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## Government of India

केंद्रीय औषध मानक नियंत्रण संगठन / Central Drugs Standard Control Organization आंचलिक कार्यालय. सी. डी. एस. सी. ओ. भवन, हैदराबाद / Zonal Office, CDSCO BHAVAN, Hyderabad, स्वास्थ्य एवं परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare, स्वास्थ्य सेवा महानिदेशालय / Directorate General of Health Services, एस.आर. नगर, हैदराबाद - ५०००३८ / S.R. Nagar, Hyderabad - 500038

ISO 9001: 2015 Certified Organization

संदर्भ सं. /Ref: 5-5(122)/HZ/2022/ 4-2 ()

दिनांक/Date: ૣ 🧷 .12.2022

To,
The Licensing Authority,
Drugs Control Administration,
Government of Telangana,
Vengalarao nagar, Hyderabad-500 038

Sub: Grant of approval for Form 37 as a public testing laboratory in respect of M/s. Abani Labs Private Limited, #5-5-35/169/1, Plot no. 19, Ground Floor, Prashanth Nagar, I.E. Kukatpally, Medchal-Malkajgiri (D), TS under the provisions of Drugs and Cosmetics Act & Rules there under - Regarding

Ref:

- 1. Application reference No. Nil dated 29.10.2022 and received on 27.11.2022
- 2. Joint Inspection Report dated 01st Dec 2022
- 3. Compliance response submitted by the firm vide letter inward dated 08.12.2022

Sir,

This is to inform you that the above mentioned subject firm was made application to this office and copy to your esteemed administration vide its application dated 13.09.2022, accordingly joint inspection was carried out on 01<sup>st</sup> Dec 2022 in order to verify the competent technical staff, facilities, equipments, physicochemical testing area, instrumentation section (HPLC area) and other requisite areas in order to meet tenets of GLP as per schedule L1 of Drugs & Cosmetics Act, 1940 and rules there under.

The joint inspection report has been reviewed by the undersigned officer and discussed with concerned CDSCO officer in respect of said firm and also there were certain observations were noticed by joint inspection team and most of the observations are found to be document related and advisory in nature to keep good practices. The firm has submitted compliance to this office vide ref (3) which is reviewed by this office and found satisfactory.

Based on the joint inspection report and compliance review report it was observed that the said firm by and large complies with most of the requirements of good laboratory practices and found to be acceptable to carry out testing as per applicable guidelines for various samples. Therefore the firm's application for grant of license in Form 37 for Drugs requiring Nuclear Magnetic Resonance (NMR) Testing may be considered

**Yours Sincerely** 

(Dr. A. Ramakishan) Deputy Drugs Controller (I)

**Encl:** Copy of Compliance review Report

Copy to: M/s. Abani Labs Private Limited, #5-5-35/169/1, Plot no. 19, Ground Floor, Prashanth Nagar, I.E. Kukatpally, Medchal- Malkaigiri (D), TS