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

ENQUIRY REF. No.	KAPL/QAD/020/2554
DATE	06-03-2025
DUE DATE	13-03-2025 (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	QSPHPL320	HPLC COLUMN 25 CM X 4.6 MM, C8, 5 MICROMETER	NOS	2
02	QSPHPL105	30 CMX3.9MM C18 5 MICRON HPLC COLUMN	NOS	2

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 Antibiotics 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

Inject the reference solution. Repeat the procedure at least five times and measure the peak responses of the peak due to omeprazole. The relative standard deviation of the replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{17}H_{19}N_3O_3S$.

Storage. Store protected from light and moisture in a refrigerator (2° to 8°).

NOTE — A combination of elevated temperatures (37° to 50°) and high humidity degrades Omeprazole. It rapidly degrades under acidic conditions.

Omeprazole Gastro-resistant Capsules

Omeprazole Capsules

Omeprazole Gastro-resistant Capsules contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of omeprazole, $C_{17}H_{19}N_3O_3S$. They are made gastro-resistant by enteric-coating or by other means.

NOTE — Perform the tests and assay in subdued light and use low-actinic glassware.

Usual strength. 20 mg.

Identification

A. To a quantity of the contents of the capsules containing 50 mg of Omeprazole in a 100-ml volumetric flask add about 70 ml of *0.1 M sodium hydroxide*. Mix in an ultrasonic bath for about 5 minutes and heat on a water-bath for 10 minutes. Cool, make up to volume with *0.1 M sodium hydroxide* and filter. Dilute 2.0 ml of the filtrate to 100.0 ml with *0.1 M sodium hydroxide*.

When examined in the range 230 nm to 360 nm (2.4.7), the resulting solution shows absorption maxima at about 276 nm and 305 nm.

B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak due to omeprazole in the chromatogram obtained with the reference solution.

Tests

Dissolution (2.5.2).

A. Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.1 M hydrochloric acid*,
Speed and time. 100 rpm and 2 hours.

Determine by liquid chromatography (2.4.14).

Test solution. Withdraw the medium completely without any loss of residue. Transfer the residue into 100-ml volumetric flask, dissolve in 20 ml of *0.1M sodium hydroxide*, with the aid of ultrasound and make up the volume with *0.1M sodium hydroxide*. Centrifuge at about 3000 rpm for 10 minutes. Dilute 5.0 ml of the solution to 50.0 ml with the mobile phase.

Reference solution. A 0.02 per cent w/v solution of *omeprazole IPRS* in *0.1M sodium hydroxide*. Dilute 5.0 ml of the solution to 50.0 ml with the mobile phase.

Use chromatographic system as described under Assay.

Inject the reference solution and the test solution.

Calculate the content of $C_{17}H_{19}N_3O_3S$ released in the acid medium by subtracting the content of $C_{17}H_{19}N_3O_3S$ in the test solution from the total content of Omeprazole $C_{17}H_{19}N_3O_3S$ determined in the Assay.

Complies with the acceptance criteria given under acid stage.

B. Apparatus No. 2 (Paddle),
Medium. 900 ml of *phosphate buffer pH 6.8*,
Speed and time. 100 rpm and 45 minutes.

Transfer another 6 capsules and run the apparatus for 2 hours in *0.1 M hydrochloric acid*. Decant the medium without losing the residue, add phosphate buffer pH 6.8 and run the apparatus for 45 minutes. Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. To 5.0 ml of the filtrate, add immediately 1.0 ml of *0.1M sodium hydroxide*.

Reference solution. A 0.055 per cent w/v solution of *omeprazole IPRS* in *0.1M sodium hydroxide*. Dilute 2.0 ml of the solution to 50.0 ml with the dissolution medium. To 5.0 ml of the solution, add immediately 1.0 ml of *0.1M sodium hydroxide*.

Use chromatographic system as described under Assay.

Inject the reference solution and the test solution.

Calculate the content of $C_{17}H_{19}N_3O_3S$ in the medium.

Q. Not less than 70 per cent of the stated amount of $C_{17}H_{19}N_3O_3S$.

Other tests. Comply with the tests stated under Capsules.

