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No: WHO-GMP/22033218/ /B
Commissioner
Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No.8, 1st floor, Gandhinagar
Date :

06 APR 2022

To,
✓ M/s. CURIS LIFESCIENCES PVT. LTD.,
PF - 23, GIDC INDUSTRIAL ESTATE,
SANAND - II, DIST.- AHMEDABAD - 382 110

Sub :- Drugs & Cosmetics Act, 1940 & Rules thereunder.
Issue of copies of WHO-GMP Certificate

Sir,

Ref:- Your letter Dated : 14/03/2022

I send herewith World Health Organisation – Good Manufacturing Practices Certificate (WHO-GMP) in
ONE copy as desired by you.

Yours faithfully,

Anwar

for Commissioner
Food & Drugs Control Administration

No: WHO-GMP/22033218/2022/

/B Gandhinagar Date

Copy forwarded to :-

1. Assistant Commissioner, AHMEDABAD - 382 110
2. Copy to Dy. Drugs Controller, CDSCO, Air Cargo Complex, Ahmedabad
3. G-Branch.

for Commissioner
Food & Drugs Control Administration



Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN : 382010



Certificate No. : **22033218**

On the basis of the inspection carried out on **21-22/03/2022** we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1 Name & Address of site : **CURIS LIFESCIENCES PVT. LTD.**
PF - 23, GIDC INDUSTRIAL ESTATE,
CITY- SANAND - II, DIST. - AHMEDABAD - 382 110
GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/25/2225** **G/28/1632**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Tablet, Capsules, Oral Liquid, External Preparation (Cream, Ointment, Gel), Sterile Ophthalmic Ointment	General	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **29/03/2025** It becomes invalid if the activities and /or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration, Block No. 8, 1ST floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State, India. - Pin : 382010

Name & function of responsible Person : **(Dr. H. G. KOSHIA)**
Commissioner

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-232-53400

Date : **30/03/2022**





LIST OF PRODUCTS FOR GRANT OF COPP AS PER WHO GMP GUIDELINES (FOR EXPORT)

License in Form No: 25 & 28
License No: G/25/2225 & G/28/1632

VALID UP TO :

01.	PARACETAMOL TABLETS BP 500 MG	EACH UNCOATED TABLETS CONTAINS : PARACETAMOL BP 500 MG. EXCIPIENTS Q.S.
02.	IBUPROFEN TABLET BP 400 MG BRAND NAME : KWIK-400	EACH FILM COATED TABLET CONTAINS : IBUPROFEN BP 400 MG. EXCIPIENTS Q.S. COLOUR : LAKE OF ERYTHROSINE
03.	LEVOFLOXACIN TABLETS USP 500 MG BRAND NAME : LIFLO 500	EACH FILM COATED TABLET CONTAINS : LEVOFLOXACIN HEMIHYDRATE USP EQ. TO LEVOFLOXACIN.....500 MG COLOUR : SUNSET YELLOW FCF EXCIPIENTS.....Q.S.
04.	RABEPRAZOLE SODIUM TABLETS 20 MG BRAND NAME : RABON-20	EACH ENTERIC COATED TABLET CONTAINS : RABEPRAZOLE SODIUM USP.....20 MG COLOUR : TARTRAZINE EXCIPIENTS.....Q.S.
05.	ESOMEPRAZOLE TABLETS 20 MG BRAND NAME : ESOZEN 20	EACH ENTERIC COATED TABLET CONTAINS : ESOMEPRAZOLE MAGNESIUM TRIHYDRATE BP EQ. TO ESOMEPRAZOLE.....20 MG COLOUR : RED OXIDE OF IRON EXCIPIENTS.....Q.S.
06.	ESOMEPRAZOLE TABLETS 40 MG BRAND NAME : ESOZEN 40	EACH ENTERIC COATED TABLET CONTAINS : ESOMEPRAZOLE MAGNESIUM TRIHYDRATE BP EQ. TO ESOMEPRAZOLE.....40 MG COLOUR : RED OXIDE OF IRON EXCIPIENTS.....Q.S.
07.	ROSUVASTATIN TABLETS 10 MG BRAND NAME : ROSORIS 10	EACH FILM COATED TABLET CONTAINS : ROSUVASTATIN CALCIUM BP EQ. TO ROSUVASTATIN.....10 MG

FOR CURIS LIFESCIENCES PVT. LTD.

