



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(112)/HZ/2021/ 3158

दिनांक/Date: 04-01-2022

To,  
Licensing Authority,  
Drugs Control Administration,  
Government of Telangana,  
Vengal Rao Nagar, Hyderabad-500 038

**Sub: Drugs and Cosmetics Act & Rules thereunder: Application of "M/s. Vyas Labs, Sy.No.17, D.No.5-75, Muneerabad (Village), Medchal (Mandal), Malkajigiri (District), Hyderabad, Telangana for grant of approval for Form 37"- Regarding.**

1. Ref: Application submitted by the firm vide Ref.No.NIL dated NIL received vide Dy.No.1970 dated 13.10.2021)
2. Letter of this office vide F.No.5-5(112)/HZ/2021/3105 dated 13.10.2021 – to Submit additional documents
3. Letter of this office vide F.No.5-5(112)/HZ/2021/3180 dated 22.10.2021 – Intimation of JI dates
4. Joint Inspection Report dated 26.10.2021 and 27.10.2021
5. Letter of this office vide F.No.5-5(112)/HZ/2021/3860 dated 22.11.2021 – to Submit additional documents
6. Letter submitted by the firm vide Ref.No.NIL dated NI Lreceived vide IR No. 1252 dated 24.12.2021 (Dy No.3048 dated 24.12.2021)

Sir,

With reference to subject cited, Joint Inspection of M/s. Vyas Labs, Sy.No.17, D.No.5-75, Muneerabad (Village), Medchal (Mandal), Malkajigiri (District), Hyderabad, Telangana was conducted on 26.10.2021 and 27.10.2021 by Shri Raghuvaran G, Drugs Inspector, CDSCO Zonal Office, Hyderabad along with area Drugs Inspector, DCA, Telangana. The joint inspection report was forwarded vide ref (5). The firm has submitted CAPA/Compliance vide ref (6).. On scrutiny of the the compliance response, submitted to this office, it is of the opinion that grant of approval in Form 37 to M/s. Vyas Labs, Sy.No.17, D.No.5-75, Muneerabad (Village), Medchal (Mandal), Malkajigiri (District), Hyderabad, Telangana may be considered for

**(a)Drugs other than those specified in Schedules C and C (1) and also excluding Homoeopathic Drugs:-**

**Animal test:**

1. Systemic injection as per USP, Chapter 88, and Biological reactivity test, In vivo.
2. Intracutaneous test as per USP, Chapter 88, Biological reactivity test, In vivo.
3. Implantation as per USP, Chapter 88, Biological reactivity test, In vivo.

**(b) Drugs specified in Schedules C and C (1):—**

**Animal test:**

1. Abnormal toxicity as per IP,BP and USP.
2. Rabbit pyrogen test as per IP,BP and USP.

Subject to the condition that the firm complies with the provisions of Drugs and Cosmetics Act, 1940 & Rules thereunder.

**Yours sincerely**

4/1/22

**(Vinod Kumar)**

**Assistant Drugs Controller (I)**

**Encl:** Copy of Joint Inspection Report

**Copy to: M/s. Vyas Labs, Sy.No.17, D.No.5-75, Muneerabad (Village), Medchal (Mandal), Malkajigiri (District), Hyderabad, Telangana**