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

| | |
|---|---|
| ENQUIRY REF. No. | KAPL/QAD/020/2421 |
| DATE | 14.02.2025 |
| DUE DATE | 21/02/2025 (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 | QSPHPL352 | 12.5CMX4.6MM 5Um ODS BONDED POROUS SILICA,C18 | NOS | 02 |
| 02 | QSPHPL208 | ENDCAPPED ODS -15CMX4.6MM,ODS 5Um,c18 | 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

Determine the weight per ml (2.4.29) of the oral suspension and calculate the content of $C_{16}H_{15}N_5O_7S_2$ weight in volume.

Repeat the procedure using a portion of the constituted suspension that has been stored at a temperature not exceeding 30°, for the period stated on the label. Calculate the content of $C_{16}H_{15}N_5O_7S_2$ weight in volume.

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

**Labelling.** The label states (1) the quantity of active ingredient in terms of the equivalent amount of cefixime; (2) the temperature of storage and the period during which the constituted suspension may be expected to be satisfactory for use.

## Cefixime Dispersible Tablets

Cefixime Dispersible Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of cefixime, $C_{16}H_{15}N_5O_7S_2$.

**Usual strengths.** The equivalent of 50 mg ,100 mg and 200 mg of cefixime.

### Identification

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).

### Tests

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

**Water** (2.3.43). Not more than 10.0 per cent.

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

*Phosphate buffer pH 7.0.* Dissolve 7.1 g *anhydrous dibasic sodium phosphate* in *water* and dilute to 500 ml with *water*. Adjust the pH of the solution to 7.0 with *monobasic potassium phosphate solution*.

*Monobasic potassium phosphate solution.* Dissolve 6.8 g of *monobasic potassium phosphate* in *water* and dilute to 500 ml with *water*.

*Test solution.* Weigh and powder 20 tablets. Disperse a quantity of the powder containing about 0.4 g of Cefixime, disperse in 100.0 ml of *phosphate buffer pH 7.0*, mix with the aid of ultrasound and centrifuge. Dilute 5.0 ml of the clear supernatant to 100.0 ml with *phosphate buffer pH 7.0*.

*Reference solution (a).* A 0.022 per cent w/v solution of *cefixime IPRS* in *phosphate buffer pH 7.0*.

*Reference solution (b).* Dissolve 10 mg of *cefixime IPRS* in 10 ml of *water*. Heat the solution at 95° for 45 minutes. Cool and inject immediately.

Chromatographic system

- a stainless steel column 12.5 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- column temperature: 40°,
- mobile phase: a mixture of 30 volumes of *tetrabutylammonium hydroxide solution* prepared by diluting 25 ml of *0.4 M tetrabutylammonium hydroxide solution* to 1000 ml with *water*, adjusted to pH 6.5 with *dilute orthophosphoric acid*, and 10 volumes of *acetonitrile*,
- flow rate adjusted so that the retention time of cefixime is about 10 minutes,
- spectrophotometer set at 254 nm,
- injection volume: 10 µl.

Inject reference solution (b).The relative retention times are about 0.9 for cefixime *E*-isomer and 1.0 for cefixime and the resolution between cefixime and cefixime *E*-isomer is not less than 2.0.

Inject reference solution (a). The column efficiency is not less than 2000 theoretical plates, the tailing factor is not less than 0.9 and not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject reference solution (a) and the test solution.

Calculate the content of $C_{16}H_{15}N_5O_7S_2$ in the tablets.

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

**Labelling.** The label states (1) the strength in terms of the equivalent amount of cefixime; (2) that the tablets should be dispersed in *water* immediately before use.

## Cefixime Tablets

Cefixime Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of cefixime, $C_{16}H_{15}N_5O_7S_2$.

**Usual strengths.** 50 mg; 100 mg; 200 mg.

### Identification

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 (a).

