DRUGS CONTROL ADMINISTRATION
Government of Telangana

L.Dis.No:68054/TS/2022

Digitally signed by Susarencu Svetlana
Date: 2024.09.10 10:34:29 BST
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Location: Moldova
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Dated:13/06/2022
Valid until:11/06/2025

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organisation G.M.P. Certificate– Regarding

Ref: 1. Your letter dated:**22/08/2021.**
2. Joint Inspection report .

-x-x-x-x-

With reference to your application cited, I forward herewith **World Health Organisation GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration,Telangana State & Drugs Inspector, CDSCO, Hyderabad vide reference 2nd cited.

Digitally Signed By
C RAJAVARDHANA CHARY
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:13-06-2022 12:42:46 PM

L.Dis.No:68054/TS/2022 **Dated:13/06/2022** **Valid until:11/06/2025**

LIST OF PRODUCTS APPROVED UNDER WHO-GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

S.No	Generic Name	Brand Name	Composition	PackSize	Market
1	ACETYLCYSTEINE INJECTION BP 1000mg/4mL		Each mL contains Acetylcysteine BP200mg Water for InjectionUSPq.s. Excipientsq.s.		Export
2	ACETYLCYSTEINE INJECTION BP 1000mg/4mL	NACEL 1000	Each mL contains Acetylcysteine BP200mg Water for InjectionUSPq.s. Excipientsq.s.		Export
3	ACETYLCYSTEINE INJECTION BP 200mg/mL		Each mL contains Acetylcysteine BP200mg Water for InjectionUSPq.s. Excipientsq.s.		Export
4	ACETYLCYSTEINE INJECTION BP 200mg/mL	NACEL 200	Each mL contains Acetylcysteine BP200mg Water for InjectionUSPq.s. Excipientsq.s.		Export

59	CYCLOPHOSPHAMIDE FOR INJECTION USP 1000 mg	CYCLOCEL 1000	Each sterile vial contains Cyclophosphamide USP equivalent to Anhydrous Cyclophosphamide 1000 mg		Export
60	CYCLOPHOSPHAMIDE FOR INJECTION USP 1000 mg	METOPHOS 1000	Each sterile vial contains Cyclophosphamide USP equivalent to Anhydrous Cyclophosphamide 1000 mg		Export
61	CYCLOPHOSPHAMIDE FOR INJECTION USP 200mg	CYCLOCEL 200	Each Sterile vial contains Cyclophosphamide USP equivalent to Anhydrous Cyclophosphamide200mg		Export
62	CYCLOPHOSPHAMIDE FOR INJECTION USP 500 mg	C-CYCLOCEL 500	Each sterile vial contains Cyclophosphamide USP equivalent to Anhydrous Cyclophosphamide 500 mg		Export
63	CYCLOPHOSPHAMIDE FOR INJECTION USP 500 mg	CYCLOCEL 500	Each sterile vial contains Cyclophosphamide USP equivalent to Anhydrous Cyclophosphamide 500 mg		Export
64	CYCLOPHOSPHAMIDE FOR INJECTION USP 500 mg	METOPHOS 500	Each sterile vial contains Cyclophosphamide USP equivalent to Anhydrous Cyclophosphamide 500 mg		Export
65	CYTARABINE INJECTION BP 1000mg/10mL	CYTALON 1000	Each mL contains CytarabineUSP100mg Sodium HydroxideUSNFq.s. Hydrochloric AcidUSNFq.s. Water for InjectionUSPq.s.		Export
66	CYTARABINE INJECTION BP 100mg/1mL		Each mL contains CytarabineUSP100mg Sodium HydroxideUSNFq.s. Hydrochloric AcidUSNFq.s. Water for InjectionUSPq.s.		Export
67	CYTARABINE INJECTION BP 100mg/1mL	CYTALON 100	Each mL contains CytarabineUSP100mg Sodium HydroxideUSNFq.s. Hydrochloric AcidUSNFq.s. Water for InjectionUSPq.s.		Export
68	CYTARABINE INJECTION BP 100mg/1mL	CYTAVEN 100	Each mL contains CytarabineUSP100mg Sodium HydroxideUSNFq.s. Hydrochloric AcidUSNFq.s. Water for InjectionUSPq.s.		Export
69	CYTARABINE INJECTION BP 2000mg/20mL	CYTALON 2000	Each mL contains CytarabineUSP100mg Excipientsq.s. Water for InjectionUSPq.s.		Export
70	CYTARABINE INJECTION BP 500mg/5mL		Each mL contains CytarabineUSP100mg Sodium HydroxideUSNFq.s. Hydrochloric AcidUSNFq.s. Water for InjectionUSPq.s.		Export
71	CYTARABINE INJECTION BP 500mg/5mL	CYTALON 500	Each mL contains CytarabineUSP100mg Sodium HydroxideUSNFq.s. Hydrochloric AcidUSNFq.s. Water for InjectionUSPq.s.		Export
72	CYTARABINE INJECTION BP 500mg/5mL	CYTAVEN 500	Each mL contains CytarabineUSP100mg Sodium HydroxideUSNFq.s. Hydrochloric AcidUSNFq.s. Water for InjectionUSPq.s.		Export
73	DACARBAZINE FOR INJECTION USP 100mg	CELDAZ 100	Each sterile lyophilized vial contains Dacarbazine USP 100mg Excipients: Anhydrous Citric acidUSPq.s. MannitolUSPq.s. Water for InjectionUSPq.s.		Export
74	DACARBAZINE FOR INJECTION USP 200mg		Each sterile lyophilized vial contains Dacarbazine USP 200mg Excipients Anhydrous Citric acidUSPq.s. MannitolUSPq.s. Water for InjectionUSPq.s.		Export

