

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

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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 Injection USPq.s. Excipientsq.s.		Export
2	ACETYLCYSTEINE INJECTION BP 1000mg/4mL	NACEL 1000	Each mL contains Acetylcysteine BP200mg Water for Injection USPq.s. Excipientsq.s.		Export
3	ACETYLCYSTEINE INJECTION BP 200mg/mL		Each mL contains Acetylcysteine BP200mg Water for Injection USPq.s. Excipientsq.s.		Export
4	ACETYLCYSTEINE INJECTION BP 200mg/mL	NACEL 200	Each mL contains Acetylcysteine BP200mg Water for Injection USPq.s. Excipientsq.s.		Export

271	VASOPRESSIN INJECTION USP 20 UNITS/1mL		Each mL contains Vasopressin USP20units Chlorobutanol USNF5mg Glacial Acetic Acid USPq.s. Water for Injection USPq.s.	Export
272	VASOPRESSIN INJECTION USP 20 UNITS/1mL	CELPRESS 20	Each mL contains Vasopressin USP20units Chlorobutanol USNF5mg Glacial Acetic Acid USPq.s. Water for Injection USPq.s.	Export
273	VASOPRESSIN INJECTION USP 20 UNITS/1mL	VASCEL 20	Each mL contains Vasopressin USP20units Chlorobutanol USNF5mg Glacial Acetic Acid USPq.s. Water for Injection USPq.s.	Export
274	VASOPRESSIN INJECTION USP 40IU/1mL	VASCEL 40	Each Pre-filled syringe contains VasopressinUSP40units ChlorobutanolUSNF5mg Glacial Acetic AcidUSPq.s. Water for injection USP q.s.	Export
275	VECURONIUM BROMIDE FOR INJECTION 10mg	VIBRO 10	Each sterile lyophilized vial contains Vecuronium Bromide USP10mg Anhydrous Citric Acid USP20.75mg Dibasic Sodium Phosphate USP16.25mg Mannitol USP97mg Phosphoric Acid USNFq.s. Sodium Hydroxide USNFq.s.	Export
276	VECURONIUM BROMIDE FOR INJECTION 4mg	VIBRO 4	Each sterile lyophilized ampoule contains Vecuronium BromideUSP4mg Anhydrous Citric Acid USP8mg Dibasic Sodium PhosphateUSP6.50mg Mannitol USP40mg Phosphoric Acid USNFq.s. Sodium Hydroxide USNFq.s.	Export
277	VINCRIStINE SULFATE FOR INJECTION USP 1mg		Each Sterile lyophilized vial contains Vincristine sulfateUSP1mg MannitolUSP100mg Sodium HydroxideUSNFq.s. Sulfuric Acid USNFq.s.	Export
278	VINCRIStINE SULFATE FOR INJECTION USP 1mg	C-VINLON LYO 1	Each Sterile lyophilized vial contains Vincristine sulfateUSP1mg MannitolUSP100mg Sodium HydroxideUSNFq.s. Sulfuric Acid USNFq.s.	Export
279	VINCRIStINE SULFATE FOR INJECTION USP 1mg	VINLON LYO 1	Each Sterile lyophilized vial contains Vincristine sulfateUSP1mg MannitolUSP100mg Sodium HydroxideUSNFq.s. Sulfuric Acid USNFq.s.	Export
280	VINCRIStINE SULFATE FOR INJECTION USP 1mg	VINQUEST	Each Sterile lyophilized vial contains Vincristine sulfateUSP1mg MannitolUSP100mg Sodium HydroxideUSNFq.s. Sulfuric Acid USNFq.s.	Export
281	VINCRIStINE SULFATE INJECTION USP 1mg		Each mL contains Vincristine Sulfate USP 1mg Mannitol USP 100mg Sodium Hydroxide USNF q.s Hydrochloric Acid USNF q.s Water for Injection USP q.s.	Export
282	VINCRIStINE SULFATE INJECTION USP1mg	VINLON 1	Each mL contains Vincristine Sulfate USP 1mg Mannitol USP 100mg Sodium Hydroxide USNF q.s Hydrochloric Acid USNF q.s Water for Injection USP q.s.	Export
283	VORICONAZOLE FOR INJECTION 200mg	VORIZ	Each sterile lyophilized vial contains VoriconazoleUSP200mg Excipientsq.s.	Export
284	ZOLEDRONIC ACID FOR INJECTION 4mg	CELDRON 4	Each sterile lyophilized vial contains Zoledronic acid Monohydrate Equivalent to Zoledronic acid 4mg Excipients q.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,INDIA** was inspected jointly by

It is certified that:

- The above products had been authorized to be placed on the market for use in the country and exported countries
- The manufacturing plant in which the product is produced is subject to inspection at suitable intervals.
- 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