

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

Certificate No.DC/D-II/WHO GMP/2015/ 599

Dated: 05-10-2015

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 18-09-2015 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 Site address of the firm	M/s Western Drugs Limited, F 271 (A), Mewar Industrial Area, Madri, Udaipur (Rajasthan)
Manufacturers Licence No. Date of issue & Validity upto	Raj-1497 11.05.2010 10.05.2020
Categories & Dosage form (s)	Category: Vitamins. <u>Starting Materials</u> (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 10.05.2015. The site of M/s Western Drugs Limited, F 271 (A), Mewar Industrial Area, Madri, Udaipur (Rajasthan) has been jointly inspected as aforesaid on 18.09.2015 and it has been recommended to revalidate/issue the said Good Manufacturing Practices Certificate for Two Years and to issue the COPP's.

In light of above recommendation the Good Manufacturing Practices Certificate as per WHO-TRS norms is hereby issued with validity upto **04.10.2017**.

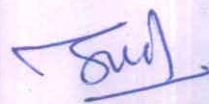
The responsibility for the quality of the individual batches of the pharmaceutical products (Bulk Drugs) manufactured through this process lies with the manufacturer.

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:- 05-10-2015

Place: - Jaipur




(Ashok Bhandari)
Licensing Authority &
Drugs Controller
Rajasthan, Jaipur

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

Certificate No.DC/D-II/WHO GMP/2015/

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. Drug Control Officer, Udaipur.
4. G/F/C-desk

(
(Ashok Bhandari)
Licensing Authority &
Drugs Controller
Rajasthan, Jaipur

