No. HFW-H(Drugs)231/05
HEALTH AND FAMILY WELFARE DEPARTMENT
HIMACHAL PRADESH

To

M/s Venus Remedies Limited,
Hill Top Industrial Estate, Jharmajri, EPIP
Phase-1 (Extn.), Bhatoli Kalan, Baddi H.P. 173205.

Subject: - Approval /Retention of (TWO) products.

Refer to your letter No _____ dated _____ on the subject cited above.

Find enclosed herewith a list of TWO approved/retained products duly approved by this office and endorsed in your Drugs manufacturing License MB/05/204 valid up to 10.10.2025. You are directed to comply with the following conditions:-

1. Licensee shall comply with all the provisions under D & C Act & Rules & standards for medicines as laid down under the Drugs and Cosmetics Rules, 1945.
2. Licensee shall comply with the provisions for manner of labeling of drugs as laid down under Rule 94, 95, 96, 97, 102, 104, 104-A, 105, 105-A, 106 etc. of the Drugs and Cosmetics Rules, 1945.
3. Licensee shall maintain records as prescribed under schedule M, L & U of the Drugs and Cosmetics Rules, 1945.
4. Licensee shall conduct periodical and accelerated stability studies for the drugs manufactured by them for at least initial three consecutive batches, in order to ensure potency and quality of drug, during its shelf life. In case of any deviation licensee shall withdraw the same from the market under intimation to the office of the Drugs Licensing Authority.
5. Licensee shall, forthwith intimate to the Licensing Authority, in the event of any adverse reaction reported by the drug.
6. Licensee shall make no claim, except those prescribed in the pharmacopoeia and permission issued by the Drugs Controller General of India.
7. The licensee will comply to all the directions/guidelines/notifications issued by DCGI/GOI by visiting website www.cdsco.gov.in .
8. The licensee will conduct BA/BE studies as per notification by Govt. of India wherever required.
9. The licensee will upload the information regarding, license/product license granted with portal SUGAM (www.cdscoonline.gov.in).
10. If any, product approved and enclosed with the application falls under the category of banned drugs as per time to time notifications /orders issued by Govt. of India, it will be treated as cancelled.
11. The licensee shall adhere to the notification No. G.S.R. 101 € dated 11th February 2020 of the Government.
12. The licensee shall ensure that at the time of dispatch of business orders of the approved drug formulations, intimation through email shall be sent to the concerned DI & Superintendent of Police under whose jurisdiction the firm is located and also to the State Drugs Controller under whose jurisdiction the drug is being sold.
13. The licensee shall submission of monthly report of the detail of raw material and furnished goods at Start of month, furnished goods manufactured and sold and stock of raw material at end of month. The report should be submitted on or before 5th of every month.
14. If any product approved and enclosed with the letter is found in contravention of any provisions of Drugs & Cosmetics Act & Rules or contrary to the undertaking submitted by you, appropriate action will be taken.

24 DEC 2021

Encl: List, Pages
Total Products :- (TWO) Only.

Digitally signed by Dumitru Iurie
Date: 2022.01.05 11:39:04 EET
Reason: MoldSign Signature
Location: Moldova

24/12/21

(Dr. Manish Kapoor)
DEPUTY DRUGS CONTROLLER
-cum-LICENSING AUTHORITY
O/o STATE DRUGS CONTROLLER
BADDI DISTRICT SOLAN, H.P-173205
E mail ddc4hp@gmail.com
Phone 01795-244288

No.:HFW-H (Drugs) /231/05 (Vol. XII)
Health and Family Welfare Department
Baddi, Himachal Pradesh

LIST OF APPROVED FORMULATION TO BE MANUFACTURED BY M/s. VENUS REMEDIES LIMITED SITUATED AT HILL TOP INDUSTRIAL ESTATE, JHARMAJRI, EPIP PHASE-I (Extn), BHATOLI KALAN, BADDI, DISTT. SOLAN, HIMACHAL PRADESH, 173205, INDIA UNDER DRUGS MANUFACTURING LICENCE No :MB/05/204, DATED 10-10-2005 ON FORM-28 AND VALID UPTO 10/10/ 2025.

Formulation for Approval (Export)

S.No	Generic Name	Composition	Ph. Ref	Pack size	Date of approval in CDSCO	Country Name
1.	Midazolam Injection USP (5 mg/5 ml)	**Each ml contains:** Midazolam USP…..1mg	USP	5 ml	15/04/1997	Moldova
2.	Midazolam Injection BP (5mg/5ml)	**Each ml contains:** Midazolam BP…....1mg	BP	5 ml	15/04/1997	Moldova

This product approval is issued on the request of firm for the supply of the drugs against the tender having tender id no 1016601000212 issued by Centre for centralized public precourement health for the quantity 49530 either in USP/BP.

Total approved products (Two) only.

24 DEC 2021

(Dr. Manish Kapoor)
DEPUTY DRUGS CONTROLLER
-cum-LICENSING AUTHORITY
O/o STATE DRUGS CONTROLLER
BADDI DISTRICT SOLAN, H.P-173205
E mail ddc4hp@gmail.com
Phone 01795-244388

Conditions of License

1. The above drug formulation manfactured only be exported to and no part of it is diverted in domastic sale in India.
2. The batched to be expoprted shall undergo quality testing at your laboratery or destined site
3. In the event of relevant export order being cancelled, you shall ensure physical destruction of all un exported quantity of drug(s).
4. You shall ensure that the drug shall case to be manfactured or exported if the drug is probhited in the inporting country.
5. You shall available for the inspection of the apporipriate authorities on completion of tender order no-1016601000212 dated 15/09/2021 tendered by Center for centralized public precourement health, situated at MD-2005, Republic of Moldova,mun,Chisinau,or. Chisinau,str.G.Vieru22/2 and export to Moldova and furnish information to cdsco regarding the actual quantity of drug produced detail regarding each consignment dispached remaning stock of the drug and related raw matiral and ingrediends in hand.
6. In case of Narcotic/Phycotropic drug, firm is required to NOC from Narcotics Commissioner of India, Central Bureau of Narcotics,Gawalior, before manfacturing of the drug for export.