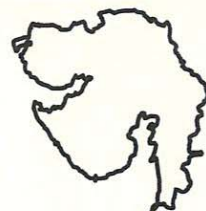




Food & Drugs Control Administration

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



Certificate No. : **19061470**

On the basis of the inspection carried out on **16-17/05/2019 & 24/06/2019** 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 : **CTX LIFE SCIENCES PVT. LTD.**

**BLOCK NO. 251/P, 252/P, 253 TO 255,
256/P, 258/P, 276/P, 277, 278/P, 279 TO 282, 283/P, 284/P, GIDC,**

City : SACHIN, Dist. SURAT

GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/25/1723**

3 Table : 1

| Dosage Form (s) | Category (ies) | Activity (ies) |
|-------------------|----------------|----------------|
| Bulk Drugs (APIs) | 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 **01/07/2022**. 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

Email : comfdca@gujarat.gov.in

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

Date : **02/07/2019**

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



Reference Copy

**LIST OF PRODUCTS APPROVED UNDER WHO-GMP CERTIFICATION AS SPECIFIED
IN FORM 25 MANUFACTURING LICENCE NO. G/25/1723 [VALID UPTO 23/01/2021]
LIST OF PRODUCTS FOR THE GRANT OF COPP AS PER WHO GUIDELINES
(FOR EXPORT ONLY)**

| Sr. No. | Name of Product (API) | Pharmacopoeia |
|---------|-------------------------------------|-----------------|
| 1. | Acetazolamide | IP/USP/EP/BP |
| 2. | Alendronate Sodium | USP/EP |
| 3. | Amiodarone Hydrochloride | EP/BP/USP |
| 4. | Candesartan Cilexetil | USP/EP |
| 5. | Carbamazepine | IP/USP/EP/BP |
| 6. | Carvedilol | USP/BP/EP |
| 7. | Chlorothiazide | IP/USP/EP/IH |
| 8. | Ciprofloxacin Hydrochloride | IP/USP/EP/BP |
| 9. | Hydrated Dihydralazine Sulfate | BP/EP |
| 10. | Hydrochlorothiazide | IP/USP/BP/EP |
| 11. | Irbesartan | USP/EP |
| 12. | Lamotrigine | IP/USP/EP/BP |
| 13. | Levetiracetam | USP |
| 14. | Mesalamine/Mesalazine | USP/EP/BP |
| 15. | Metoprolol Succinate | IP/USP/BP/EP |
| 16. | Metoprolol Tartrate | IP/USP/BP/EP |
| 17. | Olmesartan Medoxomil | IP/EP/BP/USP |
| 18. | Ondansetron Hydrochloride | USP/EP/BP |
| 19. | Oxcarbazepine | IP/IH/EP/BP/USP |
| 20. | Oxymetazoline Hydrochloride | IP/USP/BP/EP |
| 21. | Pregabalin | IP/IH/EP/BP/USP |
| 22. | Sevelamer Carbonate | IH |
| 23. | Sevelamer Hydrochloride | IH |
| 24. | Terazosin Hydrochloride Dihydrate | USP/EP/BP |
| 25. | Terbinafine Hydrochloride | USP/EP/BP |
| 26. | Xylometazoline Hydrochloride | IP/USP/BP/EP |
| 27. | Duloxetine Hydrochloride | USP/EP |
| 28. | Deferasirox | IH |
| 29. | Rosuvastatin Calcium | IP/IH/EP/BP |
| 30. | Eslicarbazepine Acetate | IH/IP |
| 31. | Saxagliptin Hydrochloride Dihydrate | IH |
| 32. | Apixaban | IH |
| 33. | Azilsartan Medoxomil Potassium | IH |
| 34. | Propranolol Hydrochloride | USP/EP/BP |

FOR CTX LIFESCIENCES PVT. LTD.

AUTHORIZED SIGNATORY

FOR COMMISSIONER
FOOD & DRUGS CONTROL ADMINISTRATION
GUJARAT STATE
- 2 JUL 2019 To 1 JUL 2022

CTX LIFESCIENCES PVT. LTD.

Works : Block No. 251-252, Sachin-Magdalla Road, GIDC, Sachin, Surat - 394 230. Gujarat, INDIA.

Tel. : 0261-2399669, 2398456 • Fax : 0261-2398547 • Website : www.ctxls.com

Redg. Off : 91, Surat - Navsari Road, Bhestan, SURAT - 395 023, Gujarat, INDIA. • Tel. : +91-261 2897800 / 2897801

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