Loss on drying (2.4.19). Not more than 3.0 per cent, determined on 0.5 g of the contents of the capsules by drying in an oven at 60° at a pressure not exceeding 0.7 kPa for 4 hours.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Mix the contents of 20 capsules. Weigh and transfer the granules containing about 20 mg of Omeprazole to a 100-ml volumetric flask, add 20 ml of *0.1 M sodium*

hydroxide, mix with the aid of ultrasound and dilute to volume with *0.1 M sodium hydroxide*. Centrifuge for 5 minutes and dilute 5.0 ml of the clear supernatant liquid to 50.0 ml with the mobile phase.

Reference solution. Take 20 mg of *omeprazole IPRS* in 100-ml volumetric flask, add 20.0 ml of *0.1 M sodium hydroxide*, shake vigorously for 5 minutes and dilute to volume with *0.1 M sodium hydroxide*. Dilute 5.0 ml of the solution with the mobile phase to produce 50.0 ml.

Chromatographic system

- a stainless steel column 30 cm x 3.9 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 65 volumes of *phosphate buffer pH 7.4* and 35 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 302 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the relative standard deviation of the replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{17}H_{19}N_3O_3S$ in the capsules.

Storage. Store protected from light and moisture.

Omeprazole and Domperidone Capsules

Omeprazole and Domperidone Capsules contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amounts of omeprazole $C_{17}H_{19}N_3O_3S$ and domperidone $C_{22}H_{24}ClN_5O_2$.

Usual strength. Domperidone, 10 mg and Omeprazole, 20 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 the reference solution.

Tests

Dissolution (2.5.2).

Domperidone —

Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.1 M hydrochloric acid*,
Speed and time. 100 rpm and 60 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 dissolution medium.

Reference solution. Weigh 20 mg of *domperidone IPRS*, transfer to a 200-ml volumetric flask, dissolve and dilute to volume with *methanol*. Dilute 2.0 ml of the solution to 20.0 ml with the dissolution medium.

Use chromatographic system as described under Assay.

Inject the reference solution. The test is not valid unless the relative standard deviation for replicate injections is not more than 2.0 per cent.

Q. Not less than 75 per cent of the stated amount of $C_{22}H_{24}ClN_5O_2$.

Omeprazole —

A. Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.1 M hydrochloric acid*,
Speed and time. 100 rpm and 2 hours.

Determine by liquid chromatography (2.4.14).

Test solution. Withdraw the medium completely without any loss of residue. Transfer the residue into 100-ml volumetric flask, dissolve in 20 ml of *0.1M sodium hydroxide*, with the aid of ultrasound and make up the volume with *0.1M sodium hydroxide*. Centrifuge at about 3000 rpm for 10 minutes. Dilute 5.0 ml of the solution to 50.0 ml with the mobile phase.

Reference solution. A 0.02 per cent w/v solution of *omeprazole IPRS* in *0.1M sodium hydroxide*. Dilute 5.0 ml of the solution to 50.0 ml with the mobile phase.

Use chromatographic system as described under Assay.

Inject the reference solution and the test solution.

Calculate the content of $C_{17}H_{19}N_3O_3S$ released in the acid medium by subtracting the content of $C_{17}H_{19}N_3O_3S$ in the test solution from the total content of Omeprazole $C_{17}H_{19}N_3O_3S$ determined in the Assay.

Complies with the acceptance criteria given under acid stage.

B. Apparatus No. 2 (Paddle),
Medium. 900 ml of *phosphate buffer pH 6.8*,
Speed and time. 100 rpm and 45 minutes.

Transfer another 6 capsules and run the apparatus for 2 hours in *0.1 M hydrochloric acid*. Decant the medium without losing the residue, add phosphate buffer pH 6.8 and run the apparatus for 45 minutes. Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. To 5.0 ml of the filtrate, add immediately 1.0 ml of *0.1M sodium hydroxide*.

Reference solution. A 0.055 per cent w/v solution of *omeprazole IPRS* in *0.1M sodium hydroxide*. Dilute 2.0 ml of

Assay. Dissolve 0.2 g in 50 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 0.03181 g of $C_{14}H_{10}Cl_2NNaO_2$.

Storage. Store protected from light.

Diclofenac Injection

Diclofenac Sodium Injection

Diclofenac Injection is a sterile solution of Diclofenac Sodium in Water for Injections. It may contain Propylene Glycol, Benzyl Alcohol and sufficient Sodium Hydroxide to adjust the pH of the solution.

Diclofenac Injection contains not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of diclofenac sodium, $C_{14}H_{10}Cl_2NNaO_2$.

Usual strength. 25 mg per ml.

Description. A clear, colourless to yellowish liquid.

