



COMMISSIONER,
FOOD & DRUGS CONTROL ADMINISTRATION,
Dr. Jivraj Mehta Bhavan, Block No.8, 1ST Floor, Gujarat State. Gandhinagar-382010.



No.Incl-AP/WHO-GMP/Curis/2022/
Date.

/B1

67101
9 NOV 2022

TO,
M/S. CURIS LIFESCIENCES PVT. LTD.,
PF-23, GIDC INDUSTRIAL ESTATE,
SANAND - II, AHMEDABAD- 382 110

SUB:- Drugs & Cosmetics Act, 1940 & Rules thereunder. (FOR EXPORT ONLY)
Inclusion of four products in the approved WHO-GMP Certificate.

Dear Sir,

REF:- (1) Your letter Dated.04.11.2022.
(2) Letter of Deputy Drugs Controller (India) CDSCO, Sub Zonal Office, Air Cargo Complex, Airport, Ahmedabad No.12/1/2022-WHO-GMP/1868, Dated.14.09.2022.

With reference to above I have to inform you that, following four additional products are included in the approved WHO-GMP Certificate issued by this Administration on Dated.**30.03.2022** No. **22033218**, which is valid up to: **29.03.2025**.

1. Doxycycline Capsules BP 100 mg DOXYZEN-100
2. Azithromycin Oral Suspension 200 mg / 5 ml AZISER 200 SUSPENSION
3. Metronidazole Tablets BP 200 mg METROWELL 200
4. Aceclofenac and Paracetamol Tablets PACE

Yours faithfully,

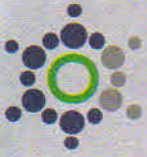

For Commissioner
Food & Drugs Control Administration,
Gandhinagar, Gujarat State

No.Incl-AP/WHO-GMP/Curis/2022/ /B1, GANDHINAGAR, Date:

Copy with a copy of attested list of product forwarded to:-

1. The Assistant Commissioner, **GANDHINAGAR** for information.
2. 'G' Branch for information.
3. The Deputy Drugs Controller (India), CDSCO, Sub Zonal Office, Air Cargo Complex, Airport, Ahmedabad for information to his letter Dated.14.09.2022.

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



LIST OF PRODUCTS FOR GRANT OF COPP AS PER WHO GUIDELINES VALID UPTO Dt.29.03.2025

LICENSE IN FORM NO: 25
LICENSE NO: G/25/2225

SR. NO.	NAME OF THE PRODUCT	COMPOSITION
01.	METRONIDAZOLE TABLETS BP 200 MG BRAND NAME : METROWELL 200	EACH FILM COATED TABLET CONTAINS: METRONIDAZOLE BP.....200 MG EXCIPIENTS.....Q.S. COLOUR :TITANIUM DIOXIDE BP
02.	ACECLOFENAC & PARACETAMOL TABLETS BRAND NAME : PACE	EACH FILM COATED TABLET CONTAINS: ACECLOFENAC BP.....100 MG PARACETAMOL BP.....500 MG: EXCIPIENTS.....QS COLOR : SUNSET YELLOW

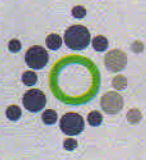
FOR CURIS LIFESCIENCE PVT. LTD.

AUTHORIZED SIGNATORY



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

7. NOV 2022



**LIST OF PRODUCTS FOR GRANT OF COPP AS PER WHO
GUIDELINES VALID UPTO Dt.29.03.2025**

LICENSE IN FORM NO: 28
LICENSE NO: G/28/1632

SR. NO.	NAME OF THE PRODUCT	COMPOSITION
01.	DOXYCYCLINE CAPSULES BP 100 MG BRAND NAME : DOXYZEN-100	EACH HARD GELATIN CAPSULE CONTAINS: DOXYCYCLINE HYCLATE BP EQ. TO ANHYDROUS DOXYCYCLINE.....100 MG EXCIPIENTS.....Q.S. APPROVED COLOUR USED IN EMPTY CAPSULE SHELL
02.	AZITHROMYCIN ORAL SUSPENSION 200 MG/5 ML BRAND NAME : AZISER 200 SUSPENSION	EACH 5 ML CONTAINS: AZITHROMYCIN DIHYDRATE USP EQ. TO ANHYDROUS AZITHROMYCIN.....200 MG COLOR: QUINOLINE YELLOW FLAVOURED SYRUPY B

FOR CURIS LIFESCIENCE PVT. LTD.

AUTHORIZED SIGNATORY



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

7 NOV 2022