### Tests

**Dissolution** (2.5.2).

Apparatus No. 1 (Basket),

Medium. 900 ml of *0.05 M potassium phosphate buffer pH 7.2*, prepared by dissolving 6.8 g of *monobasic potassium*

*...hate* in 1000 ml of *water*, adjusted to pH 7.2 with *...sodium hydroxide*,

*...peed* and time. 100 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtered solution, suitably diluted with the medium if necessary, at the maximum at about 288 nm (2.4.7). Calculate the content of $C_{16}H_{15}N_5O_7S_2$ in the medium from the absorbance obtained from a solution of known concentration of *cefixime IPRS* in the same medium.

*NOTE — A small amount of methanol not exceeding 0.1 per cent of the total volume may be used to dissolve cefixime and the solution may be mixed with the aid of ultrasound to assure complete dissolution.*

Q. Not less than 75 per cent of the stated amount of $C_{16}H_{15}N_5O_7S_2$.

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

**Water** (2.3.43). Not more than 10.0 per cent, determined on 0.5 g.

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

*Phosphate buffer pH 7.0.* Dissolve 7.1 g *dibasic sodium phosphate* in *water* and dilute to 500 ml with *water*. Adjust the pH of the solution to 7.0 with *monobasic potassium phosphate solution*.

*Monobasic potassium phosphate solution.* Dissolve 6.8 g of *monobasic potassium phosphate* in *water* and dilute to 500 ml with *water*.

*Test solution.* Weigh and powder 20 tablets. Disperse a quantity of the powder containing about 0.4 g of cefixime, disperse in 100.0 ml of *phosphate buffer pH 7.0*, mix with the aid of ultrasound and centrifuge. Dilute 5.0 ml of the clear supernatant to 100.0 ml with *phosphate buffer pH 7.0*.

*Reference solution (a).* A 0.02 per cent w/v solution of *cefixime IPRS* in *phosphate buffer pH 7.0*.

*Reference solution (b).* Dissolve 10 mg of *cefixime IPRS* in 10 ml of *water*. Heat the solution at 95° for 45 minutes. Cool and inject immediately.

Chromatographic system

- a stainless steel column 12.5 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5µm),
- column temperature: 40°,
- mobile phase: a mixture of 30 volumes of *tetrabutylammonium hydroxide solution* prepared by diluting 25 ml of *0.4 M tetrabutylammonium hydroxide solution* to 1000 ml with *water* and adjusted to pH 6.5 with *1.5 M orthophosphoric acid*, and 10 volumes of *acetonitrile*,
- flow rate adjusted so that the retention time of cefixime is about 10 minutes,
- spectrophotometer set at 254 nm,
- injection volume: 10 µl.

Inject reference solution (b).The relative retention times are about 0.9 for cefixime *E*-isomer and 1.0 for cefixime and the resolution between cefixime and cefixime *E*-isomer is not less than 2.0.

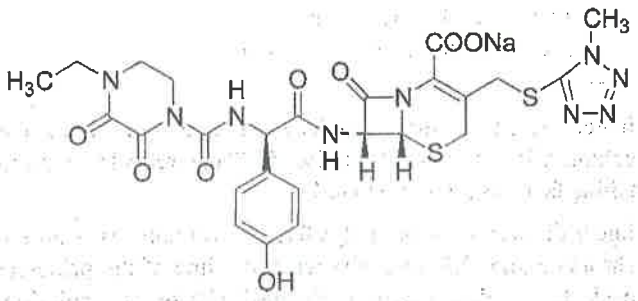
Inject reference solution (a). The column efficiency is not less than 2000 theoretical plates, the tailing factor is not less than 0.9 and not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject reference solution (a) and the test solution.

Calculate the content of $C_{16}H_{15}N_5O_7S_2$ in the tablets.

**Storage.** Store protected from moisture.

# Cefoperazone Sodium



$C_{25}H_{26}N_9NaO_8S_2$ Mol Wt. 667.7

Cefoperazone sodium is sodium salt of 7-D-(-)-α-(4-ethyl-2,3-dioxo-1-piperazinecarboxamido)-α-(4-hydroxyphenyl) acetamido-3-[(1-methyl-1*H*-tetrazol-5-yl)thio]methyl -3-cephem-4-carboxylic acid.

