Regd.

From

The State Drugs Controller-cum-Licensing Authority
Food and Drugs Administration, Haryana,
SCO No.94, Sector-5, Panchkula.

To

M/s Vardan EnviroLab,
Plot No. 82A, Sector-5, IMT Manesar,
Gurugram-122051

Memo. No. 4/157-1Drug–I-2019/ 5843
Dated: 22/7/19

Subject **Grant of approval for carrying out tests on drugs / cosmetics and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs / cosmetics.**

Please refer to your letter No. VEL/DRUG LICENSE/2019 dated 08.04.2019 on the subject cited above.

You are hereby granted approval on Form- 37(Approval No. 32Lab –HR Dated 22/7/19) for carrying out tests on the following conditions:

(i) You shall maintain records of tests for identify, purity, Quality and Strength, carried out on all samples of drugs and the results thereof together with the protocol of tests showing the reading & calculation in such forms as to available for inspections and such record shall be retained in case of substances for which an expiry date is assigned for period of two years on the expiry of said date and in case of other substances for a period of six years.

(ii) From time to time you shall report to the approving authority any change in the Person In charge of testing as the case may be and any material alterations in the premises or change in the equipment used for the purpose of testing which have been made since the date of last inspection made on behalf of approving authority for the grant of approval.

(iii) You shall have to furnish Report of the results of test or analysis in Form 39.

(iv) In case any sample of Drug is found on test to be not of standard quality, you shall furnish to the approving authority with the copy of test report of the sample with the protocol of the tests applied.

(v) You shall have to comply with the provisions of Drugs and Cosmetics Act 1940 and rules 1945 made there under and with such further requirements if any, as may be specified in the rule subsequently under chapter IV of the act under which you have been given approval.

(vi) You have to maintain an inspection book to enable the inspector to record his impressions of defects noticed.

(vii) Firm shall not conduct any test for which they do not have facilities i.e. equipments/reagents etc. and have not been allowed by this office.

(viii) Before starting of testing firm shall procure Reference standards and inform the office of State Drugs Controller, Haryana.

(xix) The firm shall calibrate all its Instruments and Equipments before start of testing.

(xx) You shall comply with the provision of GLP.

Encl: Form-37

(N. K. Ahooja) 22/7/19
State Drugs Controller-cum-Controlling &
State Drugs Controller(Licensing Authority),
Licensing Authority
Food and Drugs Administration, Haryana.
Food & Drugs Administration, Haryana

Endst. No. 4/157-1Drug–I-2019/ Dated:

A copy is forwarded to the Senior Drug Control Officer, HUDA Dispensery, Sector-45, Opp. Community Centre, Gurugram-122016 w.r.t. his letter no. SDCO/GGN/2019/1655 dated 11.07.2019 for information and necessary action.

(N. K. Ahooja)
State Drugs Controller-cum-Controlling &
State Drugs Controller(Licensing Authority),
Licensing Authority
Food and Drugs Administration, Haryana,
Food & Drugs Administration, Haryana

Endst. No. 4/157-1Drug–I-2019/ Dated:

A copy is forwarded to Deputy Drugs Controller (India) CDSCO, North Zone, CGO Building, Kamla Nehru Nagar, Hapur Road, Ghaziabad for information and necessary action.

(N. K. Ahooja)
State Drugs Controller-cum-Controlling &
State Drugs Controller(Licensing Authority),
Licensing Authority
Food and Drugs Administration, Haryana,
Food & Drugs Administration, Haryana

Form25,26,28,37,38

FORM-37
(See Rule 150– C)

Approval for carrying out tests on drugs/cosmetics and raw material used in their manufacture on behalf of licensees for manufacture for sale of drugs/cosmetics.

Number of approval and date of issue:

M/s Vardan EnviroLab,
Plot No. 82A, Sector-5, IMT
Manesar, Gurugram-122051

(1) Approval is hereby granted to **M/s Vardan EnviroLab,** for carrying out tests for identity, purity quality and strength on the following categories of drugs/items of cosmetics and the raw material used in the manufacture thereof on the premises situated at **Plot No. 82A, Sector-5, IMT Manesar, Gurugram-122051 (Haryana).**

Categories of Drugs/Cosmetics permitted for testing (For Chemical & Instrumental testing only):-

(a) Drugs other than those specified in schedule C and C(1) including/excluding Homeopathic Drugs.
   i. Surgical dressings: Only those items which are specified under Schedule F(II) of the Drugs & Cosmetics Rules. (Except medical device).
   ii. Drugs requiring the use of Ultraviolet Spectrophotometer, Infra Red Spectrophotometer, Chromatography including TLC, GLC, AAS & HPLC.
   iii. Disinfectants

(b) Drugs those specified in Schedules C and C(1):-
   i. Antibiotics
   ii. Vitamins
   iii. Parenteral preparation (Except particulate matter for large volume preparations as per USP, BP)
   iv. Drugs requiring microbiological tests.
   v. Drugs requiring the use of Ultraviolet Spectrophotometer, Infra Red Spectrophotometer, Chromatography including TLC, GLC, AAS & HPLC.

   Note:- (Except medical device)

(c) Homoeopathic drugs

(d) Cosmetics

(2) **Names of [competent technical staff] employed for testing and the Person In-charge:-**
   (i) Ms. Vandana, Technical Manager, B.Pharma, (Physical and Chemical Analysis).
   (ii) Sh. Umesh Sharma, M.Sc. Pharmaceutical, Microbiologist already approved.
   (ii) Sh. Kaushal Yadav, B.Pharma, Analytical Chemist

(3) The approval, unless sooner suspended or cancelled, shall remain valid perpetually, however, the compliance with the conditions of approval and the provisions of Drugs and Cosmetics Act, 1940 and the Drugs & Csometics 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.

Dated:.....22.07.2019.

(N. K. Ahooja) 22/7/19
State Drugs Controller-cum-Controlling &
Licensing Authority
Food & Drugs Administration, Haryana

(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 meant as provided in rule 150 – B .This approval will be deemed to extend to the item 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 from the approving authority in the name of the institution with the changed constitution.