FDA MAHARASHTRA

JAGDISH TRYAMBAK DONGARDIVE * NOTARY * GOVT. OF INDIA Reg. No. 10302

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 5/2/20[illegible]

JAGDISH TRYAMBAK DONGARDIVE * NOTARY * GOVT. OF INDIA Reg. No. 10302

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/KD/62918/2018/11/22433**

On the basis of the inspection carried out on **20-21/12/2017 and 23/01/2018** ,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 : **AUROCHEM PHARMACEUTICALS (INDIA) PVT. LTD.**
   Address : **PLOT NO. 58, PALGHAR TALUKA IND. CO-OP. ESTATE LTD BOISAR ROAD, TAL. PALGHAR, THANE 401404 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD19 In Form 25, KD21 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

No 50141

IMC CHAMBER OF COMMERCE AND INDUSTRY 06 FEB 2018 MUMBAI, 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 04 Feb 2020 . 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
1RUA1476291820180205

Name of the Authorised person : A. T. NIKHADE
Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:05 Feb 2018

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

CERTIFIED TRUE COPY

JAGDISH TRYAMBAK DONGARDIVE
Advocate & Notary, Govt. Of India)
Sarswati Chawl, Kranti Nagar,
Lokhandwadpatti, Akurli Road,
Kandivali (E), Mumbai-400 101
(Maharashtra)

05 FEB 2018

ATTESTED

JIGNA KOTHARI
Asst. Director
AUTHORISED SIGNATORY
IMC CHAMBER OF COMMERCE AND INDUSTRY
MUMBAI-INDIA

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 … f the activities and/or categories ce… e in compliance with GMP.

6. The requirements for good pr… tion of the certificate are those inclu… guidelines and related mate… 1999. World Health Organizat…

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
Country: INDIA
This public document of the type
COMMERCIAL DOCUMENT
is issued to AUROCHEM PHARMACEUTICALS (INDIA) PVT. LTD.
has been signed by JIGNA KOTHARI
with the seal / stamp of ASST. DIRECTOR, IMC CHAMBER OF COMMERCE & INDUSTRY, MUMBAI-INDIA
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 12-Feb-2018 at NEW DELHI, INDIA
with reference no. MHMC0005038818
Seal / Stamp
Signature
(DEBABRATA PAUL)
Section Officer (O.I.)
C.P.V. Division
Ministry of External Affairs
New Delhi

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

NOTARIAL