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

ENQUIRY REF. No.	KAPL/QAD/020/2305
DATE	31.01.2025
DUE DATE	05/02/2025 (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	QSPHPL218	25CMX4.6MM ENDCAPPED ODS AMOR ORGANO SILICA PORUS	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 :

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

User Requirement specifications

Material Description : HPLC COLUMN 25 cm x 4.6mm, 5u,End-capped octadecylsilyl amorphous organosilica polymer

URS Number: QC/URS/018/0125

1. Description and Quantity:

Material Description	25cm x 4.6mm, 5u , End-capped octadecylsilyl amorphous organosilica polymer
Item code	QSPHPL218
Quantity/ Box	2

2. User Specifications:

#	Requirement	Specification
1	Brand Name	25cm x 4.6mm,5u, End-capped C18 amorphous organosilica polymer
2	Make	WATERS
3	Brand	Xterra
4	Cat. Number	186000494
5	Matrix active group	MS C18
6	Particle size	5u
7	Length (mm)	250
8	Internal Diameter (I.D.)	4.6 mm
9	Particle type	End capped amorphous organosilica polymer
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	1-12
16	Maximum Pressure	6000 psi (415 Bar)
17	Pore Size	125 °A

[4]3′-*N*-demethyl-3′-*N*- formylazithromycin,
[5]14-demethyl-14-(hydroxymethyl)azithromycin,
[6]13-*O*-decladinosylazithromycin,
[7]3′-*N*-demethylazithromycin,
[8]3″-*O*-demethylazithromycin,
[9]3′-de(dimethylamino)-3′-oxoazithromycin,
[10]3′-*N*-[[4-(acetylamino)phenyl]sulfonyl]-3′-*N*-demethylazithromycin,
[11]6-demethylazithromycin,
[12]2-desethyl-2-propylazithromycin,
[13]3′-*N*-demethyl-3′-*N*-[(4-methylphenyl)sulfonyl]azithromycin,
[14]3-deoxyazithromycin.

Inject reference solution (b). The chromatogram obtained shows peaks corresponding to azithromycin and azithromycin impurity A. The test is not valid unless the resolution between these two peaks is at least 7.0.

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak eluting with an relative retention time of about 1.3 due to 3-deoxyazithromycin (azithromycin impurity B) is not more than twice the area of principal peak in the chromatogram obtained with reference solution (a) (2.0 per cent). The sum of the areas of all the other secondary peaks is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (a) (3.0 per cent). Ignore any peak with an area less than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent); ignore the peaks eluting before azithromycin impurity L and after azithromycin impurity B.

Other tests. Comply with the tests stated under Oral Liquids.

Assay. Determine by liquid chromatography (2.4.14).

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

Test solution. Weigh a quantity of the oral suspension containing about 0.1 g of Azithromycin, dissolve in the solvent mixture, dilute to 100.0 ml with the solvent mixture and filter.

Reference solution (a). A 0.1 per cent w/v solution of *azithromycin IPRS* in the solvent mixture.

Reference solution (b). A solution containing 0.01 per cent w/v of *azithromycin IPRS* and *6-demethyl-azithromycin IPRS (azithromycin impurity A IPRS)* in the solvent mixture.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with end capped polar embedded octadecylsilyl amorphous organosilica polymer (5µm) (Such as Waters Xterra),
- column temperature: 70°,
- mobile phase: a mixture of 10 volumes of a 3.484 per cent w/v solution of *dipotassium hydrogen phosphate*, previously adjusted to pH 6.5 with *orthophosphoric acid*, 35 volumes of *acetonitrile* and 55 volumes of *water*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 215 nm,
- injection volume: 100 µl.

Inject reference solution (b). The chromatogram obtained shows peaks corresponding to azithromcyin and azithromycin impurity A. The test is not valid unless the resolution between these two peaks is at least 7.0.

Inject reference solution (a) and the test solution.

Determine the weight per ml (2.4.29) of the suspension and calculate the content of $C_{38}H_{72}N_2O_{12}$, weight in volume.

Repeat the procedure using a portion of the constituted suspension that has been stored at the temperature and for the period stated on the label.

Azithromycin Tablets

Azithromycin Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of azithromycin, $C_{38}H_{72}N_2O_{12}$.

Usual strengths. 250 mg; 500 mg.

Identification

In the Assay, the retention time of 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 a buffer solution prepared by adding to 6 litres of *0.1 M dibasic sodium phosphate* about 40 ml of *hydrochloric acid*, adjusted to pH 6.0, adding 600 mg of *trypsin*, and mixing.
Speed and time. 100 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14) as described under Assay using the following solutions.

Test solution. Use the filtrate, dilute if necessary, with the mobile phase.

Reference solution. A solution of *azithromycin IPRS* in the dissolution medium suitably diluted with the mobile phase to obtain a solution having the same concentration as that of the test solution.

Inject the reference solution and the test solution.

Calculate the content of $C_{38}H_{72}N_2O_{12}$ in the medium.

Q. Not less than 75 per cent of the stated amount of $C_{38}H_{72}N_2O_{12}$.

Related substances. Determine by liquid chromatography (2.4.14).

