

NO. HFW-H(DRUGS)DML/2015/15- 2962
HEALTH AND FAMILY WELFARE DEPARTMENT
HIMACHAL PRADESH

To

M/S HIMACHAL POLYOLEFINS LIMITED,
VILLAGE KHARI, ASGARPUR MAJRA,
YAMUNA NAGAR ROAD,
KALA AMB, DISTRICT SIRMOUR, HIMACHAL PRADESH - 173030
Nahan, dated the _____

Nahan, dated the 05/12/2022

Dated: _____ the

Subject: - Approval/Retention of (02) products.

Refer to your letter no. NIC dated 05/12/2022

The subject cited above.

Find enclosed herewith a list of 02 products duly

Retained / approved by this office and endorsed in your Drugs manufacturing License No. **N-MNB/16/172 & 12.08.2021 TO 11.08.2026**. You are directed to comply with the following conditions: -

01. 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.
02. Licensee shall comply with all the provisions for manner of labelling 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.
03. Licensee shall maintain records as prescribed under schedule M, L & U of the Drugs and Cosmetics Rules, 1945.
04. 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.
05. Licensee shall, forthwith intimate to the Licensing Authority, in the event of any adverse reaction reported by the drug.
06. Licensee shall make no claim, except those prescribed in the pharmacopoeia and permission issued by the Drugs Controller General of India.
07. The licensee will comply to all the directions/guidelines/notifications issued by DCGI/GOI by visiting website www.cdsc.gov.in .
08. The licensee will conduct BA/BE studies as per notification by Govt. of India wherever required.
09. The licensee will upload the information regarding, license/product license granted with portal SUGAM (www.cdsonline.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. 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, the product will be liable for cancellation.

Encl: List, Pages

Total Products :() Only

Garima
05.12.2022
(GARIMA SHARMA)
Assistant Drugs Controller
Cum- Drugs Licensing Authority
HQ Baddi, Sirmour-(H.P.)

1972-73

1972-73

1972-73

1972-73

1972-73

LIST OF PRODUCTS APPROVED TO BE MANUFACTURED BY Himachal Polyolefins Limited Village Khari, Asgarpur Majra, Yamuna Nagar Road, Kala Amb, District Sirmour, H.P. 173030, HAVING LICENCE NO. FORM: 25: N-MNB/16/172, GRANTED ON 12.08.2021 VALID UPTO 11.08.2026

Pack size as per – P-1-Drugs and Cosmetics Rules, 1945.

S.No.	API Name	Composition	Spc.	Qty	Pack size	Reference
01	Calcium Carbonate- USP	Calcium Carbonate USP	USP	98.0 % to 100.5%	25kg/50kg/1000kg	USP
02	Calcium Carbonate- BP	Calcium Carbonate BP	BP	98.0 % to 100.5%	25kg/50kg/1000kg	BP

APPROVALS ARE SUBJECT TO THE COMPLIANCE OF ALL DIRECTIVE/GUIDELINES ISSUED BY DCGI/COSCO FROM TIME TO TIME & COMPLIANCE OF DRUGS & COSMETICS ACT 1940 RULES 1945 MADE THERE UNDER AS AMENDED FROM TIME TO TIME

Garima
05.12.2022
(GARIMA SHARMA)
Asstt. Drugs Controller,
-cum- Licensing Authority
H.Q. Baddi, Distt. Solan
Himachal Pradesh

Handwritten notes and a date: 02.11.2004

