महाराष्ट्र शासन
आयुक्त
अन्न वा औषध प्रशासन , महा. राज्य
३४१ , वांद्रे - कुर्ला संकुल , रिजर्व बँक
समोर, वांद्रे (पूर्व)
मुंबई - ४०० ०५१.

सत्यमेव जयते
FDA MAHARASHTRA
FOOD AND DRUG ADMINISTRATION

GOVERNMENT OF MAHARASHTRA
COMMISSIONER
Food and Drugs Administration (M.S.)
341, Bandra-Kurla Complex,
Opposite of RBI Buildings,
BAndra (E), Mumbai - 400 051
Tel : 022 - 26592362-65
E-Mail : comm.fda-mah@nic.in

क्र. NEW-WHO-GMP/CERT/ND/93885/2020/ 3660 /11

दिनांक. 27/11/20

प्रति.
BDA HEALTHCARE PVT LTD
NAGPUR

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजुरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 93885

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ ND/93885 (एकूण प्रमाणपत्रे 1) पाठवीण्यात येत आहेत

आपला

(जे. बी. मंत्री)
सहाय्यक आयुक्त (मुख्यालय) (डेस्क ११)
अन्न व औषध प्रशासन , म. राज्य.

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-24 Nov 2020

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/93885/2020/11/34181**

On the basis of the inspection carried out on **07/10/2020 & 08/10/2020** ,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, MH/102730 In Form 28B**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Granules	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
3	Pellets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Capsules	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 23 Nov 2023 . 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
1ADB0549388520201124
BDA HEALTHCARE PVT LTD - NEW-WHO-GMP/CERT/ND/93885/2020/11/34181

Name of the Authorised person : **J. B. MANTRI**

Signature :
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**24 Nov 2020**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

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.

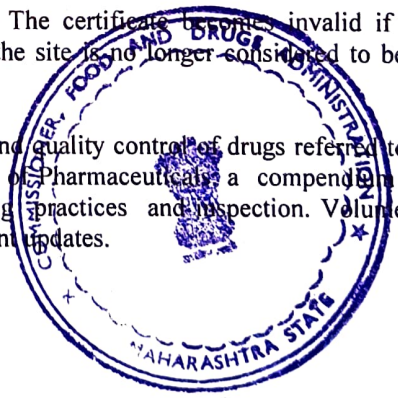
   Example - 2.

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]

of certificate : NEW-WHO-GMP/CERT/ND/93885/2020/11 /34181 **VALID UP TO :23 Nov 2023**

Name of Manufactring 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,
MH/102730 In Form 28B

Sr.No.	Name of the Product	Composition
1	Clarithromycin Taste Mask Granules 27.5%	Each 100 Mg Taste Mask Granules Contains Clarithromycin USP 27.5 mg
2	Lansoprazole EC Pellets 20% w/w	Each 100 Mg Pellets Contains Lansoprazole USP 20 mg
3	Metoprolol Succinate Extended Release Tablets USP 25 mg	Each film coated extended release tablet contains Metoprolol succinate USP 23.75 Eq.To Metoprolol Tartrate 0 25 mg Colour:Titanium Dioxide
4	Paracetamol,Aceclofenac & Serratiopetidase Tablets	Each film coated tablets contains Paracetamol BP 500 mg Aceclofenac BP 100 mg Serratiopeptidase (as enteric coated granules) IHS 15 mg Erythrosine IHS qs 0
5	ABVORM Albendazole Chewable Tablets 400 mg	Each Uncoated Chewable tablet contains Albendazole USP 400 mg Colour:Sunset Yellow
6	BD LOX Ciprofloxacin Tablets BP 750 Mg	Each Film coated Tablet Contains Ciprofloxacin Hydrochloride Eq.To Ciprofloxacin BP 750 mg Colour:Titanium Dioxide
7	DIABMET 1000 METFORMIN TABLETS BP 1000 mg	Each film coated tablet contains Metformin Hydrochloride BP 1000 mg Titanium Dioxide BP -- qs
8	FLUCOMYC FLUCONAZOLE TABLETS	Each uncoated tablet conatins Fluconazole USP 150 mg Colour:Ponceau 4R

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Name of the Authorised person : **J. B. MANTRI**

Signature :
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
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NAGPUR 441105 MAHARASHTRA STATE, INDIA

Drug License No : MH102252 In Form 25,
MH102253 In Form 28,
MH/102730 In Form 28B

Sr.No.	Name of the Product	Composition
9	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
10	IPEPRAZOLE Gastro Resistant Omeprazole Tablets BP 20 mg	Each Enteric Coated Tablet Contains Omeprazole BP 20 mg
11	JIMBUMOL DICLOFENAC SODIUM CAPSULES 50 MG	Each Hard Gelatin Capsules Contains Diclofenac Sodium BP 50 mg Colour:Approved Color use in EHG capsule shells NS
12	KETAFLOX Ofloxacin Tablets USP 200 Mg	Each Film Coated Tablet Contains Ofloxacin USP 200 mg
13	OZAPRAL 15Mg LANSOPRAZOLE DELAYED RELEASE CAPSULES USP	Each Hard Gelatin Capsules Contains Lansoprazole (As Enteric Coated Pellets) USP 15 mg Approved Color Used IHS .. 0
14	RALDOL DICLOFENAC SODIUM , PARACETAMOL, CHLORPHENAMINE MALEATE & MAGNESIUM TRISILICATE TABLETS	Each uncoated tablet contains Diclofenac Sodium (as enteric coated granules) BP 50 mg Paracetamol BP 500 mg Chlorphenamine Maleate BP 4 mg Magnesium Trisilicate BP 100 mg Tartrazine IHS qs
15	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
16	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

1 2 3

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certificate : NEW-WHO-GMP/CERT/ND/93885/2020/11 /34181 **VALID UP TO :23 Nov 2023**

Name of Manufactring 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,
MH/102730 In Form 28B

Sr.No.	Name of the Product	Composition
17	SEZOL Gastro-Resistant Omeprazole Capsules BP 20 mg	Each Hard Gelatin Capsules Contains Omeprazole(As enteric Coated Pellets). BP 20 mg
18	TERBOFINE TERBINAFINE TABLETS USP 250 mg	Each film coated tablets contains Terbinafine Hydrochloride USP Eq. To. Terbinafine 0 250 mg Erythrosine IHS qs
19	ZOLINE Levofloxacin Tablets 500 mg	Each Film coated Tablet Contains Levofloxacin(As Levofloxacin Hemihydrate) IHS 500 mg Colour:lake sunset yellow,Dosage Form: Film coated tablets, Finish product specification: In- House

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