phenyl]acetic acid.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 1500 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 5.0 per cent for both the peaks.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to aceclofenac impurity A is not more than 10 times the area of the aceclofenac peak in the chromatogram obtained with the reference solution (5.0 per cent), the area of any peak corresponding to 4-aminophenol is not more than 0.2 times the area of the paracetamol peak in the chromatogram obtained with the reference solution (0.1 per cent), the area of any peak corresponding to 4-chloroacetanilide is not more than 0.1 times the area of the paracetamol peak in the chromatogram obtained with the reference solution (0.05 per cent), the area of any other secondary peak is not more than the area of the aceclofenac peak in the chromatogram obtained with the reference

solution (0.5 per cent) and the sum of areas of all the secondary peaks, excluding aceclofenac impurity A is not more than 4 times the area of the aceclofenac peak in the chromatogram obtained with the reference solution (2.0 per cent).

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

NOTE — Use freshly prepared solutions.

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

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 325 mg of Paracetamol in 40 ml of *acetonitrile*, with the aid of ultrasound with intermittent shaking. Add 100 ml of the solvent mixture and sonicate for 15 minutes with intermittent shaking, dilute to 200.0 ml with the solvent mixture. Dilute 5.0 ml of the solution to 50.0 ml with the solvent mixture.

Reference solution (a). Dissolve 32.5 mg of *paracetamol IPRS* in 5 ml of *acetonitrile*, with the aid of ultrasound for 5 minutes and dilute to 20.0 ml with the solvent mixture.

Reference solution (b). Dissolve 25 mg of *aceclofenac IPRS* in 10 ml of *acetonitrile*, with the aid of ultrasound for 5 minutes and dilute to 50.0 ml with the solvent mixture.

Reference solution (c). Transfer 5.0 ml, each of, reference solution (a) and reference solution (b) to a 50- ml volumetric flask. Add 10 ml of *acetonitrile* and dilute to 50.0 ml with the solvent mixture.

Chromatographic system

- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as X-Terra RP 18),
- mobile phase: A. a mixture of 90 volumes of *0.005 M disodium hydrogen phosphate*, adjusted to pH 8.0 with *dilute orthophosphoric acid*, 9 volumes of *acetonitrile* and 1 volume of *methanol*,
  B. a mixture of 90 volumes of *acetonitrile* and 10 volumes of *methanol*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 280 nm,
- injection volume: 10 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	95	5
10	35	65
11	95	5
15	95	5

The elution order is paracetamol followed by aceclofenac peak.

Inject reference solution (c). The test is not valid unless the column efficiency is not less than 1500 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 5.0 per cent, for both the peaks.

Inject reference solution (c) and the test solution.

Calculate the content of $C_{16}H_{13}C_{12}NO_4$ and $C_8H_9NO_2$ in the tablets.

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

Alprazolam. Page 1402

Related substances. Change to:

Related substances. Determine by liquid chromatography (2.4.14).

NOTE—Use freshly prepared solution and carry out the test protected from light.

Solvent mixture. Equal volumes of *acetonitrile* and *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). A 0.0025 per cent w/v solution of *alprazolam IPRS* in the solvent mixture. Dilute 1.0 ml of the solution to 100.0 ml with the solvent mixture.

Reference solution (b). A solution containing 0.002 per cent w/v, each of, *alprazolam IPRS*, *alprazolam related compound A IPRS* and *2-amino-5-chlorobenzophenone IPRS* in the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as purospher star RP 18e),
- column temperature: 40°,
- mobile phase: a mixture of 50 volumes of *acetonitrile* and 50 volumes of a buffer solution prepared by dissolving 1.4 g of *monobasic potassium phosphate* in 1000 ml of *water*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 231 nm,
- injection volume: 20 µl.

Name	Relative retention time	Correction factor
Alprazolam related compound A[1]	0.8	1.32
Alprazolam	1.0	---
2-Amino-5- chloro benzophenone[2]	4.0	---

[1]2-(2-Acetylhydrazino)-7-chloro-5-phenyl-3*H*-1,4-benzodiazepine.

User Requirement specifications

Material Description : HPLC COLUMN 15cm x 4.6mm, ODS, 5u

URS Number: QC/URS/015/0125

1. Description and Quantity:

Material Description	15cm x 4.6mm, ODS, 5u
Item code	QSPHPL415
Quantity/ Box	2

2. User Specifications:

#	Requirement	Specification
1	Brand Name	15cm x 4.6mm, ODS, 5u (such as X-Terra RP 18)
2	Make	Waters
3	Brand	X-Terra
4	Part Number	186000492
5	Matrix active group	Silica
6	Particle size	5u
7	Length (mm)	150
8	Internal Diameter (I.D.)	4.6 mm
9	Particle Substrate	Hybrid
10	Particle Shape	Spherical
11	External Construction Materials	Stainless Steel
12	Endcapped	Yes
13	Endfitting Type	Waters
14	USP Classification	L1
15	Separation Mode	Reverse phase
16	P^H Range	2-12
17	Maximum Pressure	6000 psi (415 Bar)
18	Pore Size	125 °A