



Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra - Kurla Complex,
Bandra (E),
Mumbai - 400 051
Date: 26/07/2018



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/71101/2018/11/24222

On the basis of the inspection carried out on 21/05/2018, 22/05/2018 and 03/07/2018, 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.

Name of the Firm : GALENTIC PHARMA (INDIA) PRIVATE LIMITED
Address : PLOT NO R 673 TTC MIDC RABALE THANE
BELAPUR ROAD NAVI MUMBAI THANE
400701 MAHARASHTRA STATE, INDIA
Licence No. : KD214 In Form 25,
KD180 In Form 28

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	External Preparation (Liquid)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	External Preparation (Ointments / Creams / Lotion/Gel)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Sterile Ointments / Cream / Gel	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 24 Jul 2021. 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: +91-22-26591955
E-mail: fda@maharashtra.gov.in

Name of the Authorised person : A. T. NIKHADE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controller,
Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai - 400 051
Maharashtra State, India
Date: 25 Jul 2018

TRUE COPY

RAMESHCHANDRA TIWARI
ADVOCATE & NOTARY
GOVT. OF INDIA

MB.: 9820846083

ATTESTED

25 JUL 2018

ROHIT YADAV
Manager

AUTHORISED SIGNATORY
IMC CHAMBER OF COMMERCE AND INDUSTRY
MUMBAI-INDIA



No 20849





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

This public document of the type
COMMERCIAL DOCUMENT

is issued to GALENTIC PHARMA (INDIA) PVT.
LTD.

has been signed by ROHIT YADAV

with the seal / stamp of MANAGER, IMC CHAMBER OF COMMERCE
AND INDUSTRY, MUMBAI

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 03-Aug-2018 at NEW DELHI, INDIA

MHMC0025547718

Signature
(DEBAPATA RAUL) CV
Section Officer (O.I.)
विदेश प्रभाग / C.P.V. Division
विदेश प्रभाग, नई दिल्ली
Ministry of External Affairs
New Delhi

50568
GOVT OF INDIA NEW DELHI

The Ministry of External Affairs
accepts the above documents
for the purpose of the Convention



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 I
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.

No 20849



