



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

Date : **22 OCT 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/75402/2018/11/25402**

On the basis of the inspection carried out on **10/08/2018, 11/08/2018 and 06/09/2018**, 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 : **AARTI DRUGS LIMITED**
Address : **PLOT NO. E 21, MIDC TARAPUR, TARAPUR,
TAL. BOISAR, PALGHAR 401506
MAHARASHTRA STATE, INDIA**
2. Licence No. : **MH101283 In Form
25**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Synthesis, Purification, 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 19 Oct 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: +91-22-26591959
1RAA9497540220181020

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: 20 Oct 2018**



20 OCT 2018

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

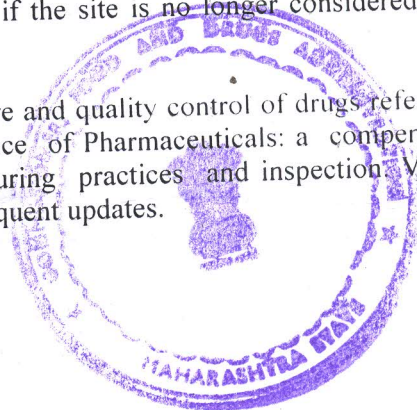
Pharmaceutical Product (s) ¹	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

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 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.



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/KD/75402/2018/11 VALID UP TO : 19 Oct 2021
/25402
Name of Manufacturing Firm : AARTI DRUGS LIMITED
PLOT NO. E 21, MIDC TARAPUR, TARAPUR, TAL.
BOISAR, PALGHAR 401506 MAHARASHTRA
STATE, INDIA
Drug License No : MH101283 In Form 25

Sr.No.	Name of the Product	Composition
1	Enrofloxacin BP	
2	Enrofloxacin EP	
3	Enrofloxacin IP	
4	Enrofloxacin USP	
5	Ketoconazole BP	
6	Ketoconazole EP	
7	Ketoconazole IP	
8	Ketoconazole USP	



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Fax: +91-22-26591959
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Name of the Authorised person : A. T. NIKHADE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
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Bandra (E), Mumbai
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Date: 20 Oct 2018

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