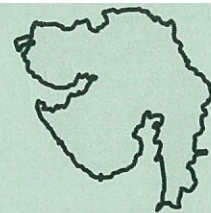




Food & Drugs Control Administration

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



Certificate No. : **1808971**

On the basis of the inspection carried out on **13-14/06/2018** 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 : **STERLING BIOTECH LIMITED**

JAMBUSAR STATE HIGHWAY, VILLAGE- MASAR, TAL- PADRA

City : **MASAR -391 421**, Dist : **VADODARA, GUJARAT STATE, INDIA**

2 Manufacturer's Licence number : **G/25/1780 G/28/1287**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drug (APIs)	General	Manufacturer
Bulk Drug (APIs)	Cytotoxic	

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 **12/08/2021**. 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 : **(Dr. H.G. KOSHIA)**
responsible Person **Commissioner**

Email : **comfdca@gujarat.gov.in**

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

Date : **13/08/2018**





STERLING BIOTECH LIMITED

Works : Jambusar State Highway, Village Masar-391 421, Ta. Padra, Vadodara.
Gujarat, India. Tel. : +91-2662237301 / 2, 320620, Fax : +91-2662237304
CIN No. : L51900 MH1985 PLC 035738

LIST OF PRODUCT

Manufacturing License No: G/25/1780 and G/28/1287

List of products applied for grant of COPP as per WHO Guidelines (For Export).

Sr. No.	NAME OF PRODUCT	Remarks	Category
1	LOVASTATIN	USP/EP/BP	General
2	DAUNORUBICIN HYDROCHLORIDE	USP/BP/EP	Cytotoxic
3	DOXORUBICIN HYDROCHLORIDE	USP/BP/EP	Cytotoxic
4	EPIRUBICIN HYDROCHLORIDE	USP/EP /BP	Cytotoxic
5	DACARBAZINE	USP/EP	General
6	SIMVASTATIN	USP/BP/EP	General
7	IDARUBICIN HYDROCHLORIDE	USP	Cytotoxic

For STERLING BIOTECH LTD,

Kalpesh R. Pathak
Vice President (Quality & RA)



FOR COMMISSIONER
FOOD & DRUGS CONTROL ADMINISTRATION
GUJARAT STATE.

13 AUG 2018 To 12 AUG 2021