FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-18 Dec 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/MD/127680/2023/11/48334**

On the basis of the inspection carried out on **10/08/2023,11/8/2023,22/11/2023** ,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 : **BDH INDUSTRIES LIMITED**
   Address : **NAIR BAUG, AKURLI ROAD KANDIVLI (EAST) MUMBAI 400101 MAHARASHTRA STATE, INDIA**
2. Licence No. : **608 in Form 25, 23 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	Dry Powders for Suspensions/Syrups	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	External Preparation (Ointments / Creams / Lotion/Gel/Ear drop/Nasal drop/Spray)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Injectables / SVP / Eye Drops / Ophthalmic Preparations	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Sterile Ointments / Cream / Gel	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
6	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 17 Dec 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
(WZ01241276402023113)
BDH INDUSTRIES LIMITED - NEW-WHO-GMP/CERT/MD/127680/2023/11/48334

Name of the Authorized 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: **18 Dec 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/MD/127680/2023/11/48334 — **VALID UP TO :17 Dec 2026**

Name of Manufacturing Firm : BDH INDUSTRIES LIMITED
NAIR BAUG, AKURLI ROAD KANDIVLI (EAST)
MUMBAI 400101 MAHARASHTRA STATE, INDIA

Drug License No : 608 In Form 25, 23 In Form 28

Sr.No.	Name of the Product	Composition
1	Acetazolamide Tablets BP 250 mg	Each uncoated tablet contains: Acetazolamide BP 250 mg
2	ALUMINIUM HYDROXIDE TABLETS BP 500mg (CHEWABLE TABLETS)	Each uncoated tablet contains: Dried Aluminium Hydroxide BP 500 mg
3	BETAMETHASONE VALERATE CREAM BP 0.1% w/w	Composition: Betamethasone Valerate BP Equivalent to Betamethasone 0.1 % w/w Cream Base qs
4	CALAMINE LOTION-8% w/v	Calamine BP 80 gm
5	DIAZEPAM TABLETS BP 5MG	Each uncoated tablet contains: Diazepam BP 5 mg
6	ISONIAZID TABLETS BP 100 mg	Each uncoated tablet contains: Isoniazid BP 100 mg
7	Methyldopa Tablets BP 250 mg	Each film coated tablet contains: Methyldopa B.P. equivalent to Anhydrous Methyldopa 250 mg Colour: Sunset Yellow Lake
8	METRONIDAZOLE TABLETS BP 250MG	Each uncoated tablet contains: Metronidazole BP 250 mg

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Fax: +91-22-26591959

DIN:E20127689202311218
BDH INDUSTRIES LIMITED - NEW-WHO-GMP/CERT/MD/127680/2023/11/48334

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

Signature and Date :

Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
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Date:**18 Dec 2023**

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NAIR BAUG, AKURLI ROAD KANDIVLI (EAST)
MUMBAI 400101 MAHARASHTRA STATE, INDIA

Drug License No : 608 In Form 25, 23 In Form 28

Sr.No.	Name of the Product	Composition
9	QUININE DIHYDROCHLORIDE INJECTION (300mg/ml)	Each ml contains: Quinine Dihydrochloride BP 300 mg Benzyl Alcohol BP 1 % v/v Water for Injection BP qs
10	TINIDAZOLE TABLETS 500MG	Each film coated tablet contains: Tinidazole BP 500 mg Colour:Quinoline Yellow
11	(FORTRIM) PAEDIATRIC CO-TRIMOXAZOLE FOR ORAL SUSPENSION	Each 5 ml (After reconstitution) contains: Trimethoprim BP 40 mg Sulfamethoxazole BP 200 mg Colour:Idacol Erythrosine supra
12	CEVIN-500 Ascorbic Acid Tablets BP 500mg	Each uncoated tablet contains: ASCORBIC ACID BP 500 mg Sunset Yellow (Lake) Colour:Sunset Yellow (Lake)
13	DEXAMETA Dexamethasone Tablets BP 0.5 mg	Each uncoated tablet contains: Dexamethasone BP 0.5 mg Colour:Tartrazine Supra FCF
14	DEXOMET-N (EYE/EAR DROPS) NEOMYCIN SULFATE AND DEXAMETHASONE SODIUM PHOSPHATE OPHTHALMIC SOLUTION USP	Each ml contains: Neomycin Sulphate USP Equivalent to Neomycin 3.5 mg Dexamethasone Sodium Phosphate USP Equivalent to Dexamethasone Phosphate 1 mg Phenyl Mercuric Nitrate NF 0.002 % w/v Sterile Buffered Vehicle qs
15	INDOSULE CAPSULES Indometacin Capsules BP 25 mg	Each hard gelatin capsule contains: Indometacin BP 25 mg
16	METADIL Chlorphenamine Tablets BP 4 mg	Each uncoated tablet contains Chlorphenamine Maleate BP 4 mg Colour:Tartrazine
1 2 3		

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

Signature :

Seal and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:18 Dec 2023

LIST OF PRODUCT APPROVED UNDER WHO GMP[3]

No. of certificate : NEW-WHO-GMP-CERT/MD/127660/2023/11/48334 — **VALID UP TO :17 Dec 2026**

Name of Manufacturing Firm : BDH INDUSTRIES LIMITED
NAIK BAUG, AKURLI ROAD KANDIVLI (EAST)
MUMBAI 400101 MAHARASHTRA STATE, INDIA

Drug License No : 608 in Form 25, 23 in Form 28

Sr.No.	Name of the Product	Composition
17	METAMOL PARACETAMOL TABLETS BP 500mg	Each uncoated tablet contains: Paracetamol BP 500 mg
18	METAMYCIN EYE OINTMENT CHLORAMPHENICOL OPHTHALMIC OINTMENT USP 1%W/W	Composition: Chloramphenicol USP 1 % w/w Sterilised Paraffin Base qs
19	METAPHAGE-500 METFORMIN TABLETS BP 500 mg	Each film coated tablet contains: Metformin Hydrochloride BP 500 mg Colour: Instacoat White
20	MICOZOL Miconazole Cream BP 2% w/w	Composition: Miconazole Nitrate BP 2 % w/w Cream Base qs
21	PV - DINE SOLUTION POVIDONE IODINE TOPICAL SOLUTION USP 10%	Composition: Povidone Iodine USP (Available Iodine 1 %w/v) 10 % w/v
22	TEGUNIL Proguanil Tablets BP 100MG	Each uncoated tablet contains: Proguanil Hydrochloride BP 100 mg

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BDH INDUSTRIES LIMITED - NEW-WHO-GMP-CERT/MD/127660/2023/11/48334

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:18 Dec 2023