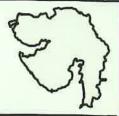


Food & Drugs Control Administration

BLOCK NO. 8, 15t FLOOR, Dr. JIVRAJ MEHTA BHAVAN, GANDHINAGAR, GUJARAT STATE, INDIA PIN: 382010



Certificate No.: **20011814**

On the basis of the inspection carried out on 02-03/11/2017 & 30/12/2017 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:

FERMENTA BIOTECH LIMITED

PLOT N O. Z-109 B & C, SEZ-II, DAHEJ, TAL - VAGRA

City: DAHEJ, Dist: BHARUCH, GUJARAT STATE, INDIA

Manufacturer's Licence number:

G/25/1983

G/28/1426

Table: 1

	Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs(APIs)		General	Manufacturer
	3		

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate was valid until **02/01/2020**. Now the validity is further extended until **02/07/2020**. 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

: comfdca@gujarat.gov.in Email

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

Date : 17/01/2020 Name & function of : (Dr.H.G. KOSHIA) responsible Person

Commissioner

menta Biotech Limited.

CIN: U99999MH1986PLC134021

Factory: Z - 109 B & C, SEEZ II, Dahej, Taluka - Vagara, Dist: Bharuch - 392 130, Gujarat, india.

Tel.: +91-2641-291440 / 444 • Email: info@fermentabiotech.com

Website.: www.fermentabiotech.com



List of product for grant of COPP as per WHO Guideline (For Export).

LIC. IN FORM NO. 28 :

Lic. No. G/28/1426

Name of Product

- 1) CHOLECALCIFEROL IP (VITAMIN D3)
- 2) CHOLECALCIFEROL USP (VITAMIN D3)
- 3) CHOLECALCIFEROL Ph.Eur (VITAMIN D3)
- 4) CHOLECALCIFEROL BP (VITAMIN D3)



For FERMENTA BIOTECH LTD.

Assuming

Authorised Signatory

For Commissioner

Food & Drugs Control Administration
Gujarat State Gandhinager

= 3 JAN 2018 - 2 JAN 2020

Regd. Office: A - 1501, Thane One, DIL Complex,

Ghodbunder Road, Majiwada,

Thane (W) - 400 610, Maharashtra, India.

Tel. : +91-22-6798 0888

Fax. : +91-22-6798 0899

Email : info@fermentabiotech.com

Website : www.fermentabiotech.com

Factory: Village Takoli, P.O. Nagwain,

Dist. Mandi - 175 121, Himachal Pradesh, India.

Tel. : +91-1905-287246 / 48 / 49 Fax : +91-1905-287250

Email : info@fermentabiotech.com Website : www.fermentabiotech.com