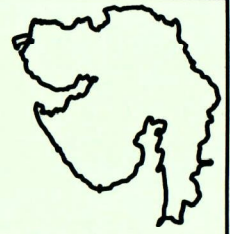




Food & Drugs Control Administration

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



Certificate No. : **21062636**

On the basis of the inspection carried out on **15-16/06/2021** 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 **27/06/2024**. 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 : 28/06/2021



STERLING BIO TECH LIMITED

Works : Jambusar State Highway, Village Masar - 391 421, Tal. Padra, Vadodara,
Gujarat India. M. : 7874726490/91
CIN NO : L51900 MH1985 PLC 035738

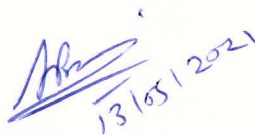
LIST OF PRODUCT

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

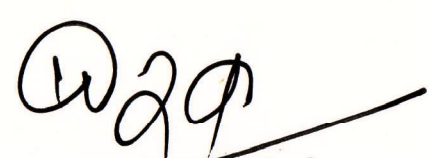
List of Products for grant of COPP as per WHO Guidelines (For Export).

Sr. No.	NAME OF PRODUCT	Remarks	Category
Drugs in Form No.: 25 bearing Licence number: G/25/1780			
1	LOVASTATIN	USP/EP/BP	General
Drugs in Form No.: 28 bearing Licence number: G/28/1287			
2	DAUNORUBICIN HYDROCHLORIDE	USP/BP/EP	Cytotoxic
3	DOXORUBICIN HYDROCHLORIDE	USP/BP/EP	Cytotoxic
4	EPIRUBICIN HYDROCHLORIDE	USP/EP /BP	Cytotoxic

For STERLING BIOTECH LTD,


Atit Desai
DGM
(Quality & RA)




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

28 JUN 2021 + 27 JUN 2024