



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(87)/HZ/2020/ 57

दिनांक/Date: 20-04-2020

To,
 The Joint Director and Licensing Authority,
 Drugs Control Administration,
 Government of Telangana,
 Vengal Rao nagar, Hyderabad-500 038

Sub: Application from "M/s. Horizon Biolabs Pvt. Ltd., Plot No. 611, Sy.No. 374, CIE, Gandhinagar Expansion, Balanagar, Quthbullapur (M), Rangareddy (D), Telangana - 500037 for grant of approval for Form 37"- Regarding.

Ref:

1. Application submitted by the firm vide letter No. Nil dated 13.02.2020 and received to this office on 17.02.2020
2. This office letter reference no 5-5(87)/HZ/2020/7745 dated 26.02.2020 to submit deficient documents
3. This office letter reference no. 5-5(87)/HZ/2020/7918 dated 05.03.2020 to conduct inspection
4. Compliance response submitted by the firm vide letter dated 26.03.2020 and this office receipt no 5430 dated 27.03.2020
5. This office letter reference no. 5-5(87)/HZ/2020/08 dated 01.04.2020 to submit deficient documents
6. Compliance response submitted by the firm vide letter dated 6.04.2020 and this office receipt no 9849 dated 7.04.2020

Sir,

With reference to subject cited, Joint Inspection of M/s. Horizon Biolabs Pvt. Ltd., Plot No. 611, Sy.No. 374, CIE, Gandhinagar Expansion, Balanagar, Quthbullapur (M), Rangareddy (D), Telangana - 500037 was conducted on 17.03.2020 & 18.03.2020 by Mr. Narendra Kumar & Mr. Venumadhav, DI, CDSCO, Hyderabad along with Mr. M Chandrasekhar, DI, DCA, Telangana. During inspection certain anomalies were noted by the inspecting team and for which firm has submitted the compliance response vide reference (4&6).

Remarks:

In view of above, it is opined that grant of license under Form 37 for chemical & instrumentation analysis (GC, HPLC, Dissolution apparatus, UV-Visible Spectro photometer, FT-IR, DSC, TGA, Photo stability chamber and stability chambers) and microbiological analysis (MLT & Sterility test) may be considered

Yours Sincerely

(A Visala)

Deputy Drugs Controller (I)

Encl: Copy of Joint Inspection Report

✓ Copy to: M/s. Horizon Biolabs Pvt. Ltd., Plot No. 611, Sy.No. 374, CIE, Gandhinagar Expansion, Balanagar, Quthbullapur (M), Rangareddy (D), Telangana - 500037