Cefoperazone Sodium contains not less than 95.0 per cent and not more than 102.0 per cent of $C_{25}H_{26}N_9NaO_8S_2$, calculated on the anhydrous and solvent-free basis.

**Category.** Antibacterial.

**Description.** A white or almost white crystalline powder.

## Identification

A. 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.

B. Gives the reactions of sodium salts (2.3.1).

## Tests

**pH** (2.4.24). 4.5 to 6.5, determined in a 25.0 per cent w/v solution.

the spectrum with that obtained with *diclofenac sodium IPRS* treated in the same manner or with the reference spectrum of diclofenac.

### Tests

**Dissolution** (2.5.2). Complies with the test stated under Tablets.

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

*Test solution.* Disperse a quantity of the powdered tablets containing 50 mg of Diclofenac Sodium with 70 ml of the mobile phase with the aid of ultrasound for 30 minutes and dilute to 100.0 ml with the mobile phase, centrifuge and filter.

*Reference solution (a).* A 0.0001 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 *diclofenac impurity A (1-(2,6-dichlorophenyl)-1,3-dihydro-2H-indol-2-one) 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 solution containing a mixture of equal volumes of 0.1 per cent w/v of *orthophosphoric acid* and 0.16 per cent w/v of *sodium dihydrogen orthophosphate dihydrate*, adjusted to pH 2.5 and 66 volumes of *methanol*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 20 µl.

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

Inject reference solution (a) and the test solution. Run the chromatogram 1.5 times the retention time of the principal peak. 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) (0.2 per cent) and sum of areas of all the secondary peaks is not more than 2.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 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 (a) (0.05 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 0.5 g of Diclofenac Sodium in *methanol* with the aid of ultrasound and dilute with the mobile phase to obtain 0.005 per cent w/v of diclofenac sodium.

*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 *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 20 volumes of equal volumes of 0.1 per cent w/v solution of *orthophosphoric acid* and 0.16 per cent w/v solution of *sodium dihydrogen orthophosphate dihydrate*, adjusted to pH 2.5 and 80 volumes of *methanol*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 20 µl.

Inject reference solution (b). The test is not valid unless the resolution between diclofenac and diclofenac impurity A is not less than 2.0.

Inject reference solution (a) and the test solution.

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

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

## Diclofenac Sodium and Paracetamol Tablets

Diclofenac Sodium and Paracetamol Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of diclofenac sodium $C_{14}H_{10}Cl_2NNaO_2$ and paracetamol $C_8H_9NO_2$.

**Usual strength.** Diclofenac sodium 50 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 the reference solution.

### Tests

**Dissolution** (2.5.2).
Apparatus No. 2 (Paddle),
Medium. 900 ml of *phosphate buffer pH 6.8*,
Speed and time. 100 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 mobile phase to obtain a solution having similar concentration to the reference solution.

*ence solution.* A solution containing 0.0032 per cent w/v *paracetamol IPRS* and 0.0005 per cent w/v of *diclofenac sodium IPRS* in the mobile phase.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 25 volumes of *water*, 75 volumes of *methanol* and 1.0 volume of *glacial acetic acid*,
- flow rate: 1.3 ml per minute,
- spectrophotometer set at 280 nm,
- injection volume: 20 µl.

Inject the reference solution and the test solution.

Calculate the content of $C_{14}H_{10}Cl_2NNaO_2$ and $C_8H_9NO_2$ in the medium.

Q. Not less than 70 per cent of the stated amount of $C_{14}H_{10}Cl_2NNaO_2$ and $C_8H_9NO_2$.

**4-Aminophenol.** Determine by liquid chromatography (2.4.14).

*Solvent mixture A.* Dissolve 4.6 g of *tetrabutylammonium hydroxide (40 per cent)* in 1000 ml of *methanol.*

*Solvent mixture B.* A *0.05 M disodium hydrogen orthophosphate dodecahydrate solution* .