NOTE — Prepare the solutions immediately before use.

Solvent mixture. Prepare a 0.173 per cent w/v solution of *ammonium dihydrogen phosphate* with the pH adjusted to 10.0 with *strong ammonia solution*. Transfer 350 ml of the solution add 300 ml of *acetonitrile* and 350 ml of *methanol*. Mix well.

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing about 0.2 g of Azithromycin, dissolve in the solvent mixture by shaking mechanically, dilute to 25.0 ml with the solvent mixture and filter.

Reference solution (a). A 0.008 per cent w/v solution of *azithromycin IPRS* in the solvent mixture.

Reference solution (b). A solution containing 0.01 per cent w/v of *azithromycin IPRS* and *azithromycin impurity A IPRS* in the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with end-cappped octadecylsilyl amorphous organosilica polymer for mass spectrometry (5 µm) (Such as Waters Xterra),
- column temperature: 60°,
- mobile phase: A. a 0.18 per cent w/v solution of *anhydrous disodium hydrogen phosphate*, adjusted to pH 8.9 with *dilute orthophosphoric acid* or with *dilute sodium hydroxide solution*,

  B. a mixture of 25 volumes of *methanol* and 75 volumes of *acetonitrile*,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 50 µl.

Time (in min.)	Mobile phase A (per cent v/v)	Mobile Phase B (per cent v/v)
0	50	50
25	45	55
30	40	60
80	25	75
81	50	50
93	50	50

Name	Relative retention time	Correction factor
Azithromycin impurity L[1]	0.29	2.3
Azithromycin impurity M[2]	0.37	0.6
Azithromycin impurity E[3]	0.43	—
Azithromycin impurity F[4]	0.51	0.3
Azithromycin impurity D[5]	0.54	—
Azithromycin impurity J[6]	0.54	—
Azithromycin impurity I[7]	0.61	—
Azithromycin impurity C[8]	0.73	—
Azithromycin impurity N[9]	0.76	0.7
Azithromycin impurity H[10]	0.79	0.1
Azithromycin impurity A[11]	0.83	—
Azithromycin impurity P	0.92	—
Azithromycin (Retention time: about 45-50 minutes)	1.0	—
Azithromycin impurity O[12]	1.23	—
Azithromycin impurity G[13]	1.26	0.2
Azithromycin impurity B[14]	1.31	—

[1]azithromycin 3′-*N*-oxide,

[2]3′-(*N*,*N*-didemethyl)-3′-*N*-formylazithromycin,

[3]aminoazithromycin,

[4]3′-*N*-demethyl-3′-*N*- formylazithromycin,

[5]14-demethyl-14- (hydroxymethyl)azithromycin,

[6]13-*O*-decladinosylazithromycin,

[7]3′-*N*-demethylazithromycin,

[8]3″-*O*-demethylazithromycin,

[9]3′-de(dimethylamino)-3′-oxoazithromycin,

[10]3′-*N*-[[4-(acetylamino)phenyl]sulfonyl]-3′-*N*-demethylazithromycin,

[11]6-demethylazithromycin,

[12]2-desethyl-2-propylazithromycin,

[13]3′-*N*-demethyl-3′-*N*-[(4-methylphenyl)sulfonyl]azithromycin,

[14]3-deoxyazithromycin.

Inject reference solution (b). The chromatogram obtained shows peaks corresponding to azithromycin and azithromycin impurity A. The test is not valid unless the resolution between these two peaks is at least 7.0

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak eluting with an relative retention time of about 1.3 due to azithromycin impurity B is not more than twice the area of principal peak in the chromatogram obtained with reference solution (a) (2.0 per cent). The sum of the areas of all the other secondary peaks is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (a) (3.0 per cent). Ignore any peak with

an area less than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent); ignore the peaks eluting before azithromycin impurity L and after azithromycin impurity B.

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

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 0.1 g of azithromycin, dissolve in the solvent mixture by shaking mechanically, dilute to 100 ml with the solvent mixture and filter.

Reference solution (a). A 0.1 per cent w/v solution of *azithromycin IPRS* in the solvent mixture.

Reference solution (b). A solution containing 0.01 per cent w/v of *azithromycin IPRS* and *azithromycin impurity A IPRS* in the solvent mixture.

Chromatographic system:

- a stainless steel column 25 cm x 4.6 mm, packed with end capped polar embedded octadecylsilyl amorphous organosilica polymer (5 µm) (Such as Waters Xterra),
- column temperature: 70°,
- mobile phase: a mixture of 10 volumes of a 3.484 per cent w/v solution of *dipotassium hydrogen phosphate*, adjusted to pH 6.5 with *orthophosphoric acid*, 35 volumes of *acetonitrile* and 55 volumes of *water*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 215 nm,
- injection volume: 100 µl.

Inject reference solution (b). The chromatogram obtained shows peaks corresponding to azithromcyin and azithromycin impurity A. The test is not valid unless the resolution between these two peaks is at least 7.0.

Inject reference solution (a) and the test solution.

Calculate the content of $C_{38}H_{72}N_2O_{12}$ in the tablets.