



Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra - Kuria Complex,
Bandra (E).
Mumbai - 400 051
Date: 19 JUN 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/MD/89412/2020/11/32179**

On the basis of the inspection carried out on 19/11/19 & 20/11/19, 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.

- Name of the Firm : **BDH INDUSTRIES LIMITED**
Address : **NAIR BAUG, AKURLI ROAD KANDIVLI (EAST)
MUMBAI 400101 MAHARASHTRA STATE,
INDIA**
- Licence No. : **606 In Form 25, 23
In Form 23**

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 18 Jun 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-Kuria Complex,
Bandra (E), Mumbai - 400 051
Maharashtra, INDIA
Tel : +91-22-26592363/54
Fax : +91-22-26591959
1H083298941226200619
BDH INDUSTRIES LIMITED - NEW-WHO-
GMP-CERT/MD/89412/2020-11/32179

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

CERTIFIED TRUE COPY

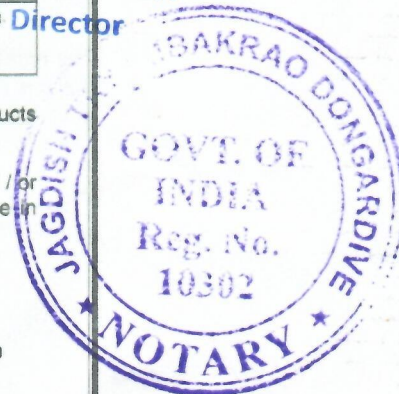


5883

ATTESTED

Authorized Signatory
Millennial India International
Chamber of Commerce
Industry & Agriculture
New Delhi, (INDIA)

GOPAL SINGH
Director



GOVT. OF INDIA
Ganesh Chawl Committee, Khandivli (East),
Zopadhatti, Akurli Road, Mumbai-400 101



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
Starting material (s)2	
Paracetamol	Analgesic

Use, whenever available, International nonproprietary names.

5. The certificate remains valid until activities and/or categories certify compliance with GMP.
6. The requirements for good practice the certificate are those included in guidelines and related materials 1999, World Health Organization,

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)

Country REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by J B MANTRI
acting in the capacity of JT COMMISSIONER & CONTROLLING
bears the seal/stamp of ADDL. DIRECTOR, MILLENNIAL INDIA
INTL. CHAMBER OF COMMERCE INDS & AGRICULTURE, ND

Certified
at NEW DELHI, INDIA the 16-Oct-2020
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. DLND0001458920

Seal / Stamp Is issued to BDH INDUSTRIES LIMITED

Signature

(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ आई)
Section Officer (OI)
सी. पी. वी. बंगला / C.P.V. Bungalow
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi



I cover - Coct M&A + Sudan