*Solvent mixture C.* A *0.05 M sodium dihydrogen orthophosphate dihydrate solution.*

*Test solution.* Disperse a quantity of powdered tablets containing 25 mg of paracetamol in 6.3 ml of solvent mixture A, with the aid of ultrasound for 10 minutes and dilute to 25.0 ml with a mixture of equal volumes of solvent mixture B and solvent mixture C.

*Reference solution.* A solution containing 0.00015 per cent w/v solution, each of *4-aminophenol IPRS* and *paracetamol 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),
- column temperature: 35°,
- mobile phase: a mixture of 325 volumes of solvent mixture A, 335 volumes of solvent mixture B and 340 volumes of solvent mixture C.
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 245 nm,
- injection volume: 20 µl.

The relative retention times are 0.75 for the peaks due to 4-aminophenol and 1.0 for paracetamol.

Inject the reference solution. The test is not valid unless the resolution between the two principal peaks is not less than 2.0.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak due to 4-aminophenol is not more than the area of the corresponding peak in the chromatogram obtained with reference solution (0.15 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 about 325 mg of Paracetamol to a 50-ml volumetric flask, add 30 ml of mobile phase and disperse with the aid of ultrasound for about 10 minutes, cool and dilute to 50.0 ml with the mobile phase, filter. Dilute 1.0 ml of the filtrate to 50.0 ml with the mobile phase.

*Reference solution.* A solution containing each of 0.013 per cent w/v of *paracetamol IPRS and* 0.002 per cent of *diclofenac sodium IPRS* in the mobile phase.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 25 volumes of *water*, 75 volumes of *methanol* and 1.0 volume of *glacial acetic acid*,
- flow rate: 1.3 ml per minute,
- spectrophotometer set at 280 nm,
- injection volume: 20 µl.

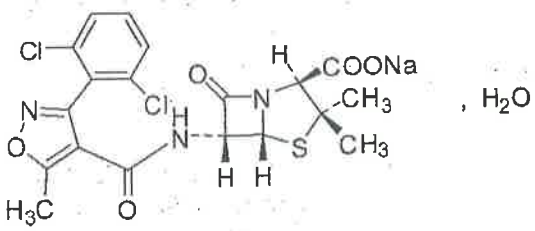
Inject the reference solution. The test is not valid unless the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{14}H_{10}Cl_2NNaO_2$ and $C_8H_9NO_2$ in the tablets.

**Storage.** Store protected from light and moisture at a temperature below 30°.

## Dicloxacillin Sodium




$C_{19}H_{16}Cl_2N_3NaO_5S,H_2O$ Mol. Wt. 510.3

Dicloxacillin Sodium is sodium (6*R*)-6-[3-(2,6-dichlorophenyl)-5-methylisoxazole-4-carboxamido] penicillanate monohydrate.

## er Requirement specifications

**Material Description :** HPLC COLUMN 12.5 cm x 4.6mm, 5u, ODS BONDED TO POROUS SILICA

**URS Number**: QC/URS/019/0125

### 1. Description and Quantity:

| | |
|---|---|
| Material Description | 12.5cm x 4.6mm, 5u , ODS bonded to porous silica |
| Item code | QSPHPL352 |
| Quantity/ Box | 2 |

### 2. User Specifications:

| # | Requirement | Specification |
|---|---|---|
| 1 | Name | 12.5cm x 4.6mm, 5u, packed with octadecylsilane bonded to porous silica |
| 2 | Matrix active group | Octadecylsilane (C18) |
| 3 | Particle size | 5u |
| 4 | Length (mm) | 125 |
| 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 | L1 |
| 11 | Separation Mode | Reverse phase |
| 12 | $P^H$ Range | 2-8 |
| 13 | Maximum Pressure | 6000 psi (410 Bar) |
| 14 | Pore Size | 100 °A |