NO. HFW-H (Drugs) 63/08 Vol II
HEALTH AND FAMILY WELFARE DEPARTMENT
HIMACHAL PRADESH

Digitally signed by Guțan Ghenadie
Date: 2022.04.18 09:08:30 EEST
Reason: MoldSign Signature
Location: Moldova

To

M/s Maya Biotech Pvt. Ltd.
Khasra No. 515/3, Village Kondi, P.O. Thana
Tehsil-Nalagarh, Distt. Solan (HP)

Dated: **the** 10/12/19

Subject: - **Approval of (** 08 **) Additional products.**

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

Find enclosed herewith a list of eight additional products duly approved by this office and endorsed in your Drugs manufacturing License **Nos. MB/08/725 Valid upto 11/11/2023.** You are directed to comply with the following conditions:-

01. 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.
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 and 106 of the Drugs and Cosmetics Rules, 1945.
03. Licensee shall maintain records as prescribed under schedule M 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. 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
08. 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the licensee will abide by the decision of Hon'ble Madras High Court & the products in the list of 294 FDC's will stand withdrawn if the stay if vacated by the Hon'ble Madras High Court.
09. 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 the directions /guidelines/notifications issued by DCGI/GOI by visiting website www.cdsco.gov.in .
11. The licensee will conduct BA/BE studies as per notification by Govt. of India wherever required.

Encl: List, Pages
Total Products :(08 **) Only**

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

Manish 10/12/19

(MANISH KAPOOR)
DEPUTY DRUGS CONTROLLER
-CUM-LICENSING AUTHORITY
O/O STATE DRUGS CONTROLLER
BADDI, DISTRICT SOLAN, H.P.-173205
PHONE NO. 01795-244288
EMAIL: SDC4HP@GMAIL.COM

Manish Kapoor
Deputy Drugs Controller,
-cum Licensing Authority,
O/o State Drugs Controller
Baddi, District-Solan, H.P.
01795-244288, sdc4hp@gmail.com.

HFW-H (DRUGS) 63/08 Vol II

HEALTH AND FAMILY WELARE DEPARTMENT

BADDI HIMACHAL PRADESH.

LIST OF ADDITIONAL PRODUCTS TO BE MANUFACTURED BY M/s MAYA BIOTECH PRIVATE LIMITED SITUATED AT VILL. KONDI UNDER DRUG MFG. LICENSE NO. MB/08/725 VALID FROM 12/11/2018 TO 11/11/2023

Sr. No.	Generic Name	Composition	Ph. Ref.	Strength	Pack Size	Reference
1	**Levetiracetam Injection USP 500 mg (For Export)**	**Each ml Contains:** Levetiracetam Water for Injection	 USP USP	 100 mg q.s.	5 ml	USP-2018
2	**Ketorolac Tromethamine Injection USP (For Export)**	**Each ml Contains :** Ketorolac Tromethamine Water for Injection	 USP USP	 30 mg q.s.	2 ml	USP-2018
3	**Dexketoprofen Injection 50 mg (For Export)**	**Each ml Contains :** Dexketoprofen Trometamol equivalent to Dexketoprofen Water for Injection	 USP	 25 mg q.s.	2 ml	DCGI-22/10/2009
4	**Sodium Chloride Injection BP 0.9 % w/v (For Export)**	**Composition:** Sodium Chloride Water for Injection	 BP BP	 0.9 % w/v q.s.	5 ml	BP
5	**Sodium Chloride Injection BP 0.9 % w/v (For Export)**	**Composition:** Sodium Chloride Water for Injection	 BP BP	 0.9 % w/v q.s.	10 ml	BP
6	**Parecoxib Injection 40 mg (For Export)**	**Each Vial Contains :** Parecoxib Sodium equivalent to Parecoxib		 40 mg	1x1 vial	DCGI-01/11/2002
7	**Ondansetron Injection USP (For Export)**	**Each ml Contains :** Ondansetron Hydrochloride Eq to Ondansetron Water for Injection	USP USP	 2 mg q.s.	4 ml	USP
8	**Desmopressin Nasal Spray BP (For Export)**	**Each Spray Delivers:** Desmopressin acetate Eq to Desmopressin **Composition:** Desmopressin acetate Eq to Desmopressin Benzalkonium Chloride Solution (As Preservative) Excipient	 BP BP BP 	 10 mcg 8.9 mcg 0.01% w/v 0.0089% w/v 0.02 % v/v q.s.	50 MD Spray	BP

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

10/12/19

(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