

HFW-H (Drugs) 208/09 Vol-III
HEALTH AND FAMILY WELFARE DEPARTMENT
HIMACHAL PRADESH.

To

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M/s Hetero Labs Ltd. Unit-II,
Vill. Kalyanpur, Chakkan Road,
Baddi, Distt. Solan (H.P.)

Dated, Baddi -173205

Subject: - Renewal of Drugs Manufacturing Licences.

With reference to your application No. nil of dated 19-02-2015 on the subject cited above.

Licence No. MNB/09/780 & MB/09/781 manufacturing for sale of Drugs.

- I) Other than those Specified products C & C (1) of the Drugs Rules, 1945.
- II) Specified in schedules C and C (1).

are sent herewith duly renewed

Please acknowledge the receipt.

23.3.15

(Navneet Marwaha)
State Drugs Controller
Controlling Council Authority
Baddi, Distt. Solan (H.P.) 173205
01952542426, sudhp@gmail.com

FORM 26
[See Rules 73 and 83]

**CERTIFICATE OF RENEWAL OF LICENCE TO MANUFACTURE FOR
SALE OF DRUGS OTHER THAN THOSE SPECIFIED IN SCHEDULE X.**

1. Certified that licence No. MNB/09/780 & MB/09/781 granted on dated 22-03-2010 to M/s Hetero Labs Ltd. Unit-II, for the manufacture of the following categories of drugs being other than those specified in Schedule C, C (1) and X & drugs specified in schedules C & C (1) of the Drugs and Cosmetics Rules, 1945, at the premises situated at Vill. Kalyanpur, Chakkan Road, Baddi, Distt. Solan (H.P.) has been renewed from: 22-03-2015 to 21-03-2020.

2. Name(s) approved (COMPETENT TECHNICAL STAFF)

1. Responsible for Manufacturing:

1. Sh. Bommavaran Balaakrishna
2. Sh. Yeddu Seshachalpathi

B. Sc
B. Pharma

2. Responsible for Testing

1. Sh. P. Murli Krishna
2. Sh. Dinesh Reddy

M. Sc
M. Sc (Chemistry)

3. Name of the Drugs :

Tablets & Capsules (General) and Tablets & Capsules (Oncology).

Date: 23-03-2015

Signature : (NAVNEET MARWAHA)
State Drugs Controller
Designation: Controlling cum Licensing Authority
Baddi Distt Solan (H P)-173205
01795-244288 sdc4hp@gmail.com

No.: HFW-H (Drugs) 208/09

Health & Family Welfare Department Baddi, Himachal Pradesh

List of already approved products to be manufactured by M/s Hetero Labs Ltd.

(Unit-II) situated at Village: Kalyanpur, Chakkan Road, Tehsil: Baddi, Distt.

Solan, Himachal Pradesh- 173 205 under the drug Manufacturing License No.

MNB/09/780 on form 25 Retained from 22-03-2020 to 21-03-2025

Sr. No.	Generic name	Composition	Ph. Ref	Strength	Manufactured for	Reference Earlier Approval on/DCGI Approval
1.	VELFA Sofosbuvir 400 mg and Velpatasvir 100 mg Tablets	Each film coated tablet contains: Sofosbuvir Velpatasvir Excipients	IH IH	400 mg 100 mg q.s.	For Export	23-04-2019 04-05-2017
2.	VELSOF Sofosbuvir 400 mg and Velpatasvir 100 mg Tablets	Each film coated tablet contains: Sofosbuvir Velpatasvir Excipients	IH IH	400 mg 100 mg q.s.	For Export	11-07-2019 04-05-2017
3.	SOFGEN-V Sofosbuvir 400 mg and Velpatasvir 100 mg Tablets	Each film coated tablet contains: Sofosbuvir Velpatasvir Excipients	IH IH	400 mg 100 mg q.s.	For Export	13-06-2017 04-05-2017
4.	HEPVEL Sofosbuvir 400mg and Velpatasvir 100mg Tablets	Each film coated tablet contains: Sofosbuvir Velpatasvir Excipients	IH IH	400 mg 100 mg q.s.	For Export	06-12-2016 04-05-2017
5.	Sofosbuvir 400mg and Velpatasvir 100 mg Tablets	Each film coated tablet contains: Sofosbuvir Velpatasvir Excipients Colours: Indigo carmine Aluminum lake, Brilliant blue FCF Aluminum lake and Titanium dioxide IP	IH IH	400 mg 100 mg q.s.	For Export	17-05-2017 04-05-2017
6.	VORILE 200 (Voriconazole Tablets IP 200mg)	Each film coated Tablet contains: Voriconazole Excipients Colour: Titanium Dioxide IP	IP	200mg q.s.	For Export	12-09-2016 22-05-2006

ALL PRODUCT APPROVALS AS ABOVE ARE VALID SUBJECT TO THE COMPLIANCE OF ALL KINDS OF DIRECTIVES/GUIDELINES BY THE MANUFACTURER WHICH ARE ISSUED BY DCGI/CDSCO OFFICE FROM TIME TO TIME & COMPLIANCE OF DRUGS & COSMETICS ACT 1940, RULES 1945 MADE THERE UNDER, INCLUDING AMENDMENTS MADE FROM TIME TO TIME

(Dr. KAMLESH NAIK)
ASSISTANT DRUGS CONTROLLER
-cum- LICENSING AUTHORITY
O/o STATE DRUGS CONTROLLER
BADDI, DISTRICT SOLAN, H.P.-173205
Email: dec4hp@gmail.com
Phone: 01795-244288

18 MAR 2020