



Food & Drugs Control Administration

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



Certificate No. : **19061470**

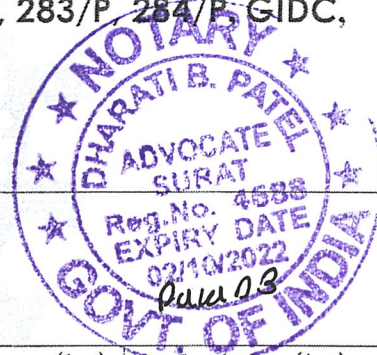
On the basis of the inspection carried out on **16-17/05/2019 & 24/06/2019** we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

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

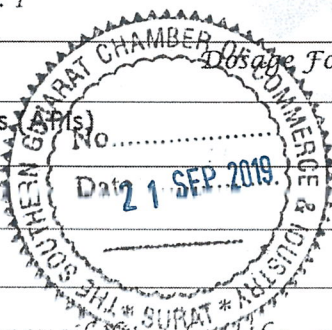
GUJARAT STATE, INDIA



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

3 Table : 1

BY ATTESTING THIS DOCUMENTS CHAMBER DOES NOT UNDERTAKE ANY FINANCIAL OR OTHER RESPONSIBILITIES		Category (ies)	Activity (ies)
ATTESTED		General	Manufacturer
(J. P. SAIGAL) CEO THE SOUTHERN GUJARAT CHAMBER OF COMMERCE & INDUSTRY, SURAT.			



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

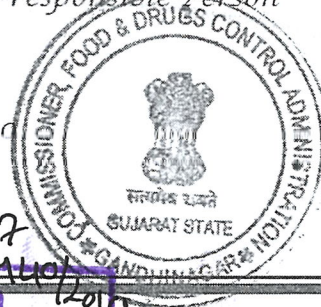
Food & Drugs Control Administration,
Block No. 8, 1ST floor, Dr. Jivraj Mehta
Bhavan, Gandhinagar, Gujarat State,
India. – Pin : 382010

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253117, Fax : 91-79-232-53100

Date : **02/07/2019**

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



ATTESTED

Patel DB

DHARATI B. PATEL
ADVOCATE & NOTARY
Govt. of India
SURAT (Gujarat)

BOOK NO. 32

Register
Date: **19 SEP 2019**
My Commission Expires
on 2nd Oct-2022

19 SEP 2019



 भारत सरकार / **GOVERNMENT OF INDIA**
अपीस्टिल / **APOSTILLE**
(Convention de La Haye du 5 octobre 1961)

The Ministry of External Affairs
for the

Country **REPUBLIC OF INDIA**

This public document
COMMERCIAL DOCUMENT
has been signed by **H.G. KOSHIA**
acting in the capacity of **COMMISSIONER**
bears the seal/stamp of **CEO, THE SOUTHERN GUJARAT
CHAMBER OF COMMERCE AND INDUSTRY, SURAT**

Certified
at **NEW DELHI, INDIA** the **12-Feb-2020**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **GJST0004153020**

Seal / Stamp  Signature 

is issued to **CTX LIFE SCIENCES PVT. LTD.**
(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (OI)
श्री. पी. वी. प्रभास / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi



**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.

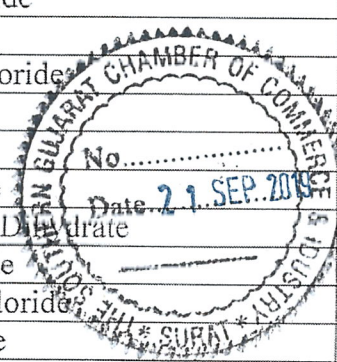
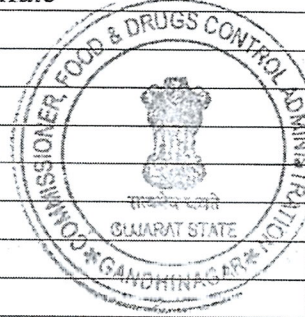
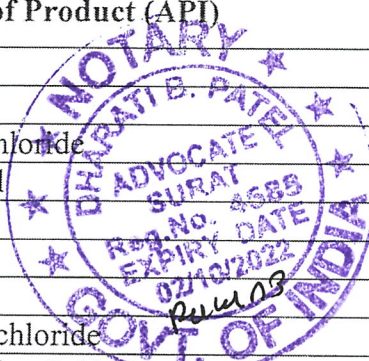
AUTHORIZED SIGNATORY

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



FOR COMMISSIONER
FOOD & DRUGS CONTROL ADMINISTRATION
GUJARAT STATE

- 2 JUL 2022 to 1 JUL 2022



Administración de Control de Alimentos & Medicamentos

BLOCK NO. 8, 1^{er} Piso, Dr. JIVRAJ MEHTABHAVAN,
GANDHINAGAR, ESTADO DE GUJARAT, INDIA PIN: 382010



Certificado No: **19061470**

En base a la inspección llevada a cabo el **16-17/05/2019 & 24/06/2019** certificamos que el sitio indicado en este certificado cumple con las Buenas Prácticas de Manufactura para las formas de dosis, categorías y actividades listadas en la Tabla 1.

1. Nombre & Dirección del sitio: **CTX LIFE SCIENCES PVT. LTD.**
BLOCK NO. 251/P, 252/P, 253 A 255,
256/P, 258/P, 276/P, 277, 278/P, 279 A 282, 283/P, 284/P, GIDC.
Ciudad: SACHIN, Dist: SURAT,
ESTADO DE GUJARAT, INDIA

2. Número de Licencia del Fabricante: **G/25/1723**

3. Tabla: 1

Forma(s) de Dosis	Categoría(s)	Actividad(es)
Medicamentos en Lote (APIs)	General	Fabricante

La responsabilidad por la calidad de los lotes individuales de productos farmacéuticos fabricados a través de este proceso recae en el fabricante.

