FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 20 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/74700/2018/11/25368**

On the basis of the inspection carried out on **16/08/2018, 17/08/2018 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 : **E-22, MIDC, TARAPUR, TAL-PALGHAR. DIST-THANE 401506 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD582 In Form 25, KD408 In Form 28**

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 15 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: +91-22-26591956
1RAA7817470020161016

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:16 Oct 2018

16 OCT 2018

NOTARY
Name C. H. Shukla
Area Gr. Mumbai
Reg. No. 121/84
GOV. OF MAHARASHTRA

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY
BOMBAY CHAMBER
1836

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 GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/74700/2018/11 /25368 VALID UP TO : 15 Oct 2021

Name of Manufactring Firm : AARTI DRUGS LIMITED
E-22, MIDC, TARAPUR, TAL-PALGHAR, DIST-THANE 401506 MAHARASHTRA STATE, INDIA

Drug License No : KD582 In Form 25,
KD408 In Form 28

Sr.No.	Name of the Product	Composition
1	Clopidogrel Hydrogen Sulfate EP	
2	Celecoxib EP	
3	Celecoxib USP	
4	Ciprofloxacin HCL BP	
5	Ciprofloxacin HCL IP	
6	Ciprofloxacin HCL USP	
7	Ciprofloxacin HCP EP	
8	Diclofenac Epolamine	

1 2 3 4

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Fax: +91-22-26591959
1RAA7817470020181016

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:16 Oct 2018

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Name of Manufactring Firm : AARTI DRUGS LIMITED
E-22, MIDC, TARAPUR, TAL-PALGHAR, DIST-THANE 401506 MAHARASHTRA STATE, INDIA

Drug License No : KD582 In Form 25,
KD408 In Form 28

Sr.No.	Name of the Product	Composition
9	Gatifloxacin Sesquihydrate	
10	Metoprolol Succinate BP	
11	Metoprolol Succinate EP	
12	Metoprolol Succinate USP	
13	Niacin USP	
14	Raloxifene HCl EP	
15	Raloxifene HCl USP	
16	Rivastigmine Hydrogen Tartrate	
1 2 3 4		

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Name of the Authorised person : A. T. NIKHADE

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Food & Drug Administration, M.S.
Bandra (E), Mumbai
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Date:16 Oct 2018

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/25368

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E-22, MIDC, TARAPUR, TAL-PALGHAR, DIST-
THANE 401506 MAHARASHTRA STATE, INDIA

Drug License No . KD582 In Form 25.
KD408 In Form 28

Sr.No.	Name of the Product	Composition
17	Terbinafine Hcl BP	
18	Terbinafine Hcl EP	
19	Tinidazole BP	
20	Tinidazole EP	
21	Tinidazole IP	
22	Tinidazole USP	
23	Zolpidem Tartrate BP	
24	Zolpidem Tartrate EP	

1 2 3 4

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Bandra (E) Mumbai – 400 051
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
IRAA78174700/181015

Name of the Authorised person : A. T. NIKHADE

Signature
Stamp and Date

Joint Commissioner (HQ) & Controlling Authority
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Drug License No : KD582 In Form 25,
KD408 In Form 28

Sr.No.	Name of the Product	Composition
25	Zolpidem Tartrate USP	
1	2	3 4

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Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:16 Oct 2018

16 OCT 2018

A copy of this document / has been recorded with the Chamber

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No 25897 Date 30 NOV 2018

PRATIK RALE
EXECUTIVE

NOTARY
Name G. H. Shukla
Area Gr. Mumbai
Reg. No. 1/1-84
GOV. OF MAHARASHTRA

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NOTARY
Name G. H. Shukla
Area Gr. Mumbai
Reg. No. 12-84
GOV. OF MAHARASHTRA

NOTARY
Name G. H. Shukla
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Reg. No. 12-84
GOV. OF MAHARASHTRA

ATTESTED TRUE COPY

G. H. SHUKLA,
NOTARY GREATER MUMBAI
Jagdamba Bhavan, Ground Floor,
Ganpatrao Kadam Marg, Lower Parel
MUMBAI - 400 013.
30 NOV 2018

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

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 AARTI DRUGS LTD.

has been signed by PRATIK RALE

with the seal / stamp of EXEC. BOMBAY CHAMBER OF COMMERCE AND INDUSTRY

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS

on 04-Dec-2018 at NEW DELHI, INDIA

with reference no. MHMC0036292618

Seal / Stamp

Signature

(प्रतिव्रत पाल)
(PRATIBRAT PAUL)
अनुभाग अधिकारी (वी.आई.)
Section Officer (O.I.)
वी.आई. प्रभाग/C.V. Division
विदेश मंत्रालय, भारत सरकार
Ministry of External Affairs
New Delhi

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