NO. HFW-H(Drugs)298/095/08
HEALTH AND FAMILY WELFARE DEPARTMENT
HIMACHAL PRADESH

To

M/s Nootan Pharmaceuticals,
Vill. Tipra, Barotiwala,
Haripur Road, Distt. Solan (H.P.)

Dated: the 8/2/21

Subject: - Approval/**Retention of (** One **) products.**

Refer to your letter No _____ dated _____ on the subject cited above. Find enclosed herewith a list of One additional products duly approved by this office and endorsed in your Drugs manufacturing License **MNB/09/800 & MB/09/801 valid upto 26.03.2025.** 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 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.
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.cdsco.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.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. 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 :(01 **) Only**

8/2/21
(Dr. Manish Kapoor)
DEPUTY DRUGS CONTROLLER
-cum-LICENSING AUTHORITY
O/o STATE DRUGS CONTROL
BADDI DISTRICT SOLAN, H.P.
E mail ddc4hp@gmail.com
Phone 01795-244288

No. HFW-H (Drugs) 298/09

HEALTH & FAMILY WELFARE DEPARTMENT
BADDI, HIMACHAL PRADESH

List of drugs to be manufactured by M/s Nootan Pharmaceuticals situated at village Tipra,Barotiwala Klaka Road, Tehsil Baddi,Distt.Solan under manufacturing license No.MNB/09/800 & MB/09/807 ON FORM 25& 28 valid upto 26.03.2025

Preparation Products **FOR EXPORT ONLY**

S.NO.	Name	Composition	Ph. Ref.	Strength	Pack Size	Manufactured for
01	**CEFOBACT** (Cefoperazone & Sulbactam)	Each vial contains: Cefoperazone Sodium (sterile) Eq to Cefoperazone Sulbactam sodium (sterile) Eq to Sulbactam	 USP USP	 1000mg 500mg	1.5g/vial	Export

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 OFFI TIME TO TIME & COMPLIANCE OF DRUGS & COSMETICS ACT RULES 1945 MADE THERE UNDER, INCLUDING AMENDMENTS FROM TIME TO TIME

8/2/24

(Dr. Manish Kapoor)
DEPUTY DRUGS CONTROLLER
-cum-LICENSING AUTHORITY
O/o STATE DRUGS CONTROLLER
BADDI DISTRICT SOLAN, H.P-173
E mail ddc4hp@gmail.com
Phone 01795-