FORM CT-07C

[See rules 38C and 38D(3)]

GRANT OR RENEWAL OF REGISTRATION OF CLINICAL RESEARCH ORGANIZATION

Registration No : CRO/MH/2026/000168

The Central Licencing Authority hereby registers M/s Anazeal Analyticals & Research Pvt. Ltd., C-404, TTC Industrial Area, MIDC Pawane Opposite JISL, Navi Mumbai, Thane, Maharashtra (India) – 400705, Telephone No.: 9867311115 FAX: 9867311115, for conduct of clinical trial or bioavailability or bioequivalence study of new drugs and investigational new drugs under the New Drugs and Clinical Trials Rules, 2019.

Place: New Delhi
Date : 02-Apr-2026

RAJEEV SINGH RAGHUVANSHI
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Date: 2026.04.02 14:50:45 +05'30'
Central Licensing Authority stamp

Conditions of registration :

The registration granted under rule 38C or renewal granted under rule 38D shall be subject to the conditions specified in rule 25, rule 35 and the requirements specified in the Ninth Schedule including the following

1. The registration is valid for a period of five years from the date of its grant, unless suspended or cancelled by the Central Licensing Authority. Provided that if the application for renewal of registration is received by the Central Licensing Authority prior to the date of expiry, the registration shall continue to be in force until the orders are passed by the Central Licensing Authority on the application.

2. The organisation shall maintain the facilities and adequately qualified and trained personnel as specified in the Ninth Schedule for performing its functions.

3. The organisation shall initiate conduct of any clinical trial or bioavailability or bioequivalence study of any new drug or investigational new drug in human subjects after approval of the protocol and other related documents by the Ethics Committee for clinical trial or bioavailability or bioequivalence study, as the case may be, and permission of such study granted by the Central Licensing Authority.

4. Where a clinical trial site or bioavailability or bioequivalence center does not have its own Ethics Committee, the study at that site or center may be initiated after obtaining approval of the protocol from another Ethics Committee of another trial site or an independent Ethics Committee for clinical trial or bioavailability or bioequivalence study registered under Rule 8: Provided that the approving Ethics Committee shall be responsible for the study at the trial site or center, as the case may be, and both the approving Ethics Committee and the trial site or the center are located within the same city or within a radius of fifty kilometers of the trial site or the center.

5. The Central Licensing Authority shall be informed about the approval of the Ethics Committee for clinical trial or bioavailability or bioequivalence study.

6. Clinical trial of new drug or investigational new drug shall be registered with the Clinical Trial Registry of India before enrolling the first subject for the study.

7. Bioavailability or bioequivalence study of investigational new drug shall be registered with the Clinical Trial Registry of India before enrolling the first subject for the study.

8. The study shall be conducted in accordance with the approved protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and provisions of the Act and these rules.

9. In case of termination of any such study prematurely, the detailed reasons for such termination shall be communicated to the Central Licensing Authority immediately.

10. Any report of serious adverse event occurring during study to the subject of such study shall, after due analysis, be forwarded to the Central Licensing Authority within fourteen days of its occurrence in the format as specified in Table 5 of the Third Schedule and in compliance with the procedures as specified in Rule 42.

11. In case of an injury to the study subject during study, the complete medical management and compensation in the case of study-related injury shall be provided in accordance with the provisions of Chapter VI, and details of compensation paid to the trial subject in such cases shall be intimated to the Central Licensing Authority within thirty days of receipt of the order.

12. In case of death, permanent disability, or injury other than death and permanent disability, as the case may be, of a study subject, compensation shall be provided in accordance with the provisions of Chapter VI, and details of compensation paid to the trial subject or his legal heir, as the case may be, in such cases shall be intimated to the Central Licensing Authority within thirty days of receipt of the order.

13. If there is any change in constitution or ownership of the Clinical Research Organisation, the organisation shall intimate about the change in writing to the Central Licensing Authority within thirty days of such change.

14. The Clinical Research Organisation shall maintain data, records, and other documents related to the conduct of the clinical trials for a period of five years after completion of such study or for at least two years after the expiration date of the batch of the new drug or investigational new drug studied, whichever is later.

15. The Clinical Research Organisation shall allow any officer authorised by the Central Licensing Authority, who may be accompanied by an officer authorised by the State Licensing Authority, to enter the premises with or without prior notice, to inspect any record, statistical observation or results or any documents related to clinical trials and furnish information to the queries raised by such authorised person in relation to the conduct of the said study.

16. The Central Licensing Authority may, if considered necessary, impose additional conditions, in writing with justification, in respect of specific clinical trials regarding the objective, design, subject population, subject eligibility, assessments, conduct and treatment of such specific study.