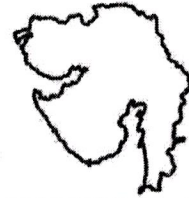




Food & Drugs Control Administration

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



Certificate No. : **19081538**

On the basis of the inspection carried out on **09-10/07/2019 & 13/08/2019** 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 : **OPES HEALTHCARE PRIVATE LIMITED**
11, TRIMUL ESTATE., KHATRAJ, TAL -KALOL,
City : KHATRAJ, Dist. GANDHINAGAR
GUJARAT STATE, INDIA

- 2 Manufacturer's Licence number : **G/25-A/5142-A** **G/28-A/6287-A**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Oral Liquid, Ophthalmic Preparations/Solutions, and SVP Liquid and SVP Dry Powder formulations	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 **21/08/2022**. 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

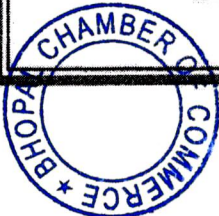
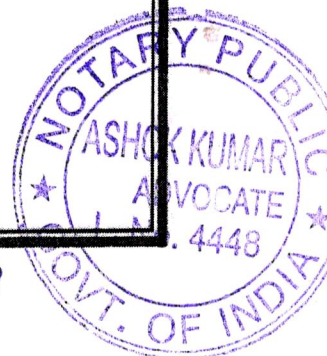
Food & Drugs Control Administration,
Block No. 8, 1ST floor, Dr. Jivraj Mehta
Bhavan, Gandhinagar, Gujarat State,
India. - Pin : 382010

Email : comfdca@gujarat.gov.in

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

Date : **29/08/2019**

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




19 JUN 2020

ATTESTED

BHOPAL CHAMBER OF COMMERCE

ATTESTED

NOTARY PUBLIC
DELHI (INDIA)

 भारत सरकार / The Ministry of External Affairs
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by DY. COMMISSIONER
acting in the capacity of DY. COMMISSIONER
bears the seal/stamp of BHOPAL CHAMBER OF COMMERCE

Certified
NEW DELHI, INDIA the 22-Jun-2020
SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
MPBP0009522320

Seal / Stamp is issued to OPES HEALTHCARE PVT. LTD. Signature



(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ. आई.)
Section Officer (OI)
सी. पी. ओ. प्रभाग / C.P.V. Division
मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

ATTESTED

BHOPAL CHAMBER OF COMMERCE



TRADUCCION GMP



Food & Drugs Control Administration
BLOCK NO. 8, 1ST FLOOR, DR. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA PIN-382010



Certificado No.: **19081538**

En las bases de inspección llevada a cabo desde el 09-10/07/2019 y 13/08/2019 nosotros certificamos que el sitio indicado cumple con las Buenas Prácticas de Manufactura para las formas farmacéuticas, categorías y actividades listadas en la tabla 1

- 1.- Nombre y Dirección del sitio: **OPES HEALTHCARE PRIVATE LIMITED**
11, TRIMUL ESTATE, KHATRAJ TAL-KALOL
City: KHATRAJ, Dist. GANDHINAGAR
GUJARAT STATE, INDIA
- 2.- Licencia de Manufactura No: G/25-A/5142-A G/28-A/6287-A

3. Tabla 1:

Forma Farmacéutica (s)	Categoría (s)	Actividad (s)
Líquidos orales, Preparaciones y soluciones oftálmicas y formulaciones SVP (Soluciones Parenterales de Pequeño volumen) Líquidas y Polvo seco.	General	Fabricación

La responsabilidad por la calidad de los lotes individuales de la fabricación de productos farmacéuticos en todo este proceso es del fabricante.

Este certificado es válido hasta el **21/08/2022**. Se convierte en no válido si se cambian las actividades y/o categorías certificadas adjunto o si el sitio ya no se considera para estar en conformidad con las BPF.

El formato del Certificado está de acuerdo con WHO TRS No. 908 of 2003.

Address of certifying authority Food & Drugs Control Administration, Block No. 8, 1 ST 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 : 29/08/2019		Name & function of responsible Person  (Dr. H.G. KOSHTIA) Commissioner	
			
			
ATTESTED BHOVAL CHAMBER OF COMMERCE		ATTESTED NOTARY PUBLIC DELHI (INDIA)	



Traducido por:

QF. Patricio Iturra Diaz.

PATRICIO ITURRA D.
16.282.809-6
Químico Farmacéutico