

L.Dis.No:67711/TS/2022

Dated:17/06/2022
Valid until:15/06/2025

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: **17/08/2021**.
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:17-06-2022 16:00:40 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	ABIRATERONE ACETATE TABLETS USP 250mg	CELBIRA 250	Each Uncoated Tablet contains Abiraterone Acetate USP 250mg Excipients q.s.		Export
2	ANASTROZOLE TABLETS USP 1mg	AMTRAZ	Each film coated tablet contains Anastrozole USP 1mg Excipients q.s. Colour: Titanium Dioxide USP.		Export
3	ANASTROZOLE TABLETS USP 1mg	ARMILON	Each film coated tablet contains Anastrozole USP 1mg Excipients q.s. Colour: Titanium Dioxide USP.		Export
4	ANASTROZOLE TABLETS USP 1mg	C-ARMILON	Each film coated tablet contains Anastrozole USP 1mg Excipients q.s. Colour: Titanium Dioxide USP.		Export
5	BICALUTAMIDE TABLETS USP 50mg		Each film coated tablet contains Bicalutamide USP 50mg Excipients q.s. Colour: Titanium Dioxide USP.		Export

6	BICALUTAMIDE TABLETS USP 50mg	C-COSALON 50	Each film coated tablet contains BicalutamideUSP50mg Excipientsq.s. Colour: Titanium Dioxide USP.	Export
7	BICALUTAMIDE TABLETS USP 50mg	CALUTRIX	Each film coated tablet contains BicalutamideUSP50mg Excipientsq.s. Colour: Titanium Dioxide USP.	Export
8	BICALUTAMIDE TABLETS USP 50mg	COSALON 50	Each film coated tablet contains BicalutamideUSP50mg Excipientsq.s. Colour: Titanium Dioxide USP.	Export
9	BUSULFAN TABLETS USP 2mg	BUCELON 2	Each film coated tablet contains BusulfanUSP2mg Excipientsq.s. Colour: Titanium Dioxide USP.	Export
10	BUSULFAN TABLETS USP 2mg	C-BUCELON 2	Each film coated tablet contains BusulfanUSP2mg Excipientsq.s. Colour: Titanium Dioxide USP.	Export
11	CAPECITABINE TABLETS USP 150mg	CAPCEL 150	Each film coated tablet contains CapecitabineUSP150mg Excipientsq.s. Colours: Iron Oxide of Red & Titanium Dioxide USP.	Export
12	CAPECITABINE TABLETS USP 150mg	CAPTIVA 150	Each film coated tablet contains CapecitabineUSP150mg Excipientsq.s. Colours: Iron Oxide of Red & Titanium Dioxide USP.	Export
13	CAPECITABINE TABLETS USP 150mg	XELOCEL 150	Each film coated tablet contains CapecitabineUSP150mg Excipientsq.s. Colours: Iron Oxide of Red & Titanium Dioxide USP.	Export
14	CAPECITABINE TABLETS USP 500mg	CAPCEL 500	Each film coated tablet contains CapecitabineUSP500mg Excipientsq.s. Colours: Iron Oxide of Red & Titanium Dioxide USP.	Export
15	CAPECITABINE TABLETS USP 500mg	CAPTIVA 500	Each film coated tablet contains CapecitabineUSP500mg Excipientsq.s. Colours: Iron Oxide of Red & Titanium Dioxide USP.	Export
16	CAPECITABINE TABLETS USP 500mg	CXELOCEL 500	Each film coated tablet contains CapecitabineUSP500mg Excipientsq.s. Colours: Iron Oxide of Red & Titanium Dioxide USP.	Export
17	CAPECITABINE TABLETS USP 500mg	XELOCEL 500	Each film coated tablet contains CapecitabineUSP500mg Excipientsq.s. Colours: Iron Oxide of Red & Titanium Dioxide USP.	Export
18	CAPECITABINE TABLETS USP 500mg	XELORIX	Each film coated tablet contains CapecitabineUSP500mg Excipientsq.s. Colours: Iron Oxide of Red & Titanium Dioxide USP.	Export
19	CHLORAMBUCIL TABLETS USP 2mg		Each film coated tablet contains ChlorambucilUSP2mg Excipientsq.s. Colours: Iron oxide of yellow & Titanium Dioxide USP.	Export
20	CHLORAMBUCIL TABLETS USP 2mg	C-CELKERAN 2	Each film coated tablet contains ChlorambucilUSP2mg Excipientsq.s. Colours: Iron oxide of yellow & Titanium Dioxide USP.	Export
21	CHLORAMBUCIL TABLETS USP 2mg	CELKERAN 2	Each film coated tablet contains ChlorambucilUSP2mg Excipientsq.s. Colours: Iron oxide of yellow & Titanium Dioxide USP.	Export
22	CHLORAMBUCIL TABLETS USP 5mg	C-CELKERAN 5	Each film coated tablet contains ChlorambucilUSP5mg Excipientsq.s. Colours: Titanium Dioxide USP.	Export

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:17-06-2022 16:00:40 PM

This Document is Digitally Signed. Signature is not required