FDA MAHARASHTRA

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.

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**
2.	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.

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
[illegible]
HOLDEN MEDICAL LABORATORIES PVT. LTD
NEW-WHO-GMP/CERT/NKD/91974/2020/11/31704

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:06 May 2020

NOTARY ★ GOVT. OF INDIA ★ FIROZ AHMAD NCT DELHI Regd. No. 10636

ATTESTED

NOTARY PUBLIC
DELHI (INDIA)

364

Millennial India International Chamber of Commerce Industry & Agriculture

01 JUN 2020

ATTESTED

Authorized Signatory
Millennial 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 [illegible]

Use, whenever available, Internati[illegible] nonproprietary names.

5. The certificate remains valid until [illegible] activities and/or categories certified [illegible] compliance with GMP.

6. The requirements for good practices [illegible] the certificate are those included in [illegible] guidelines and related materials , [illegible] 1999. World Health Organization, Ge[illegible]

The Ministry of External Affairs accepts no responsibility for the contents of the above document.

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
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. DLND0008690720

Seal / Stamp Signature
is issued to HOLDEN MEDICAL LABORATORIES PVT. LTD

Millennial India International Chamber [illegible] Culture
01 JUN

Ministry of External Affairs, Govt. of India, New Delhi
मं 0568

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

GAURAV RAVISH
Addl. 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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FIROZ AHMAD
NCT DELHI
Regd. No. 10636
GOVT. OF INDIA

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 **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* : 91-79-23[illegible]0

Date : 20/03/2020

COMMISSIONER, FOOD & DRUGS CONTROL ADMINISTRATION * GANDHINAGAR * GUJARAT STATE

Name & function of Responsible Person : *(Dr. H.G. KOSHIA)* *Commissioner*

ATTESTED 366

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

Millennial India International Chamber of Commerce Industry & Agriculture
01 JUN 2020

GAURAV RAVISH
Addl. Director

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

The Ministry of External Affairs accepts no responsibility for the content of the above document.

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 *Signature*

is issued to AARTI DRUGS LTD.

MINISTRY OF EXTERNAL AFFAIRS GOVT. OF INDIA NEW DELHI

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

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