FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-**08 Nov 2023**

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/129773/2023/11/47896**

On the basis of the inspection carried out on **26/10/23 & 27/10/23** ,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	Granules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Oral Powders	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Pellets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

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 07 Nov 2026 . 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
1ADB05412977320231108
BDA HEALTHCARE PVT LTD - NEW-WHO-GMP/CERT/ND/129773/2023/11/47896

Name of the Authorised person : **MR BHUSHAN PATIL , J.C**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**08 Nov 2023**

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.

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/ND/129773/2023/11/47896 **VALID UP TO :07 Nov 2026**

Name of Manufacturing Firm : BDA HEALTHCARE PVT LTD
PLOT NO B-123 NEAR ITI MIDC PARSEONI
NAGPUR 441105 MAHARASHTRA STATE, INDIA

Drug License No : MH102252 In Form 25,
MH102253 In Form 28

Sr.No.	Name of the Product	Composition
1	Albendazole Chewable Tablets 400 mg	Each uncoated chewable Tablets Contains Albendazole USP 400 mg Colour:Sunset Yellow
2	Artemether & Lumefantrine Tablets (80 mg / 480 mg)	Each uncoated tablet contains Artemether Ph.Int 80 mg Lumefantrine Ph.Int 480 mg Colour:Tartrazine
3	Ciprofloxacin Tablet BP 500 mg	Each tablet contains Ciprofloxacin Hydrochloride Equivalent to Ciprofloxacin BP 500 mg
4	Clarithromycin Taste Mask Granules 27.5%	Each 100 mg Taste Mask Granules Contains Clarithromycin USP 27.5 mg Colour:NA, Dosage Form: Taste Mask Granules
5	Co-trimoxazole Tablets BP	Each uncoated tablet contains Sulfamethoxazole BP 400 mg Trimethoprim BP 80 mg
6	Lansoprazole EC Pellets 20% w/w	Each 100 Mg Pellets Contains Lansoprazole USP 20 mg Colour:NA, Dosage Form: Pellets
7	Paracetamol Tablets BP 500 mg	Each uncoated tablet conatins Paracetamol BP 500 mg
8	BD LOX Ciprofloxacin Tablets BP 750 Mg	Each Film coated Tablet Contains Ciprofloxacin Hydrochloride Eq.To Ciprofloxacin BP 750 mg Colour:Titanium Dioxide

1 2 3 4

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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

1ADB05412977320231108
BDA HEALTHCARE PVT LTD - NEW-WHO-GMP/CERT/ND/129773/2023/11/47896

Name of the Authorised person : **MR BHUSHAN PATIL ; J.C**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**08 Nov 2023**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/ND/129773/2023/11/47896 **VALID UP TO :07 Nov 2026**

Name of Manufacturing Firm : BDA HEALTHCARE PVT LTD
PLOT NO B-123 NEAR ITI MIDC PARSEONI
NAGPUR 441105 MAHARASHTRA STATE, INDIA

Drug License No : MH102252 In Form 25,
MH102253 In Form 28

Sr.No.	Name of the Product	Composition
9	DIABMET 1000 METFORMIN TABLETS BP 1000 mg	Each film coated tablet contains Metformin Hydrochloride BP 1000 mg Titanium Dioxide BP -- qs
10	EVIDAN Domperidone Tablets BP 10 mg	Each Uncoated Tablet Contains Domperidone Maleate Eq. to Domperidone BP 10 mg Colour:Quinoline yellow
11	FLUCOMYC FLUCONAZOLE TABLETS	Each uncoated tablet conatins Fluconazole USP 150 mg Colour:Ponceau 4R
12	FLUCTOR Paracetamol, Phenylephrin HCl, Pheniramine Maleate & Ascorbic Acid Sachet	Each 5 g Sachet Contain Paracetamol BP 500 mg Pheniramine Maleate BP 20 mg Ascorbic Acid (Vitamin C) BP 50 mg Phenylephrine HCl BP 10 mg
13	INIGAST 20 Esomeprazole Tablets 20 mg	Each Enteric Coated Tablet Contains Esomeprazole Magnesium Trihydrate Eq. to Esomeprazole USP 20 mg Colour:Titanium Dioxide
14	INIGAST 40 Esomeprazole Tablets 40 mg	Each Enteric Coated Tablet Contains Esomeprazole Magnesium Trihydrate Eq.to Esomeprazole USP 40 mg Colour:Titanium Dioxide, Dosage Form: Enteric coated tablet , Finished Product Specification:In-house
15	IPEPRAZOLE Gastro Resistant Omeprazole Tablets BP 20 mg	Each Enteric Coated Tablet Contains Omeprazole BP 20 mg
16	KETAFLOX Ofloxacin Tablets USP 200 Mg	Each Film Coated Tablet Contains Ofloxacin USP 200 mg
1 2 3 4		

