

No: HFW-N/ADC/DRUGS/DMLL/2020/53 -2267
HEALTH AND FAMILY WELFARE DEPARTMENT
HIMACHAL PRADESH

To

M/s Hetero Labs Limited
C/o M/s Nitin Lifesciences limited Unit-III,
Rampurghat road, Paonta Sahib,
District sirmour-173025 (H.P)

18/11/2020

Dated: Nahan-173025

Subject: - Approval of () Additional products For Domestic

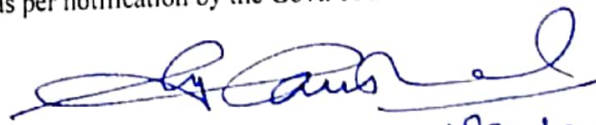
Refer to your letter No _____ dated _____ on the subject cited above.

Find enclosed herewith a list of _____ additional products duly approved by this office and endorsed in your Drugs manufacturing under loan License No. NL-MB/2020/263 Dated : 21-09-2020 to 20-09-2025. You are directed to comply with the following conditions:-

1. Licensee shall comply with all the provisions under D & C Act & standards for patent and proprietary medicines as laid down in the Schedule V of 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 and 106 of the Drugs and Cosmetics Rules, 1945.
3. Licensee shall maintain records as prescribed under schedule M 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. Licensee will comply with the contents of the letter as mentioned in letter no. F.No.4-01/2013/DC/Misc.13 PSC dt. 15.01.2013 from DCGI
8. That the licensee will abide by the decision of Hon'ble Madras High Court & the products in the list of 294 FDC's will stand withdrawn if the stay is vacated by the Hon'ble Madras High Court.
9. The licensee will strictly abide by the procedure for clearance of cases with respect to subsequent applicants in respect of Fixed Dose Combinations declared as rational by Prof. Kokate committee and approved by Drugs Controller General of India, as per this office order No. HFW-H(Drugs)122/99-1500-1507 dated 30.06.2017 and DCG(I) letter No.4-01/2013-DC(Misc. 13-PSC) dated 05.06.2017.
10. The licensee will comply to all directions/guidelines/notifications issued by DCGI/GIO by visiting website www.cdsc.gov.in.
11. The licensee will conduct BA/BE studies as per notification by the Govt. of India wherever required.

Encl: List, Pages

Total Products : (0) Only



(Sunny kaushal)

Assistant Drug Controller,

-cum-drug licensing Authority

H.Q.Nahan District Sirmour, H.P-173001

01702-244543, adc3sirmaur@gmail.com

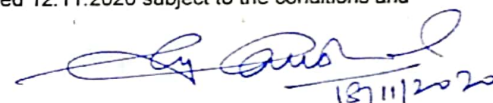
18/11/2020

No: HFW-N/ADC/DRUGS/DMLL/2020/53-
Health & Family Welfare Department
Himachal Pradesh

List of products approved to be manufactured by M/s Hetero Labs Ltd. C/O M/s Nitin Lifesciences Ltd., Unit-III situated at Rampurghat Road, Paonta Sahib, Distt. Sirmour-173025, Himachal Pradesh on loan license in Form 28A under the drug Manufacturing License No. NL-MB/2020/263 issued on 21-09-2020 & valid up to 20-09-2025

Sr. No.	Brand name and dosage form	Composition	To be manufactured for
1.	Remedesivir for injection 100mg/vial	Each Lyophilized vial contains: Remedesivir.....100mg	Domestic only

Note: The product is approved on the basis of DCG(I) letter No. SND/MA/20/000293 dated 12.11.2020 subject to the conditions and restrictions as stipulated in the Form CT-23 No. MF-ND-107/2020 dated 20.06.2020.



(SUNNY KAUSHAL)
Assistant Drugs Controller
-Cum-Drugs Licensing Authority
District Sirmour, H.Q. Nahan, H.P.
01702-222543, adc@sirmour@gmail.com

No: HFW-N/ADC/DRUGS/DMLL/2020/53- *2266*
HEALTH & FAMILY WELFARE DEPARTMENT
HIMACHAL PRADESH

Certificate of Good Manufacturing Practices

This one page certificate conforms to the format recommended by the World Health Organization (General instructions & Explanatory notes attached).

Certificate No. HFW-N/ADC/DRUGS/DMLL/2020/53-

On the basis of inspection carried out on 22nd & 23rd May 2019, We certify that the site indicated on this certificate complies with the Good Manufacturing Practices for the dosage form, Categories & activities listed in Tablet I:

Name and Address of Site:

M/s HETERO LABS LIMITED
C/o M/s Nitin Lifesciences limited Unit-III
Khasra No. 492/161/13, Rampurghat
Road, Paonta Sahib, District Sirmour-
173025 (H.P)

1. Manufacturer's License No: NL-MB/2020/263 Form 28A: valid up to 03.09-2023
2. Table-I:

Dosage Form[s]	Category[ies]	Activity[ies]
Small volume Injectables Liquid injections (vials & ampoules) Dry powder injections (vials), Unit Lyophilized injections (vials) Lyophilized powder (sterile)	General category	Production, Packing , labeling & Quality Control

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with manufacturer.

