



**KARNATAKA ANTIBIOTICS &  
PHARMACEUTICALS LIMITED**

(A Government of India Enterprise)

ENQUIRY REF. No.	KAPL/QAD/020/0041
DATE	07.02.2025
DUE DATE	11/02/2025 (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	QSPHPL249	25CMX4.0MM,OCTADECYSILANE,POROUS SILICA 5.0µM	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 Antibiotics and Pharmaceuticals Limited Plot No.37, Arka The Business Centre ,NTTF Main Road, Peenya Industrial Area 2<sup>nd</sup> 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             | :                |
| 6. ATTACHED PAGES               | : 02 PAGES       |

**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

QUALITY CONTROL DEPARTMENT		KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED (A Government of India Enterprise)
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### User Requirement specifications

**Material Description :** HPLC COLUMN 25 cm x 4.0mm, 5 $\mu$ , ODS BONDED TO POROUS SILICA

#### 1. Description and Quantity:

Material Description	25cm x 4.0mm, 5 $\mu$ , packed with octadecylsilane bonded to porous silica
Item code	QSPHPL249
Quantity/ Box	2

#### 2. User Specifications:

#	Requirement	Specification
1	Name	25cm x 4.0mm, 5 $\mu$ m, packed with octadecylsilane bonded to porous silica
2	Matrix active group	Octadecylsilane (C18)
3	Particle size	5 $\mu$
4	Length (mm)	250
5	Internal Diameter (I.D.)	4.0 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	pH Range	2-8
13	Maximum Pressure	6000 psi (410 Bar)
14	Pore Size	100 $^{\circ}$ A

Inject reference solution (e). The test is not valid unless the resolution between two peaks corresponding to ranitidine impurity J and ranitidine hydrochloride is not less than 1.5.

Inject reference solution (a), (b), (c), (d) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than the area of principal peak in the chromatogram obtained with reference solution (a) (2.0 per cent); the area of not more than one secondary peak is more than the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent); the area of not more than two other secondary peaks is more than the area of the principal peak in the chromatogram obtained with reference solution (c) (0.5 per cent); the area of not more than two further secondary peaks is more than the area of the principal peak in the chromatogram obtained with reference solution (d) (0.2 per cent) and the sum of the areas of all the secondary peaks is not more than 2.5 times the areas of the principal peak in the chromatogram obtained with reference solution (a) (5.0 per cent). Ignore any peak with an area less than 0.25 times the area of the principal peak in the chromatogram obtained with reference solution (d) (0.05 per cent).

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

**Assay.** Determine by liquid chromatography (2.4.14)

**Test solution.** Dilute a volume of oral solution with the mobile phase to obtain a solution containing 0.0025 per cent w/v of ranitidine.

**Reference solution.** A 0.0028 per cent w/v solution of ranitidine hydrochloride IPRS in the mobile phase.

#### Chromatographic system

— a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),

— mobile phase: a mixture of 85 volumes of methanol and 15 volumes of buffer solution prepared by dissolving 7.71 gm of ammonium acetate in 200 ml of water, add 1 ml of acetic acid and dilute to 1000 ml with water.

— flow rate: 1 ml per minute,

— spectrophotometer set at 322 nm,

— injection volume: 10 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 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.

Inject the reference solution and the test solution.

Calculate the content of  $C_{13}H_{22}N_4O_3S$ .

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

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

## Ranitidine Tablets

### Ranitidine Hydrochloride Tablets

Ranitidine Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of the ranitidine,  $C_{13}H_{22}N_4O_3S$ . The tablets are coated.

**Usual strengths.** The equivalent of 150 mg, 300 mg of ranitidine (1.12 g of ranitidine hydrochloride is approximately equivalent to 1 g of ranitidine).

### Identification

A. Shake a quantity of the powdered tablets containing 25 mg of ranitidine with 5 ml of methanol for 5 minutes, filter and evaporate the filtrate to dryness. Add 1 ml of light petroleum (60° to 80°) to the resulting residue, scratch the side of the vessel with a glass rod to induce crystallisation, evaporate to dryness and dry the residue at 60° for 10 minutes. The residue complies with the following test.

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with ranitidine hydrochloride IPRS or with the reference spectrum of ranitidine hydrochloride.

B. In the Assay, 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 water,

Speed and time. 50 rpm for 45 minutes.

