FORM 37

(See Rule 150-C)

APPROVAL FOR CARRYING OUT TESTS ON DRUGS AND RAW MATERIALS USED IN THEIR MANUFACTURE ON BEHALF OF LICENCEES FOR MANUFACTURE FOR SALE OF DRUGS OR FOR AN INDIVIDUAL OR ORGANISATION OR PROCUREMENT AGENCY.

Number of approval and date of issue **KTK/37/84/2024,** dated **11.06.2024**

1. Approval is hereby granted to **M/S. EUROFINS BIOPHARMA PRODUCT TESTING INDIA PRIVATE LIMITED** for carrying out tests for identity, purity, quality and strength on the following categories of drugs / items of Cosmetics and the raw materials used in the manufacture thereof on the premises situated at **D-BLOCK, UPPER GROUND FLOOR, (ROOM NO'S: 201 TO 232)*PLOT NO'S. 21 & 22, PHASE II, PEENYA INDUSTRIAL AREA, BENGALURU – 560 058.**
*241, 242 & 244 TO 269),

   CATEGORIES OF DRUGS:

   As per List of approved Categories enclosed

2. Names of approved Competent Technical Staff:

~~Sri. V. Srinivasan~~	~~M.Sc Chemistry~~	-	~~Person in-charge of Testing~~ Deleted
Sri. V. Trinadh	M.Sc Chemistry	-	Expert Staff Employed for Testing
Sri. Sivaramireddy Chitte	M.Sc Chemistry	-	Expert Staff Employed for Testing
Sri. K. Eswaran	M.Sc Chemistry	-	Expert Staff Employed for Testing

3. The approval, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of approval and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.

4. The approval is subject to the conditions stated below and such other conditions as may be specified in the rules for the time being in force under the Act.

Date: **11.06.2024**

OFFICE OF THE DRUGS CONTROLLER FOR THE STATE OF KARNATAKA

(BHAGOJI .T. KHANAPURE)
DRUGS CONTROLLER &
APPROVING AUTHORITY

CONDITIONS OF APPROVAL

1. This approval and any certificate shall be kept in the approved premises and shall be produced at the request of the Inspectors appointed under the Act.

2. If the approved institution wishes to undertake during the currency of the approval the testing of any other category of drugs or items of cosmetics, it should apply to the Approving Authority for necessary endorsement as provided in Rule 150B. This approval will be deemed to extend to the items so endorsed.

3. Any change in the analytical staff or in the person in-charge of the testing shall be forthwith reported to the Approving Authority.

4. The approved institution shall inform the Approving Authority in writing in the event of any change of the constitution of the institution operating under this Form. Where any change in the constitution of the institution takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless in the meantime, a fresh approval has been taken from the Approving Authority in the name of the institution with the changed constitution.

OFFICE OF THE DRUGS CONTROLLER FOR THE STATE OF KARNATAKA

Necessary Inclusion in the firm address & deletion/ addition of the following CTS are made & endorsed as per order dated: 07.04.2025.

1. Sri. V. Dhayanithi - Ph.D Chemistry - Person in-charge of Testing
2. Sri. P Ramasamy - M.Sc Microbiology - Person in Charge for Testing
3. Sri. P Shakthivel - M.Sc Chemistry - Expert Staff Employed for Testing
4. Sri. V Rajkumar - M.Sc Microbiology - Expert Staff Employed for Testing

(B. P. ARUN)
DEPUTY DRUGS CONTROLLER &
APPROVING AUTHORITY

CATEGORIES OF DRUGS AND RAW MATERIALS APPROVED FOR CARRYING OUT TEST / EXAMINATION BY M/S. EUROFINS BIOPHARMA PRODUCT TESTING INDIA PRIVATE LIMITED, D-BLOCK, UPPER GROUND FLOOR, (ROOM NO'S: 201 TO 232)* PLOT NO'S. 21 & 22, PHASE II, PEENYA INDUSTRIAL AREA, BENGALURU – 560 058. UNDER APPROVAL IN FORM 37 BEARING NO. KTK/37/84/2024, DATED 11.06.2024, VALID FROM 11.06.2024 TO 10.06.2029 VIDE REF NO. DCD/MFG/SR-66/2024-2025.

* 241, 242 & 244 TO 269),

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NAME OF THE CATEGORIES

A. **Drugs other than those specified in Schedule C & C (1) and also excluding Homeopathic Drugs:**

1. Drugs requiring the use of Ultravoilet/ Infra Red. or Chromatography.
2. Other Drugs.

B. **Drugs specified in Schedule C and C (1):**

1. Antibiotics.
2. Vitamins.
3. Parenteral Preparations.
3. Drugs requiring the use of Ultravoilet/ Infra Red/ Spectrophotometer or Chromatography.
4. Other Drugs.

OFFICE OF THE DRUGS CONTROLLER FOR THE STATE OF KARNATAKA

(BHAGOJI T. KHANAPURE)
DRUGS CONTROLLER &
APPROVING AUTHORITY

Necessary Inclusion in the firm address is made & endorsed as per order dated: 07.04.2025.

(B. P. ARUN)
DEPUTY DRUGS CONTROLLER &
APPROVING AUTHORITY