This certificate remains valid until **24-04-2022**. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of Certifying Authority:

Assistant Drug Controller,
-cum-drug licensing Authority
HQ, Nahan Distt. Sirmour-173001

Name & Function of responsible person:

(Sunny Kaushal)
Assistant Drug Controller,
-cum-drug licensing Authority

Telephone/Fax No.: 01702-222543-
Date: 18.11.2020

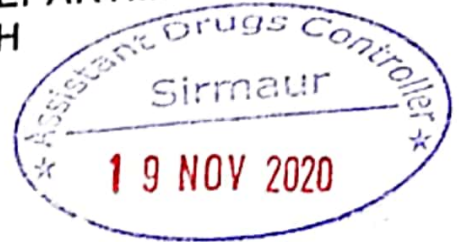


Signature:
Stamp:

[Handwritten Signature]
18/11/2020

(SUNNY KAUSHAL)
Assistant Drugs Controller
-Cum-Drugs Licensing Authority
District Sirmour, H.Q. Nahan, H.P.
01702-222543, adc3sirmour@gmail.com

No: HFW-N/ADC/DRUGS/DMLL/2020/53-
HEALTH & FAMILY WELFARE DEPARTMENT
HIMACHAL PRADESH




Dated: 18.11.2020 - 2269

G. M.P. CERTIFICATE

This is to certify that M/s HETERO LABS LIMITED C/o M/s Nitin Lifesciences limited Unit-III, Rampurghat Road, Paonta Sahib, District sirmour-173025 (H.P), is holding Drugs Manufacturing Under loan License bearing No. NL-MB/2020/263 issued on 21-09-2020 in the form No. 28A and is valid up to 20-09-2025 for manufacture & sale.

1. The firm is following **GOOD MANUFACTURING PRACTICES** as stipulated under the provisions of "**REVISED Schedule "M"**" of Drugs & Cosmetics rules, 1945 in respect of category of drugs: Injectables.
2. The firm should however carry out self - inspection from time to time to ensure that the requirements of Good Manufacturing Practices are complied with.
3. This certificate is issued on the request of the firm for the limited purpose of submitting the same in connection with participating in the Tenders in Government Hospitals, Defense, Supply to Non - regulated markets & institutions.
4. This certificate is valid upto 17.11.2022.



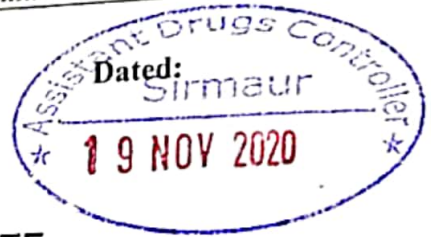

18/11/22

(SUNNY KAUSHAL)
Assistant Drug Controller,
-cum-drug licensing Authority
H.Q.Nahan District Sirmour, H.P-173001
01702-244543, adc3sirmour@gmail.com

Issued to:-
M/s HETERO LABS LIMITED
C/o M/s Nitin Lifesciences limited Unit-III
Rampurghat Road, Paonta Sahib,
District sirmour-173025 (H.P)

Health & Family Welfare Department, Himachal Pradesh
DRUGS CONTROL ADMINISTRATION H.P.
Office of Assistant Drugs Controller-cum-Drugs Licensing Authority
CMO Office Complex Nahan (H.Q) District Sirmour, 173001 INDIA
Phone No. 01702-222543, email:adc3sirmour@gmail.com

No. HFW-N/ADC/DRUGS/DMLL/2020/53 - 2270

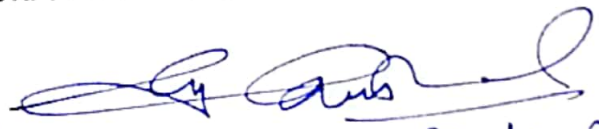


NON CONVICTION CERTIFICATE

This is to certify that M/s HETERO LABS LIMITED C/o M/s NitinLifesciences limited Unit-III, Rampurghatroad, paontasahib, District sirmour-173025 (H.P), is holding Drugs Manufacturing Under loan License bearing No. NL-MB/2020/263 issued on 21-09-2020 in the form No. 28A and is valid up to 20-09-2025, issued by this Department under the provisions of Drugs and cosmetics Act, 1940 and Rules made there under. It is further certified that the said firm has neither been convicted by the courts of Law in this state under the provisions of Drugs and cosmetics Act, 1940 and Rules made there under nor this Directorate has filed any prosecution against the Company under the provisions of the Act and Rules.

This Certificate is issued on the request of firm for participations in various Tender Enquires floated and /or to be floated by various Govt. & Semi – Government Institutions and Hospitals from time to time.




18/11/2020

(SUNNY KAUSHAL)
Assistant Drugs Controller
-cum-Drugs Licensing Authority
H.Q. Nahan Distt. Sirmour (H.P.)

ISSUED TO :

M/s HETERO LABS LIMITED
C/o M/s NitinLifesciences limited Unit-III
Rampurghat Road, Paonta Sahib,
District sirmour-173025 (H.P)