DIRECTOR



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For, Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar.

30 MAR 2022 to 29 MAR 2025

CIN No.: U24230GJ2016PTC086559

Plot No. PF/23, Nr. Acme Pharma, Opp. P & G Pharma, Sanand GIDC-II,
Sanand, Ahmedabad-382110, Gujarat (INDIA)
E-mail :- info@curisls.com



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License in Form No: 25 & 28
License No: G/25/2225 & G/28/1632

VALID UP TO :

		COLOUR : RED OXIDE OF IRON EXCIPIENTS.....Q.S.
08.	ROSUVASTATIN TABLETS 20 MG BRAND NAME : ROSORIS 20	EACH FILM COATED TABLET CONTAINS : ROSUVASTATIN CALCIUM BP EQ. TO ROSUVASTATIN.....20 MG COLOUR : RED OXIDE OF IRON EXCIPIENTS.....Q.S.
09.	LOSARTAN POTASSIUM & HYDROCHLOROTHIAZIDE TABLETS USP BRAND NAME : LOSAZEN-H	EACH FILM COATED TABLET CONTAINS : LOSARTAN POTASSIUM USP.....50 MG HYDROCHLOROTHIAZIDE BP.....12.5 MG COLOUR : TITANIUM DIOXIDE BP EXCIPIENTS.....Q.S.
10.	PANTOPRAZOLE SODIUM TABLETS 40 MG. BRAND NAME : P-ZOLE 40	EACH ENTERIC COATED TABLET CONTAINS : PANTOPRAZOLE SODIUM USP EQ. TO PANTOPRAZOLE 40 MG. COLOR : REC OXIDE OF IRON EXCIPIENTS Q.S.
11.	LEVOCETIRIZINE DIHYDROCHLORIDE TABLET IP 5 MG.	EACH FILM COATED TABLET CONTAINS : EACH FILM COATED TABLET CONTAINS : LEVOCETIRIZINE HYDROCHLORIDE IP..5 MG. COLOR : TITANIUM DIOXIDE IP EXCIPIENTS Q.S.
12.	TADALAFIL TABLETS USP 20 MG. BRAND NAME : TADASTAR 20	EACH FILM COATED TABLET CONTAINS : TADALAFIL USP 20 MG. COLOR : YELLOW OXIDE OF IRON & TITANIUM DIOXIDE EXCIPIENTS Q.S.



FOR, CURIS LIFESCIENCES PVT. LTD.

DIRECTOR

Ramesh
For, Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar.

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30 MAR 2022 to 29 MAR 2025



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License in Form No: 25 & 28
License No: G/25/2225 & G/28/1632

VALID UP TO :

13.	ETORICOXIB TABLETS 90 MG BRAND NAME : ZETCOXI	EACH FILM COATED TABLET CONTAINS : ETORICOXIB 90 MG. EXCIPIENTS Q.S. COLOR : TITANIUM DIOXIDE
14.	ITRACONAZOLE CAPSULE 100 MG.	EACH HARD GELATIN CAPSULE CONTAINS : ITRACONAZOLE BP 100 MG. (AS PELLETS) EXCIPIENTS Q.S. APPROVED COLOURS USED IN EMPTY CAPSULE SHELL.
15.	CELECOXIB CAPSULES 200 MG. BRAND NAME : BEECOX	EACH HARD GELATIN CAPSULE CONTAINS : CELECOXIB BP 200 MG. EXCIPIENTS Q.S. APPROVED COLOUR USED IN EMPTY CAPSULE SHELL.
16.	PARACETAMOL ORAL SUSPENSION BP 125MG/5ML	EACH 5 ML. CONTAINS : PARACETAMOL BP 125 MG. FLAVOURED SYRUP BASE Q.S. COLOUR : PONCEAU 4R
17.	METHYL SALICYLATE OINTMENT 25% W/W	METHYL SALICYLATE BP 25% W/W OINTMENT BASE Q.S.
18.	ACICLOVIR EYE OINTMENT IP 3% W/W	ACICLOVIR IP 3% W/W BENZALCONIUM CHLORIDE IP 0.01% W/W (AS PRESERVATIVE) STERILE OINTMENT BASE Q.S.



FOR, CURIS LIFESCIENCES PVT. LTD.


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Ramesh
For, Commissioner
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