MAT/F/001

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

ENQUIRY REF.NO. : PRm/DRm/FD/
DATE : 20/5/22
DUE DATE : 23/5/22 till 14:00hrs

Dear Sir,

Please submit your lowest and competitive offer in a COURIER/POST I ONLINE DULY SUPERSCRIBING OUR ABOVE ENQUIRY REF NO, DATE AND DUE DATE on it with other details.

ITEM CODE	:	DRM00265
ITEM DESCRIPTION	:	ISOFLUPREDONE ACETATE IP
QUANTITY REQUIRED	:	1kg (Specification attached)
DELIVERY SCHEDULE	:	Immediate
MAKE	:	Any make
RATE	:	
F.O.R TERMS	:	DOOR DELIVERY PREFERRED
GST	:	
PACKING & FORWARDING CHARGES	:	
TAXES	:	
CREDIT PERIOD	:	90 DAYS REQUESTED
DELIVERY OFFERED	:	
PRICE VALIDITY	:	Should Be Valid For 07 Workingdays from due date
NAME OF MANUFACTURER	:	Please Indicate the Name
OTHER DETAILS	:	Age of the material should not be more than three months on the date of despatch.
NOTE		1.In case of Sterile Raw Materials. Please provide MINIATURE Sample for each canister along with the consignment.
		2.Incase you are not quoting please send a regret letter.
		3.The Material Should have minimum shelf life of ____months.

Please ensure that your offer reaches us on or before DUE DATE.

Thanking You

Yours faithfully

for **KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED.**

AUTHORISED SIGNATORY

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Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 0.5 g of the substance under examination in 10.0 ml of *water*.

Reference solution (a). Dissolve 0.5 g of *myo-inositol RS* in 10.0 ml of *water*.

Reference solution (b). Dilute 2.0 ml of test solution to 100.0 ml with *water* and dilute 5.0 ml of this solution to 100.0 ml with *water*.

Reference solution (c). Dissolve 0.5 g of *myo-inositol RS* and 0.5 g of *mannitol RS* in 10.0 ml of *water*.

Chromatographic system
- a stainless steel column 30 cm x 7.8 mm, packed with strong cation-exchange resin (calcium form) (9 µm),
- column temperature: 85°,
- mobile phase: *water*,
- flow rate: 0.5 ml per minute,
- refractometer at a constant temperature,
- injection volume: 20 µl.

Name	Relative retention time
myo-inositol impurity A[1]	1.3
myo-inositol impurity B[2]	1.4
myo-inositol (Retention time: about 17.5 minutes)	---

[1] D- mannitol,

[2] propane-1,2,3-triol (glycerol).

Inject reference solution (c). The test is not valid unless the resolution between the peaks due to *myo*-inositol impurity A and *myo*-inositol is not less than 4.0.

Inject reference solution (b) and the test solution. The area of the peak corresponding to each impurity A and B is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.3 per cent). The area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.1 per cent). The sum of the areas of the secondary peaks is not more than 10 times the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Barium. To 10 ml of solution A add 1.0 ml of dilute *sulphuric acid*. When examined after 1 hour, the solution is not more opalescent than a mixture of 1.0 ml of *distilled water* and 10.0 ml of solution A.

Lead (2.3.15). Not more than 0.5 ppm, determined by the following method.

Prepare the test solution by dissolving 20.0 g of the substance to be examined in 100 ml of *water*; heat if necessary, and dilute to 200.0 ml with *dilute acetic acid*.

Water (2.3.43). Not more than 0.5 per cent.

Assay. Determine by liquid chromatography (2.4.14) as described under Related substances.

Inject reference solution (a) and the test solution.

Calculate the content of $C_6H_{12}O_6$.

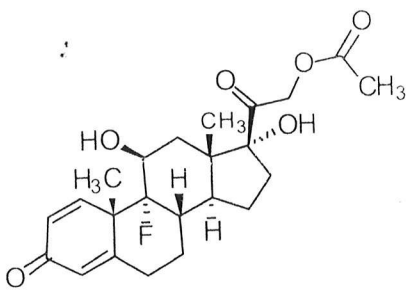
Iron Dextran Injection

Usual strengths. 250 mg per ml contains 50 mg elemental iron.

Dose. *All species*: 5 to 10 ml in large animals and 1 to 2 ml in small animals.

For Identification and Tests refer to IP Volume II.

Isoflupredone Acetate



$C_{23}H_{29}FO_6$ Mol Wt. 420.5

Isoflupredone Acetate is Pregna-1, 4-diene-3, 20-dione, 21-(acetyloxy)-9-fluoro-11, 17-dihydroxy-(11β)-.

