

**GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT**

No. DCD/MFG/SR-66/2024-2025

Office of the Drugs Controller
for the State of Karnataka
Palace Road, Bengaluru - 01.

Date: **12 JUN 2024**

To,
M/s. Eurofins Biopharma Product Testing India Private Limited,
D-Block, Upper Ground Floor, (Room No's: 201 To 232), **241, 242 & 244 To 263**,
Plot No's. 21 & 22, Phase II, Peenya Industrial Area,
Bengaluru - 560 058.

Sir,

Sub: Drugs & Cosmetics Act, 1940 & Rules 1945 - application for
grant of fresh approval in Form 37.

Ref: 1) Your application dated 18.04.2024 for grant of fresh approval in
Form 37.

2) DDC(I), CDSCO, Zonal Office, Bengaluru letter Ref. No.
DDC/BZ/07-161/2024-25/443, dated 04.06.2024.

I am to state that, you are granted approval in Form 37 bearing no.
KTK/37/84/2024, dated 11.06.2024, for carrying out tests as mentioned in the
approved list. The approval is valid from 11.06.2024 to 10.06.2029.

The above permission is subject to conditions to implement the following
suggestions:

1. Implement Drugs and Cosmetics (Third Amendment) Rules 2008 with effect
from 1st day of November 2010 with respect to Good Laboratory Practices as
stipulated under Schedule L-1.
2. To comply with Rule 150-E (Condition of licence) of Drugs and Cosmetics
Rules, 1945.
3. To report the results of analysis in Form 39/Form 39A as applicable.

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


(B. P. ARUN)

DEPUTY DRUGS CONTROLLER &
APPROVING AUTHORITY



Yours faithfully,


(BHAGOJI T. KHANAPURE)
DRUGS CONTROLLER &
APPROVING AUTHORITY

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 <i>Deleted</i>
➤ 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




(BHAGOJI .T. KHANAPURE)
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,

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 Ultraviolet/ 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 Ultraviolet/ Infra Red/ Spectrophotometer or Chromatography.
4. Other Drugs.



(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