GOVERNMENT OF RAJASTHAN DRUGS CONTROL ORGANISATION SWASTHYA BHAWAN, TILAK MARG, JAIPUR

Certificate No.DC/D-2/WHO GMP/2019/278

Dated: 05/11/2019

Certificate of Good Manufacturing Practices

On the basis of the Joint inspection carried out by officers of CDSCO, (North Zone) Ghaziabad and State Drugs Control Officer on 26 and 27 August, 2019 it is certified that the site indicated on this certificate complies with Good Manufacturing Practices as recommended by WHO in general instruction and explanatory notes for the starting material (API's) categories and activities listed in table below:

Name of firm	M/s Western Drugs Limited,
Site address of the firm	F 271 (A), Mewar Industrial Area, Madri, Udaipur (Rajasthan)
Manufacturers Licence No. Date of	Raj-1497
issue &	11.05.2010
Validity upto	10.05.2020
	(Retention Applied for 11.05.2020 to 10.05.2025)
Categories & Dosage form (s)	Category: Vitamins.
	Starting Materials
	(Active Pharmaceutical Ingredients)
	1. Niacin-IP/USP
	2. Niacinamide-IP/USP
	3. Nicotinic Acid BP/EP/JP
	4. Nicotinamide BP/EP/JP
Activity (ies)	Synthesis, Purification, Packing, Labeling

The certificate earlier issued under WHO-TRS norms is valid till 04-10-2019. The site of M/s Western Drugs Limited, F 271 (A), Mewar Industrial Area, Madri, Udaipur (Rajasthan) has been jointly inspected as aforesaid on 26 and 27 August, 2019 and it has been recommended to revalidate the COPPs and issue the said Good Manufacturing Practices Certificate for Three Years.

In light of above recommendation, the Good Manufacturing Practices Certificate as per WHO-TRS norms is hereby issued with validity upto **04.10.2022**.

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

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. This certificate issued as per WHO-TRS norms.

Date of issue:- 5/11/2019 Place: - Jaipur

(Raja Ram Sharma)
Licensing Authority &
Drugs Controller
Rajasthan, Jaipur

M/s Western Drugs Limited, F 271 (A), Mewar Industrial Area, Madri, Udaipur (Rajasthan)

Certificate No.DC/D-2/WHO GMP/2019/

Dated:

Copy for information & n/a to :-

- 1. Drugs Controller General (India), FDA Bhawan, CHEB Campus, Kotla Road, New Delhi-110002.
- 2. Dy. Drugs Controller (India), CDSCO North Zone, Kamla Nehru Nagar, Ghaziabad (UP)
- 3. Asstt. Drugs Controller, Udaipur.
- 4. Drug Control Officer, Udaipur.
- 5. G/F/C-desk

(Raja Ram Sharma)
Licensing Authority &
Drugs Controller
Rajasthan, Jaipur