Regd.

From

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

To

M/s AAL Biosciences Research Pvt. Ltd.
Plot No. 287, HSIIDC, Industrial Area, Phase-I,
Barwala, District Panchkula-134118 (Haryana).

Memo No. 1/179-1Drug-1-2025/ 6017
Dated 09/09/25

Subject: **Approval for carrying out tests on drugs and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs or for an individual or organization or procurement agency (Due to change in premises).**

Please refer to the subject cited above.

You are hereby granted approval on Form- 37 bearing number of approval - 40-Lab – HR Date for carrying out tests of drugs mentioned on your approval 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 protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in the case of substances for which an expiry date is assigned for period of two years on the expiry of such date and in the case of other substances for a period of six years.

(ii) You shall from time to time report to the approving authority any changes in the person-in-charge of testing of drugs or in the expert staff responsible for testing as the case may be and any material alteration in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the approving authority before the grant of approval.

(iii) You shall furnish report of the results of test or analysis on the samples received from manufacturer in Form 39 and from an individual or organization or procurement agency in Form 39A.

(iv) In case any sample of a drug is found on test to be not of standard quality, you shall furnish the approving authority [and the licensing authority of the State where the manufacturer and/or sender of the drug or cosmetic is located] with copy of the test report on the sample with the protocols of the tests applied.

(v) You shall comply with the provisions of the Act and Rules made thereunder and with each further requirements, if any, may be specified in the rules subsequently made under Chapter IV of the Act of which the approving authority has given the approved institution not less than four months notice.

(vi) You shall maintain an Inspection Book to enable the Inspectors to record his impression of defects noticed.

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

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

(ix) You shall calibrate all instruments and equipments before start of testing and from time to time as per rules.

(x) You shall comply with the provisions of GLP.

(xi) You shall allow the Inspector appointed under this Act to enter with or without prior notice the premises where the testing is carried on and to inspect the premises and the equipment used for test and the testing procedures employed. The institution shall allow the Inspectors to inspect the registers and records maintained under these Rules and shall supply to such Inspectors such information as they may require for the purpose of ascertaining whether the provisions of the Act and Rules made thereunder have been observed.

(xii) That you will apply for Retention of your approval on or before 08/09/2030

* Old license no. 40-Lab(HR) at existing premises i.e. M/s AAL Biosciences Research Pvt. Ltd., SCO- 134-135, First Floor, Sector-14, Panchkula (Haryana) is hereby cancelled with immediate effect and as per request of firm same license no. 40-Lab(HR) is granted at new premises i.e. M/s AAL Biosciences Research Pvt. Ltd. Plot No. 287, HSIIDC, Industrial Area, Phase-I, Barwala, District Panchkula-134118 (Haryana).

Encl: Form-37

09 SEP 2025

(LALIT KUMAR GOEL)
State Drugs Controller-Cum-Controlling &
Licensing Authority
Food & Drugs Administration, Haryana

Endst. No. 1/179-1Drug-1-2025/ Dated:

A copy is forwarded to the Senior Drug Control Officer, Ambala (Haryana) w.r.t. his office letter no. FDA/SDCO/Ambala/2025/1385 dated 27.08.2025 for information and necessary action.

(LALIT KUMAR GOEL)
State Drugs Controller-Cum-Controlling &
Licensing Authority
Food & Drugs Administration, Haryana

Endst. No 1/179-1Drug-1-2025/ Dated:

A copy is forwarded to Deputy Drug Controller (India), Govt. of India, Central Drugs Standard Control Organization (Baddi), Directorate General of Health Services, Ministry of Health and Family Welfare, Container Corporation of India Building, Village Sheetlapur, Tehsil Baddi, District Solan (HP)-173205 for information and necessary action.

(LALIT KUMAR GOEL)
State Drugs Controller-Cum-Controlling &
Licensing Authority
Food & Drugs Administration, Haryana

(Due to change in premises)

FORM-37
(See Rule 150– C)

Approval for carrying out tests on drugs and raw materials used in their manufacture on behalf of licensees for manufacture for sale of drugs or for an individual or organization or procurement agency.

Number of approval: 40-Lab (HR) **Date of issue: 08.09.2025**

(1) Approval is hereby granted to **M/s AAL Biosciences Research Pvt. Ltd.** for carrying out tests for identity, purity, quality and strength on the following categories of drugs and the raw materials used in the manufacture thereof on the premises situated at **Plot No. 287, HSIIDC, Industrial Area, Phase-I, Barwala, District Panchkula-134118 (Haryana).**

Categories of Drugs: -

(a) Drugs other than those specified in Schedules C and C(I) and also excluding Homoeopathic Drugs: -

1. Crude vegetable drugs.
2. Drugs requiring the use of Ultraviolet/Spectrophotometer
3. Disinfectants (except Medical Devices).
4. Other drugs.

b) Drugs specified in Schedules C and C(1):-

1. Toxicology Studies only
   - Sera, Vaccines, Antigens, Toxins, Antitoxins, Toxoids, Bacteriophages and similar Immunological Products.
   - Antibiotics
   - Vitamins
   - Parenteral preparations
2. Drugs requiring the use of animals for their test.
3. Drugs requiring microbiological tests.
4. Drugs requiring the use of Ultraviolet/ Spectrophotometer or Chromatography.
5. Other drugs (i.e. Anti-factor I1a & Xa for Heparin Sodium/Enoxaparin Sodium).

(2) **Names of competent technical staff employed for testing and the Person In-charge:-**

(a) Person In-charge: - Anubhav Shrivastava.

(b) Technical Staff employed for testing: -

Sr. No.	Name	Qualification	Approved for Section
1	Mr. Virender Kumar	B. Pharma	Chemical, Instrumental & Microbiological
2	Mr. Hanumanth Gada Yerukala	M.Pharma	Chemical & Biological
3	Ms. Aayushi	M.Pharma	Chemical, Instrumental & Microbiological
4	Mr. Vibhor Ukey	M.Pharma	Chemical, Instrumental & Microbiological

(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 Act, 1940 and the Drugs 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.

Constitution of firm – Private Limited
Name of Directors: -

1. Mrs. Sasmita Nayak C/o Antaryami Nayak, H. No. 471, Sector-2, Panchkula, Haryana-134112
2. Mr. Sridhar Muthayala S/o Satyanarayana Muthyala, H. No. 2008, 1st Floor, Near Alchemist Hospital, Sector-21, Panchkula, PO: Panchkula, Sector-4, District Panchkula, Haryana-134112.

Dated: 09/09/25

09 SEP 2025

(LALIT KUMAR GOEL)
State Drugs Controller-Cum-Controlling & Licensing Authority
Food & Drugs Administration, Haryana

CONDITIONS OF APPROVAL

1. This approval 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 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.