Este certificado es válido hasta el **01/07/2022**. Queda invalidado si las actividades y/o categorías certificadas en el mismo son cambiadas o si el sitio deja de ser considerado como en cumplimiento con las BPM.

El formato de este certificado está según OMS TRS No. 908 del 2003.

Dirección de la autoridad certificadora

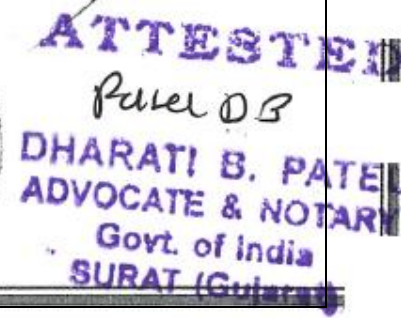
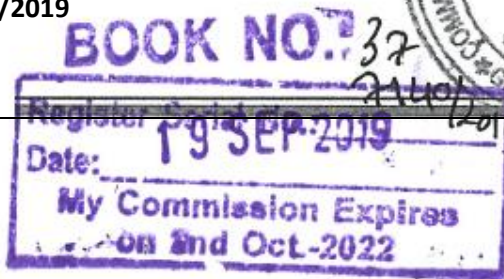
Administración de Control de Alimentos & Medicamentos, Block No. 8, 1^{er} piso, Dr. Jivraj Mehta Bhavan, Gandhinagar, Estado de Gujarat, India. – Pin : 382010

Email : comfdca@gujarat.gov.in

Teléfono: 91-79-23253417, Fax : 91-79-2 32-53400

Fecha : **02/07/2019**

Nombre & función de : (Dr. H.G. KOSHIA)
la Persona responsable Comisionado



19 SEP 2019

Vani Silva Sepúlveda
Asesor Técnico
Ascend Laboratories SpA



 भारत सरकार / GOVERNMENT OF INDIA
अपिष्टित / APOSTILLE for the
(Convention of La Haye du 5 octobre 1961)

The Ministry of External Affairs

Country **REPUBLIC OF INDIA**

This public document
COMMERCIAL DOCUMENT
has been signed by **H.G. KOSHIA**
acting in the capacity of **COMMISSIONER**
bears the seal/stamp of **CEO, THE SOUTHERN GUJARAT
CHAMBER OF COMMERCE AND INDUSTRY, SURAT**

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 (सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (OI)
श्री. पी. वी. प्रधान / C.P.V. Division
विदेश संचालक, नई दिल्ली
Ministry of External Affairs, New Delhi

**LISTA DE PRODUCTOS APROBADOS BAJO CERTIFICACIÓN OMS-BPM SEGÚN LO ESPECIFICADO
EN FORMA 25 LICENCIA DE FABRICACIÓN NO. G/25/1723 | VÁLIDO HASTA EL 23/01/2021 |
LISTA DE PRODUCTOS PARA EL OTORGAMIENTO DEL COPP SEGÚN LAS DIRECTRICES OMS
(SOLO PARA EXPORTACIÓN)**

Sr. No.	Nombre del Producto (API)	Farmacopea
1.	Acetazolamida	IP/USP/EP/BP
2.	Alendronato de Sodio	USP/EP
3.	Clorhidrato de Amiodarona	EP/BP/USP
4.	Candesartán Cilexetil	USP/EP
5.	Carbamazepina	IP/USP/EP/BP
6.	Carvedilol	USP/BP/EP
7.	Clorotiazida	IP/USP/EP/IH
8.	Clorhidrato de Ciprofloxacina	IP/USP/EP/BP
9.	Sulfato de Dihidralazina Hidratada	BP/EP
10.	Hidroclorotiazida	IP/USP/BP/EP
11.	Irbesartán	USP/EP
12.	Lamotrigina	IP/USP/EP/BP
13.	Levetiracetam	USP
14.	Mesalamina/Mesalazina	USP/EP/BP
15.	Succinato de Metoprolol	IP/USP/BP/EP
16.	Tartrato de Metoprolol	IP/USP/EP/BP
17.	Olmesartán Medoxomilo	IP/EP/BP/USP
18.	Clorhidrato de Ondansetron	USP/EP/BP
19.	Oxcarbazepina	IP/IH/EP/BP/USP
20.	Clorhidrato de Oximetazolina	IP/USP/BP/EP
21.	Pregabalina	IP/IH/EP/BP/USP
22.	Carbonato de Sevelamer	IH
23.	Clorhidrato de Sevelamer	IH
24.	Clorhidrato de Terazosina Dihidrato	USP/EP/BP
25.	Clorhidrato de Terbinafina	USP/EP/BP
26.	Clorhidrato de Xilometazolina	IP/USP/BP/EP
27.	Clorhidrato de Duloxetina	USP/EP
28.	Deferasirox	IH
29.	Rosuvastatina de Calcio	IP/IH/EP/BP
30.	Acetato de Eslicarbazepina	IH/IP
31.	Dihidrato de hidrocloreuro de saxagliptina	IH
32.	Apixaban	IH
33.	Azilsartán medoxomilo potasio	IH
34.	Propranolol clorhidrato	USP/EP/BP

PARA CTX LIFESCIENCES PVT. LTD.

SIGNATARIO AUTORIZADO

CTX LIFESCIENCES PVT. LTD.*

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

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