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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
1ADB05412977320231108
BDA HEALTHCARE PVT LTD - NEW-WHO-GMP/CERT/ND/129773/2023/11/47896

Name of the Authorised person : **MR BHUSHAN PATIL , J.C**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**08 Nov 2023**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/ND/129773/2023/11 /47896 **VALID UP TO :07 Nov 2026**

Name of Manufacturing Firm : BDA HEALTHCARE PVT LTD
PLOT NO B-123 NEAR ITI MIDC PARSEONI
NAGPUR 441105 MAHARASHTRA STATE, INDIA

Drug License No : MH102252 In Form 25,
MH102253 In Form 28

Sr.No.	Name of the Product	Composition
17	KETAFLOX Ofloxacin Tablets USP 400 Mg	Each film coated tablets contains Ofloxacin USP 400 mg
18	Mizolgan Metamizole Sodium Tablets 500 mg	Each uncoated tablet contains Metamizole Sodium Ph.Eur 500 mg
19	Notache - 50 DT Diclofenac Sodium Dispersible Tablets 50 mg	Each uncoated tablet contains Diclofenac sodium BP 50 mg
20	OZAPRAL 15Mg LANSOPRAZOLE DELAYED RELEASE CAPSULES USP	Each Hard Gelatin Capsules Contains Lansoprazole (As Enteric Coated Pellets) USP 15 mg Approved Color Used IHS
21	OZAPRAL 30 Mg LANSOPRAZOLE DELAYED RELEASE CAPSULES USP	Each Hard Gelatin Capsules Contains Lansoprazole (As Enteric Coated Pellets) USP 30 mg Approved Color Used IHS
22	REGULIX 40 Drotaverine HCl Tablets 40 mg	Each Film coated Tablet Contains Drotaverine Hydrochloride IHS 40 mg Colour:Tartrazine, Dosage Form: Film Coated Tablets, Finished product specification: In - House
23	REGULIX 80 Drotaverine HCl Tablets 80 mg	Each film coated tablets contains Drotaverine HCl IHS 80 mg Colour:Tartrazine, Dosage Form: Film Coated Tablets, Finished product specification: In - House
24	SEZOL Gastro-Resistant Omeprazole Capsules BP 20 mg	Each Hard Gelatin Capsules Contains Omeprazole(As enteric Coated Pellets). BP 20 mg
1 2 3 4		

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
1ADB05412977320231108
BDA HEALTHCARE PVT LTD - NEW-WHO-GMP/CERT/ND/129773/2023/11/47896

Name of the Authorised person : MR BHUSHAN PATIL , J.C.

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**08 Nov 2023**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/ND/129773/2023/11/47896 **VALID UP TO :07 Nov 2026**

Name of Manufacturing Firm : BDA HEALTHCARE PVT LTD
PLOT NO B-123 NEAR ITI MIDC PARSEONI
NAGPUR 441105 MAHARASHTRA STATE, INDIA

Drug License No : MH102252 In Form 25,
MH102253 In Form 28

Sr.No.	Name of the Product	Composition
25	ZOLINE Levofloxacin Tablets 500 mg	Each film coated tablet contains Levofloxacin(As Levofloxacin Hemihydrate) IH 500 mg Colour: lake sunset yellow, Dosage Form: Film coated tablets, Finish product specification: In- House
1 2 3 4		

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
1ADB05412977320231108
BDA HEALTHCARE PVT LTD - NEW-WHO-GMP/CERT/ND/129773/2023/11/47896

Name of the Authorised person : MR BHUSHAN PATIL , J.C

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**08 Nov 2023**

FOOD AND DRUGS ADMINISTRATION COMMISSIONER MAHARASHTRA STATE