



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

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/NKD/91974/2020/11/31704**

On the basis of the inspection carried out on 20/01/2020, 21/01/2020 & 21/04/2020, 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.

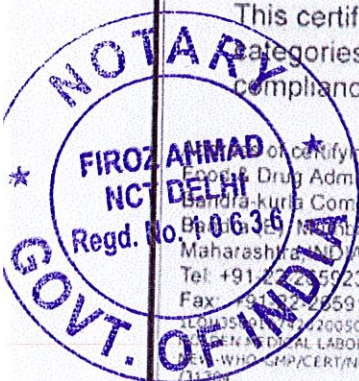
- Name of the Firm : **HOLDEN MEDICAL LABORATORIES PVT. LTD.**
Address : **PLOT NO. C-35, C-36 AND C-37, M.I.D.C. MALEGAON, SINNAR, NASHIK 422113 MAHARASHTRA STATE, INDIA**
- Licence No. : **NKD34 In Form 25, NKD19 In Form 28**

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	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 05 May 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.



Authorizing authority :
Food & Drug Administration, M.S.
Bandra-Kurla Complex,
Bandra (E), Mumbai - 400 051
Maharashtra, INDIA
Tel: +91 22 2592363/64
Fax: +91 22 2591959
HOLDEN MEDICAL LABORATORIES PVT. LTD.
NEW-WHO-GMP/CERT/NKD/91974/2020/11/31704

Name of the Authorised person : J.B. MANTRI

ATTESTED

Signature :

Stamp and Date :

Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai

Maharashtra State, India

Date: 06 May 2020

**NOTARY PUBLIC
DELHI (INDIA)**

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

GAURAV RAVISH
Addl. Director

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

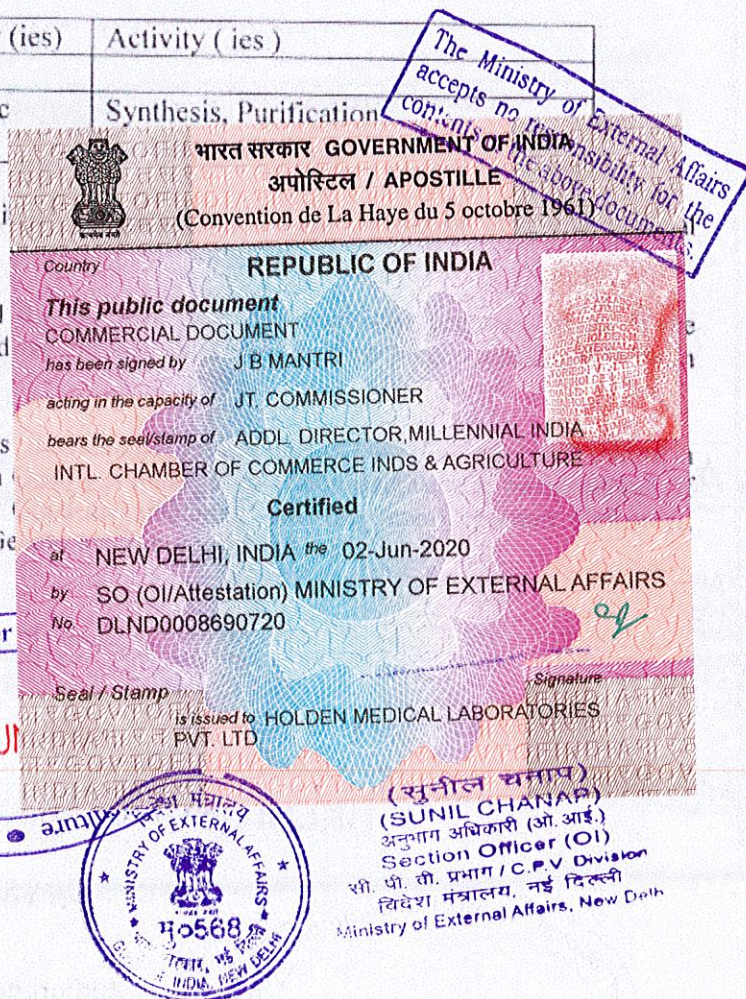
Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

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

Use, whenever available. International nonproprietary names.

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



GAURAV VARMA
Aqbl. Director



Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, DR. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA PIN - 382010



Certificate No. : **20031933**

On the basis of the inspection carried out on 16-17/01/2020 & 16/03/2020 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 & Address of site : **AARTI DRUGS LIMITED (UNIT - II)**

**PLOT NO. - 211 & 213, ROAD - 2, G.I.D.C. AT &
POST :- SARIGAM**

City : SARIGAM - 396 155, Dist. VALSAD

GUJARAT STATE, INDIA

2 Manufacturer's Licence
number :

G/25/2038

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drug (APIs)	General	Manufacturer

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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 **19/03/2023**. It becomes invalid if the activities and categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration, Block
No. 8, 1ST floor, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, India. - Pin
382010

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-23253410

Date : 20/03/2020

Signature & function of : (Dr. J. G. KOSHIA)
Commissioner

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



**GAURAV RAVISH
Addl. Director**

CHAM + VET
TO
Duke

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 **H G KOSHIA**
acting in the capacity of **COMMISSIONER**
bears the seal/stamp of **ADDL. DIRECTOR, MILLENNIAL INDIA**
INTL. CHAMBER OF COMMERCE INDS & AGRICULTURE

Certified
at **NEW DELHI, INDIA** the **02-Jun-2020**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No **DLND0008690520**

Seal / Stamp is issued to **AARTI DRUGS LTD.** Signature

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



GAURAV VARAISH
Addl. Director