

Office of The Commissioner, Food & Drugs Administration M.S. Bandra – Kurla Complex, Bandra (E), Mumbai – 400 051

Date: 20 4 20 8

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization. (General instructions and explanatory notes attached).

Certificate No.: NEW-WHO-GMP/CERT/ND/69229/2018/11/23368

On the basis of the inspection carried out on 03 - 04/04/2018 and 17/04/2018 ,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 of the Firm

BDA HEALTHCARE PVT LTD

Address

PLOT NO B-123 NEAR ITI MIDC PARSEONI NAGPUR 441105 MAHARASHTRA STATE,

INDIA

2. Licence No.

MH102252 In Form

25, MH102253 In Form 28

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)	
1	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
2	Oral Powders	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance Production, Filling, Packing, labelling, Quality Control, Quality Assurance	
3	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)		

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 19 Apr 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.

Address of certifying authority: Food & Drug Administration, M.S.

Bandra-kurla Complex, Bandra (E), Mumbai – 400 051.

Maharashtra,INDIA.

Tel: +91-22-26592363/64 Fax: +91-22-26591959

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Name of the Authorised person : A. T. NIKHADE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling

Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai: Maharashtra State, India

Maharashtra State, Ind Date: 20 Apr 2018

Explanatory notes

- 1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
- 2. The certification number should be traceable within the regulatory authority issuing the certificate.
- 3. Where the regulatory authority issues a licence for the site, this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.
- 4. Table 1
 List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)	
Dosage form (s)			
Tablets	Cytotoxic	Packaging	
	Hormone	Production, Packaging, Quality control.	
Injectables	Penicillin	Repackaging & Labelling.	
	Cefalosporin	Aseptic preparation, Packaging,	
		Labelling.	

Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

- 5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
- 6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.