

Health & Family Welfare Department
Drugs Control Administration HP
F D A Bhawan, Zonal Hospital Complex,
Office of the Assistant Drug Controller cum Licensing Authority
H.Q. Mandi-175001, Himachal Pradesh. INDIA

HSR/ADC/MND/2018-338

27 September 2018

WHO-GMP COMPLIANCE CERTIFICATION

Certified that **M/s. FERMENTA BIOTECH LIMITED**, situated at Village Takoli, P.O. Nagwain-175121, District Mandi, Himachal Pradesh, INDIA is holding valid drugs manufacturing licenses in **Form 25 (MNB/2000/32 granted on 02.12.2000 and valid up to 31.12.2021)** and **Form 28 (MB/2004/NZ/5 granted on 26.03.2004 and valid up to 25.03.2019)** issued by this administration under the provisions of Drugs & Cosmetics Act, 1940 & Rules, 1945 there under.

Under the said licences, the firm is permitted to manufacture for sale or for distribution their products covered under the category of "**Active Pharmaceutical Ingredients**" in their manufacturing facility, which is subject to inspection at suitable intervals by competent authorities.

The unit was jointly inspected by the officers of Central Drugs Standard Control Organization and Drugs Control Administration, Himachal Pradesh for revalidation of COPPs. The joint inspection team observed and reported the manufacturing facility complies with WHO-GMP certification scheme.

It is therefore certified that the firm conforms to the requirements for **GOOD MANUFACTURING PRACTICES** in the manufacture and quality control as **WORLD HEALTH ORGANISATION** specification in respect of products, mentioned below:

1. Cholecalciferol (IP/USP/Ph. Eur.)
2. Cholecalciferol Solution/Concentrate (Oily Form) in Corn Oil (USP/ Ph. Eur.)
3. Cholecalciferol Solution/Concentrate (Oily Form) in Soyabean Oil (USP/ Ph. Eur.)
4. Cholecalciferol Solution/Concentrate (Oily Form) in MCT Oil (USP/ Ph. Eur.)
5. Phenyramidol Hydrochloride
6. Silicon Powder

The compliance certification is valid for a period of **Three years** from **12.08.2018** to **11.08.2021**



ASSISTANT DRUG CONTROLLER
CUM DRUGS LICENSING AUTHORITY
Drugs Control Administration,
H.Q. Mandi, H.P. INDIA-175001


27-9-18
(MANISH KAPOOR)

**Assistant Drug Controller cum Licensing Authority
H.Q. Mandi, Himachal Pradesh. INDIA-175001**