Identification

Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel GF254*.

Mobile phase. A mixture of 90 volumes of *chloroform*, 5 volumes of *acetone* and 5 volumes of *formic acid* in a saturated chamber.

Test solution. Dilute a suitable volume of the injection containing 25 mg of Diclofenac Sodium to 10 ml with *methanol*.

Reference solution. A 0.25 per cent w/v solution of *diclofenac sodium IPRS* in *methanol*.

Apply to the plate 2 µl of each solution. After development, dry the plate in a current of warm air and examine under ultraviolet light at 254 nm. Alternatively, spray with a 0.5 per cent w/v solution of *potassium dichromate* in *sulphuric acid (20 per cent)*. By both methods of visualisation, the principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.

Tests

pH (2.4.24). 8.1 to 9.0.

Other tests. Comply with the tests stated under Parenteral Preparations (Injections).

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dilute a suitable volume of the injection containing 50 mg of Diclofenac Sodium to 100.0 ml with the mobile phase. Dilute 1.0 ml of the solution to 10.0 ml with the mobile phase.

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

Reference solution (b). A solution containing 0.0005 per cent w/v each of *diclofenac sodium IPRS* and *1-(2,6-dichlorophenyl)-1,3-dihydro-2H-indol-2-one IPRS (diclofenac impurity A IPRS)* in the mobile phase.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 34 volumes of a mixture of equal volumes of a 0.1 per cent w/v solution of *orthophosphoric acid* and a 0.16 per cent w/v solution of *sodium dihydrogen orthophosphate*, adjusted to pH 2.5, and 66 volumes of *methanol*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 10 µl.

Inject reference solution (b). The test is not valid unless the resolution between diclofenac and diclofenac impurity A is not less than 6.5.

Inject reference solution (a) and the test solution.

Calculate the content of $C_{14}H_{10}Cl_2NNaO_2$ in the injection.

Diclofenac Gastro-resistant Tablets

Diclofenac Tablets; Diclofenac Sodium Gastro-resistant Tablets; Diclofenac Sodium Tablets

Diclofenac Gastro-resistant Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of diclofenac sodium, $C_{14}H_{10}Cl_2NNaO_2$. They are made gastro-resistant by enteric-coating or by other means.

Usual strengths. 25 mg; 50 mg.

Identification

Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel 60 F254* or using a precoated *silica gel 60 F254* plate.

Mobile phase. A mixture of 100 volumes of *toluene*, 10 volumes of *hexane* and 10 volumes of *anhydrous formic acid*.

Test solution. Shake a quantity of the powdered tablets containing 50 mg of Diclofenac Sodium with 5 ml of *methanol*, centrifuge and use the supernatant liquid.

Reference solution. A 1 per cent w/v solution of *diclofenac sodium IPRS* in *methanol*.

User Requirement specifications

Material Description : HPLC COLUMN 25 cm x 4.6mm, 5u, OCTYLSILANE BONDED TO POROUS SILICA
URS Number: QC/URS/021/0325

1. Description and Quantity:

Material Description	25cm x 4.6mm, 5u ,packed with octylsilane bonded to porous silica
Item code	QSPHPL320
Quantity/ Box	2

2. User Specifications:

#	Requirement	Specification
1	Name	25cm x 4.6mm, 5u, packed with octylsilane bonded to porous silica
2	Matrix active group	Octylsilane (C8)
3	Particle size	5u
4	Length (mm)	250
5	Internal Diameter (I.D.)	4.6 mm
6	Particle type	Base-Deactivated Silica
7	Particle Shape	Spherical
8	External Construction Materials	Stainless Steel
9	Endcapped	Yes
10	USP Classification	L7
11	Separation Mode	Reverse phase
12	P^H Range	2-8
13	Maximum Pressure	6000 psi (410 Bar)
14	Pore Size	100 °A

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

User Requirement specifications

Material Description : HPLC COLUMN 30 cm x 3.9mm, 5u, ODS BONDED TO POROUS SILICA

URS Number: QC/URS/022/0325

1. Description and Quantity:

Material Description	30cm x 3.9mm, 5u ,packed with octadecylsilane bonded to porous silica
Item code	QSPHPL105
Quantity/ Box	2

2. User Specifications:

#	Requirement	Specification
1	Name	30cm x 3.9mm, 5u, packed with octadecylsilane bonded to porous silica
2	Matrix active group	Octadecylsilane (C18)
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