9-Fluoro-11β, 17, 21-trihydroxypregna-1, 4-diene-3, 20-dione 21-acetate.

Isoflupredone Acetate contains not less than 97.0 per cent and not more than 103.0 per cent of $C_{23}H_{29}FO_6$, calculated on the dried basis.

Category. Antiinflammatory; immunosuppressive.

Description. A white to pale yellow crystalline powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *isoflupredone acetate RS* or with the reference spectrum of isoflupredone acetate.

B. The absorbance of a 0.00125 per cent w/v solution in *ethanol (95 per cent)* at 240 nm (2.4.7) is 0.440 to 0.480.

Tests

Specific optical rotation (2.4.22). +110° to +120°, determined in a 1.0 per cent w/v solution in *dioxane*.

Related substances. Determine by liquid chromatography (2.4.14).

Solution A. a mixture of 500 volumes of *water*, 350 volumes of *methanol*, 150 volumes of *acetonitrile* and 3 volumes of *glacial acetic acid*.

Solution B. a mixture of 500 volumes of *acetonitrile*, 500 volumes of *methanol* and 3 volumes of *water*.

Test solution. A 0.03 per cent w/v solution of substance under examination in solution A.

NOTE—Use this solution within same day.

Reference solution. Dissolve a quantity of *isoflupredone acetate RS* and *prednisolone acetate RS* in the Solution A by shaking and mixing if necessary, with the aid of ultrasound and dilute to obtain a solution of 0.003 per cent of each.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica particles (1.5 to 10 µm),
- mobile phase: a mixture of Solution A and B,
- a gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 50 µl.

Time (in min.)	Solution A (per cent v/v)	Solution B (per cent v/v)
0	100	0
32.5	100	0
47.5	0	100
50.5	0	100
51.5	100	0
61.5	100	0

Inject the reference solution. The test is not valid unless the resolution between the peaks due to isoflupredone acetate and prednisolone acetate is not less than 1.2 and the column efficiency determined from isoflupredone is not less than 6000 theoretical plates. The retention time for isoflupredone acetate is between 21 and 26 minutes and the relative retention time for prednisolone acetate is 1.1 and for isoflupredone acetate is 1.0.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than 0.1 times the area of the principle peak in the chromatogram obtained with reference solution (1.0 per cent). The sum of areas of all the secondary peaks is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (2.0 per cent). Ignore any peak the area is 0.005 times the area of the principle peak in the chromatogram obtained with the reference solution (0.05 per cent).

Sulphated ash (2.3.18). Not more than 0.5 per cent.

Loss on drying (2.4.19). Not more than 1.0 per cent, determined on 1.0 g by drying in an oven at 105° for 4 hours.

Assay. Determine by liquid chromatography (2.4.14).

Internal Standard Solution. Dissolve a quantity of *fluoxymesterone* in *water-saturated chloroform* to obtain a solution having a known concentration of about 0.9 mg per ml.

Test solution. Dissolve 4 mg of substance under examination in 8.0 ml of internal standard solution and 32.0 ml of *water-saturated chloroform*, centrifuge and use the clear chloroform portion.

Reference solution. Dissolve 4 mg of *isoflupredone acetate RS* in 8.0 ml of internal standard solution and 32.0 ml of *water-saturated chloroform*.

Chromatographic system

- a stainless steel column 30 cm x 4.0 mm, packed with octadecylsilane bonded to porous micro silica particles (1.5 to 10 µm),
- mobile phase: a mixture of 475 volumes of *n-butyl chloride*, 475 volumes of *water-saturated n-butyl chloride*, 70 volumes of *tetrahydrofuran*, 35 volumes of *methanol* and 30 volumes of *glacial acetic acid*,
- flow rate: 0.7 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 12 µl.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to isoflupredone acetate and fluoxymesterone is not less than 2.0, and the relative standard deviation for the replicate injection is not more than 2.0 per cent. The relative retention time for isoflupredone acetate is 1.0 and for fluoxymesterone is 1.2.

Inject the reference solution and the test solution.

Calculate the content of $C_{23}H_{29}FO_6$.

Isoflupredone Acetate intended for use in the manufacture of parenteral preparations without a further appropriate procedure for removal of bacterial endotoxin complies with the following additional requirements.

Bacterial endotoxins (2.2.3). Not more than 125 Endotoxin units per mg of isoflupredone acetate.

Isoflupredone Acetate intended for use in the manufacture of parenteral preparations without a further appropriate sterilization procedure complies with the following additional requirements.

Sterility (2.2.11). Complies with the test for sterility.

Storage. Store protected from light.