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

ENQUIRY REF. No.	KAPL/QAD/020/0948
DATE	29/07/2024
DUE DATE	01/08/2024 (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	QSPHPL2401	SUPELCO DISCOVERY C18,25CMX4.6MM, 5MICROMETER (END CAPPED)	NOS	01

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: IN CASE YOU ARE NOT QUOTING PLEASE SEND THE REGRET LETTER.

Thanking you,

Yours faithfully,
For KARNATAKA ANTIBIOTICS
& PHARMACEUTICALS LIMITED

29/7

YUVARAJA M
DEPUTY MANAGER PURCHASE DEPT

All entries in this edition are legally effective

Amikacin Injection

General Notices

Action and use

Aminoglycoside antibacterial.

DEFINITION

Amikacin Injection is a sterile solution of *Amikacin* Sulfate in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of *amikacin*, $C_{22}H_{43}N_5O_{13}$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

In the test for Assay, the principal peak in the chromatogram obtained with solution (1) has the same retention time as that of the principal peak in the chromatogram obtained with solution (2).

Acidity

pH, 3.5 to 5.5, Appendix V L.

TESTS

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in *water*.

(1) Dilute a volume of the injection, if necessary, to produce a solution containing the equivalent of 1.0% w/v of *amikacin*.
(2) 0.013% w/v of *amikacin sulfate BPCRS*.
(3) 1.0% w/v of *amikacin for system suitability EPCRS*.
(4) Dilute 1 volume of solution (2) to 10 volumes.
(5) *Water* (blank solution).

Derivatise the solutions prior to analysis using the following method.

Transfer 0.2 mL of the solution being examined to a ground glass stoppered vial. Add 2 mL of a 1.0% w/v solution of *2,4,6-trinitrobenzenesulfonic acid*. To this solution add 3 mL of *pyridine* and close the vial tightly. Shake vigorously for 30 seconds and heat on a water bath at 75° for 2 hours. Cool in cold water for 2 minutes and add 2 mL of *glacial acetic acid*. Shake vigorously for 30 seconds. Store the derivatised solutions at 10° prior to and during analysis.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Spherisorb ODS 2 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use a column temperature of 30°.
(e) Use a detection wavelength of 340 nm.
(f) Inject 20 µL of each solution.
(g) For solution (1) allow the chromatography to proceed for 4 times the retention time of *amikacin*.

MOBILE PHASE

30 volumes of a 0.27% w/v solution of *potassium dihydrogen orthophosphate*, adjusted to pH 6.5 with a 2.2% w/v solution of *potassium hydroxide*, and 70 volumes of *methanol*.

When the chromatograms are recorded under the prescribed conditions the relative retention of *amikacin* impurity A with reference to that of *amikacin* (retention time, about 12 minutes), is about 1.5.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to *amikacin* and impurity A is at least 3.5.

LIMITS

In the chromatogram obtained with solution (1):

the area of any *secondary peak* is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (1.5%);

the sum of the areas of all secondary peaks is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (3%).

Disregard any peaks corresponding to the peaks in the chromatogram obtained with solution (5), any peak eluting before the principal peak, and any peak with an area of less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%).

Bacterial endotoxins

Carry out the *test for bacterial endotoxins*, Appendix XIV C. Dilute the injection, if necessary, with *water BET* to give a solution containing the equivalent of 10 mg per mL of *amikacin* (solution A). The endotoxin limit concentration of solution A is 3.3 IU of endotoxin per mL.

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in the mobile phase.

(1) Dilute a volume of the injection containing the equivalent of 37 mg of *amikacin* to 10 mL.
(2) 0.50% w/v of *amikacin sulfate BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Supelco Discovery C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use a column temperature of 40°.
(e) Use a detection wavelength of 200 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

0.18% w/v of *sodium octanesulfonate* and 2.00% w/v *anhydrous sodium sulfate* in a mixture of 68 volumes of *acetonitrile R1*, 40 volumes of 0.2M potassium dihydrogen phosphate adjusted to pH 3.0 with *dilute phosphoric acid*, and 936 volumes of *water*.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{43}N_5O_{13}$ in the injection using the declared content of $C_{22}H_{43}N_5O_{13},2H_2SO_4$ in *amikacin sulfate BPCRS*. Each mg of $C_{22}H_{43}N_5O_{13},2H_2SO_4$ is equivalent to 0.7488 mg of $C_{22}H_{43}N_5O_{13}$.

LABELLING

The strength is stated in terms of the equivalent amount of *amikacin* in a suitable dose-volume.

IMPURITIES