Withdraw a suitable volume of the medium and filter, rejecting the first few ml of filtrate. Dilute a suitable volume of the filtrate with the medium, if necessary. Measure the absorbance of the resulting solution at the maximum at about 314 nm (2.4.7). Calculate the content of ranitidine,  $C_{13}H_{22}N_4O_3S$  in the medium from the absorbance obtained from a solution of known concentration of Ranitidine hydrochloride IPRS in the dissolution medium.

Q. Not less than 80 per cent of the stated amount of  $C_{13}H_{22}N_4O_3S$ .

**Related substances.** Determine by liquid chromatography (2.4.14).

**Test solution.** Disperse a quantity of powdered tablets containing about 0.13 g of Ranitidine in 100.0 ml of water, filter.

**Reference solution (a).** Dilute 1.0 ml of the test solution to 200.0 ml with mobile phase A.

**Reference solution (b).** Dilute 1.0 ml of the test solution to 20.0 ml with mobile phase A. Dilute 3.0 ml of the solution to 50.0 ml with mobile phase A.

**Reference solution (c).** A solution containing 0.002 per cent w/v of ranitidine impurity J IPRS (1,1'-N-[methylenebis(sulphanediy-ethylene)]-bis(N'-methyl-2-nitroethene-1,1-diamine IPRS) in mobile phase A. Transfer 1.0 ml of the solution to a 100-ml volumetric flask containing 13 mg of ranitidine hydrochloride IPRS, add 40 ml of water, shake to dissolve and dilute to volume with water.

#### Chromatographic system

- a stainless steel column 10 cm x 4.6 mm, packed with octadecylsilane amorphous organosilica polymer (3.5 µm) (Such as Xterra MS C18),
- column temperature: 35°
- mobile phase: A. a mixture of 2 volumes of acetonitrile and 98 volumes of 0.05 M potassium dihydrogen orthophosphate, adjusted to pH 7.1 with sodium hydroxide solution,
- B. a mixture of 22 volumes of acetonitrile and 78 volumes of 0.05 M potassium dihydrogen orthophosphate, adjusted to pH 7.1 with sodium hydroxide solution,
- a gradient programme using the conditions given below,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 230 nm,
- injection volume: 20 µl.

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
10	0	100
15	0	100
16	100	0
20	100	0

Inject reference solution (c). The test is not valid unless the resolution between two principal peaks is not less than 1.5.

Inject reference solution (a), (b) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent). The area of not more than one secondary peak is more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent) and the area of not more than three other secondary peaks is more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent).

**Other tests.** Comply with the tests stated under Tablets.

**Assay.** Determine by liquid chromatography (2.4.14)

**Test solution.** Weigh and powder 20 tablets. Disperse a quantity of the powder containing 300 mg of Ranitidine with

80 ml of the mobile phase for 10 minutes and dilute to 100 ml with mobile phase, filter and dilute the filtrate with the mobile phase to obtain a solution containing the equivalent of 0.01 per cent w/v of ranitidine.

**Reference solution.** A 0.0112 per cent w/v solution of ranitidine hydrochloride IPRS in the mobile phase.

#### Chromatographic system

- a stainless steel column 25 cm x 4.0 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 85 volumes of methanol and 15 volumes of 0.1 M ammonium acetate,
- flow rate: 2 ml per minute,
- spectrophotometer set at 322 nm,
- injection volume: 20 µl.

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.

Inject the reference solution and the test solution.

Calculate the content of  $C_{13}H_{22}N_4O_3S$  in the tablets.

**Storage.** Store protected from light and moisture.

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

## Purified Rayon

Viscose Fibre; Absorbent Viscose

**Category.** Regenerated cellulose used in surgical dressings.

**Description.** White or very slightly yellow, purified rayon is a fibrous form of bleached regenerated cellulose, which can be produced with a lustrous or matt appearance, and is soft to the touch. The fibres can be produced with average staple length between 32 mm to 80 mm.

#### Identification

A. When examined under a microscope in the dry state, or when mounted in ethanol (95 per cent) and water, the following characteristics are observed. They are usually of more or less uniform width. Many longitudinal parallel lines are distributed unequally over the width in the case of standard viscose fibres, but such lines are absent or very few in fibres produced through the zinc-free process. The ends are cut more or less straight. Matt fibres contain numerous granular particles of approximately 1 µ average diameter.

B. Treat with iodinated zinc chloride solution; the fibres become violet.

C. To 0.1 g add 10 ml of zinc chloride-formic acid solution, heat to 40° and allow to stand for 2 hours 30 minutes, shaking occasionally. The fibres dissolve completely except for the matt variety where titanium dioxide particles remain.