

Due to change in
Constitution
with effect from 05.09.2018

FORM 37
(See Rule 150-C)

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

Number of approval and date of issue KTK/37/11/2000, dated 03.06.2021

1. Approval is hereby granted to M/S. SHIVA ANALYTICALS (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 PLOT NO. 24 D (P) & 34 D, KIADB INDUSTRIAL AREA, HOSKOTE – 562 114, BENGALURU.

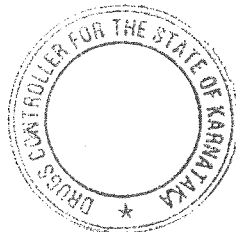
CATEGORIES OF DRUGS:


As per List of approved Categories enclosed

2. Names of approved Competent Technical Staff employed for testing and the person in-charge of testing:

➤ Sri. M. Sathya Moorthy	-	M.Sc
➤ Sri. Kalyan Chakravarthy K.B.	-	M.Sc
➤ Sri. Pitale Sachin Ravindra	-	M.Sc
➤ Sri. B. Tulasiram	-	B.Sc
➤ Sri. Nagesh B. G	-	M.Sc
➤ Sri. Raghavendra R N	-	M.Sc
➤ Smt. Kalpana C	-	B.Sc
➤ Sri. Raghavendra R N	-	M.Sc
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.

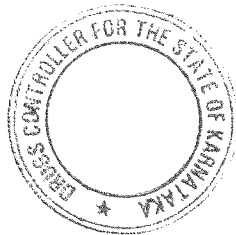
Date: 03.06.2021




(BHAGOJI T. KHANAPURE)
DRUGS CONTROLLER &
APPROVING AUTHORITY

CONDITIONS OF APPROVAL

1. This approval and any certificate of renewal in Form 38 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.



CATEGORIES OF DRUGS AND RAW MATERIALS APPROVED FOR CARRYING OUT TEST / EXAMINATION BY M/S. SHIVA ANALYTICALS (INDIA) PRIVATE LIMITED, PLOT NO. 24 D (P) & 34 D, KIADB INDUSTRIAL AREA, HOSKOTE – 562 114, BENGALURU. UNDER APPROVAL IN FORM 37 BEARING NO. KTK/37/11/2000, DATED 03.06.2021, DUE TO CHANGE IN CONSTITUTION WITH EFFECT FROM 05.09.2018 VALID FROM 05.09.2018 TO 04.09.2023 VIDE REF NO. DCD/MFG/SR-991/2018-2019.

NAME OF THE CATEGORIES

(1) DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULE C & C (I) EXCLUDING HOMEOPATHIC DRUGS:-

- (a) Drugs requiring the use of Ultraviolet / Infrared Spectrophotometer or Chromatography
- (b) Drugs requiring the use of Optical emission spectrometry, Mass Spectrometry, Atomic absorption spectroscopy and surface area analyser.

(2) DRUGS THOSE SPECIFIED IN SCHEDULE C AND C I

- (a) Drugs requiring the use of Ultraviolet/Infrared Spectrophotometer or Chromatography.
- (b) Drugs requiring the use of Optical emission Spectrometry, Mass Spectrometry, Atomic absorption spectroscopy and surface area analyser.



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

**GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT**

No. DCD/MFG/SR-991/2018-2019

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

Date: 09 JUN 2021

To,
M/s. Shiva Analyticals (India) Private Limited,
Plot No. 24 D (P) & 34 D,
KIADB Industrial Area,
Hoskote – 562 114,
Bengaluru.

Sir,

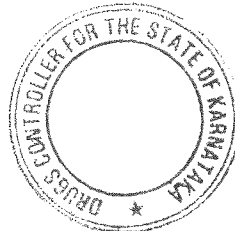
Sub: Drugs & Cosmetics Act, 1940 and Rules 1945 – application for grant of fresh approval in Form 37 (due to change in Constitution).

Ref: Your application dated 26.02.2019 & subsequent letter dated 01.06.2021 for grant of fresh approval in Form 37 (due to change in Constitution).

I am to state that, you are granted approval in Form 37 bearing no. KTK/37/11/2000 dated 03.06.2021 due to change in constitution with effect from 05.09.2018 for carrying out tests as mentioned in the approved list. The approval is valid from 05.09.2018 to 04.09.2023.

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.



Yours faithfully,

(BHAGOJI T. KHANAPURE)
DRUGS CONTROLLER &
APPROVING AUTHORITY