


**KARNATAKA ANTIBIOTICS &
PHARMACEUTICALS LIMITED**

(A Government of India Enterprise)

ENQUIRY REF. NO. : PRM/FN/121/1056
 DATE : 09/8/24
 DUE DATE : 12/8/24 (23:59 hrs)

Dear Sir,

Please submit your lowest and competitive offer in our tender wizard (www.tenderwizard.com/KAPL)
 SUPERSUBSCRIBING OUR ABOVE ENQUIRY REF.NO. DATE AND DUE DATE on it, with other details.

ITEM CODE : 1PR1196
 ITEM DESCRIPTION : Fluconazole IP (Compacted)
 QUANTITY REQUIRED : 400 Kgs
 DELIVERY SCHEDULE : within a week from the date of PO.
 MAKE : Virupaksha, Granules. [Specification Enclosed]
 RATE :
 F.O.R. TERMS : DOOR DELIVERY PREFERRED
 GST : PLEASE SPECIFY
 TYPE OF PACKING : DRUM / CANISTER ONLY
 CREDIT PERIOD : 90 DAYS REQUESTED
 DELIVERY OFFERED :
 PRICE VALIDITY : Should Be Valid For 07 Working Days 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.
 1. In case of Sterile Raw Materials. Please provide MINIATURE Sample for each canister along with the consignment.
 2. In case you are not quoting please send a regret letter.
 3. The Material should have minimum shelf life ofMonths

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

Thanking You,

Yours faithfully

for **KARNATAKA ANTIBIOTICS &
PHARMACEUTICALS LIMITED**

AUTHORISED SIGNATORY

Corporate Office : Arka The Business Centre, Plot No. 37, Site No. 34/4, NTT Main Road, 2nd Phase, Peenya Industrial Area, BENGALURU - 560058. INDIA Phone : (080) 2357 1590

Factory : Plot No. 14, 2nd Phase, Peenya Industrial Area, BENGALURU - 560 058., INDIA
 Ph : +91 (80) 2839 5186 / 87 /88 Dir. : +91 (80) 2839 4669 Email : purchase@kaplindia.com

KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED, BENGALURU



**FORMULATION
DEVELOPMENT**

| | |
|--------------------------|----------------------------|
| Specification No. | FD/API/1PR1158/001/0824/V1 |
| Compendia | IP 2022/IH |
| Review Date | 07 AUG 2027 |


ACTIVE PHARMACEUTICAL INGREDIENT SPECIFICATION

| | | | |
|------------------|---------|-------------------------------------|-------------|
| ITEM CODE | 1PR1196 | FLUCONAZOLE I.P. (COMPACTED) | Page 1 of 2 |
|------------------|---------|-------------------------------------|-------------|

| # | Tests | Specifications | |
|-----|---------------------------------------|---|--|
| 1. | Description | White to almost white, crystalline powder | |
| 2. | Solubility | Practically insoluble in water (0.001 mg/ml). Sparingly soluble in ethanol (20 mg/ml) and DMSO (33 mg/ml). | |
| 3. | Identification | | |
| | A | Infrared absorption spectrophotometry | Compare the spectrum with that obtained with Fluconazole IPRS or with reference spectrum of Fluconazole |
| | B | UV Spectroscopy | When examined in the range 200 nm to 350 nm, a 0.025% w/v solution in methanol shows absorption maximum at about 266 nm and 261 nm |
| 4. | Related substances by HPLC | | |
| | A | Impurity at RRT 0.6 | Not more than 1.0% |
| | B | Impurity A or Impurity C | Not more than 0.2% |
| | C | Impurity B | Not more than 0.1% |
| | D | Any secondary Impurity | Not more than 0.1% |
| | E | Sum of all secondary Impurity | Not more than 1.5% |
| 5. | Appearance of solution | A 5.0% w/v solution in methanol is clear and colorless | |
| 6. | Iron | Not more than 20 ppm | |
| 7. | Sulphated ash | Not more than 0.1% w/w | |
| 8. | Loss on Drying (@105° C for 3 hours) | Not more than 0.5% w/w | |
| 9. | Assay of Fluconazole (On dried basis) | Not less than 98.5% and Not more than 101.5% of C ₁₃ H ₁₂ F ₂ N ₆ O | |
| 10. | Particle Size (Sieve Analysis) | 20 / 30 (No material should retain on 20 # and Not more than 5 % material should pass through 30 #) | |
| 11. | Bulk Density (g/cm ³) | 0.60 to 0.70 | |

| Effective date | Prepared By | Reviewed By | Checked By | Approved By |
|----------------|------------------------|------------------------|------------------------|--------------------------------|
| 08 AUG 2024 | Akshay Analyst - FD | Shreeshail T AM- FD | Mahesha NC DGM - FD | ▲ Venkata Subbaiah DGM - QA |
| Signature/Date | 08/08/2024 | 08/08/2024 | 08/08/2024 | 08/08/2024 |

KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED, BENGALURU

| | | | |
|---|--------------------------------|-------------------|----------------------------|
|  | FORMULATION DEVELOPMENT | Specification No. | FD/API/1PR1158/001/0824/V1 |
| | | Compendia | IP 2022/IH |
| | | Review Date | 07 AUG 2027 |

ACTIVE PHARMACEUTICAL INGREDIENT SPECIFICATION

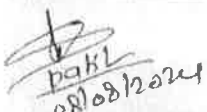
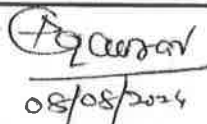
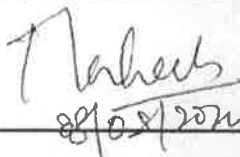
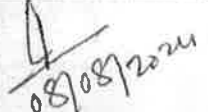
| | | | |
|-----------|---------|------------------------------|-------------|
| ITEM CODE | 1PR1196 | FLUCONAZOLE I.P. (COMPACTED) | Page 2 of 2 |
|-----------|---------|------------------------------|-------------|

Internal Specifications

| | | |
|-----|---------------------|---|
| 12. | Labelling | Each and every container/bag shall be labelled thus; |
| | a. | Name of the material Fluconazole I.P. (Compacted) |
| | b. | Batch number |
| | c. | Date of manufacture See 13 (a) below |
| | d. | Date of expiry 60 months from the date of manufacture |
| | e. | Actual gross, tare & net weights |
| | f. | Manufacturer/Supplier's name and address/country of origin. |
| 13. | Storage | Store protected from light and controlled room temperature |
| 14. | Re-test Date | Six months from the date of test. |

Delivery specifications

| | | |
|-----|----|--|
| 15. | a. | Age of the material shall not be more than three months old from the date of manufacture at the time of receipt at our Stores. |
| | b. | Material shall be sealed in double polythene bags, packed in rigid, undamaged airtight, light proof containers. |
| | c. | Net weight of each container shall not be more than 50 Kg. |
| | d. | Preferably one batch / lot per consignment. |
| | e. | The test report of each batch / lot shall accompany the consignment. |

| Effective date | Prepared By | Reviewed By | Checked By | Approved By |
|----------------|---|---|--|---|
| 08 AUG 2024 | Akshay Analyst - FD | Shreeshail T AM- FD | Mahesha NC DGM - FD | Venkata Subbaiah DGM - QA |
| Signature/Date |  08/08/2024 |  08/08/2024 |  08/08/2024 |  08/08/2024 |