285	ZOLEDRONIC ACID FOR INJECTION 4mg	CELDRON 4	Each sterile lyophilized vial contains Zoledronic acid Monohydrate Equivalent to Zoledronic acid 4mg Excipients q.s. Accompanying ampoule contains Water for Injection USP 5mL		Export
286	ZOLEDRONIC ACID FOR INJECTION 4mg	ZOLETRIX 4	Each sterile lyophilized vial contains Zoledronic acid Monohydrate Equivalent to Zoledronic acid 4mg Excipients q.s. Accompanying ampoule contains Water for Injection USP 5mL		Export
287	ZOLEDRONIC ACID FOR INJECTION 4mg	CELDRON	Each sterile lyophilized vial contains Zoledronic Acid Monohydrate Equivalent to Zoledronic Acid 4mg Mannitol USP 220mg Sodium Citrate USP 24mg		Export

Manufacturer: M/S **M/s CELON LABORATORIES PRIVATE LIMITED, PLOT NO-2,ALEAP INDUSTRIAL ESTATE,GAJULARAMARAM,MEDCHAL DISTRICT., GAJULARAMARAM VILLAGE, QUTHBULLAPUR MANDAL, MEDCHAL - MALKAJGIRI DISTRICT,PINCODE 500090,TELANGANA STATE,INDIA**

Drug License No: **14/RR/AP/2008/F/CC,**
Dated:18/08/2015 **Under Form 28** ,valid upto **17/08/2025**

When applicable Placing the product on the market as detailed below.

The Unit M/S **M/s CELON LABORATORIES PRIVATE LIMITED, PLOT NO-2,ALEAP INDUSTRIAL ESTATE,GAJULARAMARAM,MEDCHAL DISTRICT., GAJULARAMARAM VILLAGE, QUTHBULLAPUR MANDAL, MEDCHAL - MALKAJGIRI DISTRICT,PINCODE 500090,TELANGANA STATE,INDIATelangana State,India** was inspected jointly by

It is certified that:

i. The above products had been authorized to be placed on the market for use in the country and exported countries
ii. The manufacturing plant in which the product is produced is subject to inspection at suitable intervals.
iii. The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacture and Quality Control (As recommended by the World Health Organisation) in respect of products to be sold or distributed with in the Country of origin (or to be exported).

Digitally Signed By
C RAJAVARDHANA CHARY
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
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This Document is Digitally Signed. Signature is not required