DRUGS CONTROL ADMINISTRATION
Government of Telangana

Digitally signed by Susarencu Svetlana
Date: 2024.09.10 10:34:40 BST
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L.Dis.No:68054/TS/2022 **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

75	DACARBAZINE FOR INJECTION USP 200mg	CARBAVEN 200	Each sterile lyophilized vial contains Dacarbazine USP 200mg Excipients Anhydrous Citric acidUSPq.s. MannitolUSPq.s. Water for InjectionUSPq.s.		Export
76	DACARBAZINE FOR INJECTION USP 200mg	CELDAZ 200	Each sterile lyophilized vial contains Dacarbazine USP 200mg Excipients Anhydrous Citric acidUSPq.s. MannitolUSPq.s. Water for InjectionUSPq.s.		Export
77	DACARBAZINE FOR INJECTION USP 500mg		Each sterile lyophilized vial contains Dacarbazine USP500mg Excipients Anhydrous Citric acidUSPq.s. MannitolUSPq.s. Water for InjectionUSPq.s.		Export
78	DACARBAZINE FOR INJECTION USP 500mg	CELDAZ 500	Each sterile lyophilized vial contains Dacarbazine USP500mg Excipients Anhydrous Citric acidUSPq.s. MannitolUSPq.s. Water for InjectionUSPq.s.		Export
79	DACTINOMYCIN FOR INJECTION USP 0.5mg/VIAL		Each sterile lyophilized vial contains Dactinomycin USP0.5mg MannitolUSP20mg Water for InjectionUSPq.s.		Export
80	DACTINOMYCIN FOR INJECTION USP 0.5mg/VIAL	CELON DACTILON 0.5	Each sterile lyophilized vial contains Dactinomycin USP0.5mg MannitolUSP20mg Water for InjectionUSPq.s.		Export
81	DACTINOMYCIN FOR INJECTION USP 0.5mg/VIAL	DACILON 0.5	Each sterile lyophilized vial contains Dactinomycin USP0.5mg MannitolUSP20mg Water for InjectionUSPq.s.		Export
82	DACTINOMYCIN FOR INJECTION USP 0.5mg/VIAL	DACTILON 0.5	Each sterile lyophilized vial contains Dactinomycin USP0.5mg MannitolUSP20mg Water for InjectionUSPq.s.		Export
83	DACTINOMYCIN FOR INJECTION USP 0.5mg/VIAL	DACTIVEN 0.5	Each sterile lyophilized vial contains Dactinomycin USP0.5mg MannitolUSP20mg Water for InjectionUSPq.s.		Export
84	DACTINOMYCIN FOR INJECTION USP 0.5mg/VIAL	TINODACT 0.5	Each sterile lyophilized vial contains Dactinomycin USP0.5mg MannitolUSP20mg Water for InjectionUSPq.s.		Export
85	DOCETAXEL INJECTION USP 120mg/3.0mL WITH SOLVENT FOR DOCETAXEL INJECTION 120mg		Each combipack contains One vial of Docetaxel Injection USP 120mg/3.0mL Each sterile vial contains Docetaxel Trihydrate USP Equivalent to Docetaxel Anhydrous120mg Anhydrous Citric AcidUSP16.5mg Polysorbate 80USNF3096mg Accompanying with one vial of solvent for Docetaxel Injection 120mg Each sterile vial contains Alcohol USP 1170mg Water for Injection USP q.s. to 9.0mL		Export
86	DOCETAXEL INJECTION USP 120mg/3.0mL WITH SOLVENT FOR DOCETAXEL INJECTION 120mg	C-CELTERE 120	Each combipack contains One vial of Docetaxel Injection USP 120mg/3.0mL Each sterile vial contains Docetaxel Trihydrate USP Equivalent to Docetaxel Anhydrous120mg Anhydrous Citric AcidUSP16.5mg Polysorbate 80USNF3096mg Accompanying with one vial of solvent for Docetaxel Injection 120mg Each sterile vial contains Alcohol USP 1170mg Water for Injection USP q.s. to 9.0mL		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
Date:13-06-2022 12:42:46 PM

This Document is Digitally Signed. Signature is not required