

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date: 1706 2017

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/58604/2017/11/19684

On the basis of the inspection carried out on 14/03/2017, 15/03/2017 and 20/04/2017 ,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 LTD

Address

PLOT NO G-60 MIDC TARAPUR TAL-PALGHAR DIST THANE 401506 MAHARASHTRA STATE,

DIST THANE 401506 MAHARASHTRA INDIA

Licence No.

KD217 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 16 Jun 2019. 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 1RAA6395860420170617 Name of the Authorised person : O S SADHWANI

Signature
Stamp and Date : Joint Commissioner (HQ) & Controlling

Authority
Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India

Date:17 Jun 2017

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate

NEW-WHO-GMP/CERT/KD/58604/2017/11 VALID UP TO:16 Jun 2019

/19684

Name of Manufactring Firm

AARTI DRUGS LTD

PLOT NO G-60 MIDC TARAPUR TAL-PALGHAR DIST THANE 401506 MAHARASHTRA STATE,

INDIA

Drug License No

KD217 In Form 25

Name of the Product	Composition
CIPROFLOXACIN HYDROCHLORIDE BP	
CIPROFLOXACIN HYDROCHLORIDE EP	
CIPROFLOXACIN HYDROCHLORIDE	
CIPROFLOXACIN HYDROCHLORIDE USP	
CLOPIDOGREL BISULPHATE IP	
CLOPIDOGREL BISULPHATE USP	
CLOPIDOGREL HYDROGENSULFATE BP	
CLOPIDOGREL HYDROGENSULFATE	
	CIPROFLOXACIN HYDROCHLORIDE BP CIPROFLOXACIN HYDROCHLORIDE EP CIPROFLOXACIN HYDROCHLORIDE IP CIPROFLOXACIN HYDROCHLORIDE USP CLOPIDOGREL BISULPHATE IP CLOPIDOGREL BISULPHATE USP CLOPIDOGREL HYDROGENSULFATE BP

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Fax: +91-22-26591959 1RAA6395860420170617

Name of the Authorised person : O S SADHWANI

Signature: DSB WWQ Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India Date: 17 Jun 2017

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Name of Manufactring Firm

AARTI DRUGS LTD

PLOT NO G-60 MIDC TARAPUR TAL-PALGHAR DIST THANE 401506 MAHARASHTRA STATE,

INDIA

Drug License No

KD217 In Form 25

Sr.No.	Name of the Product	Composition
9	DICLOFENAC DIETHYL AMMONIUM BP	
10	DICLOFENAC POTASSIUM BP	
11	DICLOFENAC POTASSIUM EP	
12	DICLOFENAC POTASSIUM USP	
13	DICLOFENAC SODIUM BP	
14	DICLOFENAC SODIUM EP	
15	DICLOFENAC SODIUM IP	
16	DICLOFENAC SODIUM JP	
<u>123</u>		

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 1RAA6395860420170617

Name of the Authorised person : O S SADHWANI

Signature BSWW Stamp and Date . Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai. Maharashtra State, India Date:17 Jun 2017

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Name of Manufactring Firm

AARTI DRUGS LTD

PLOT NO G-60 MIDC TARAPUR TAL-PALGHAR DIST THANE 401506 MAHARASHTRA STATE,

INDIA

Drug License No

KD217 In Form 25

Sr.No.	Name of the Product	Composition
17	DICLOFENAC SODIUM USP	
18	GATIFLOXACIN SESQUIHYDRATE	
19	METFORMIN HYDROCHLORIDE BP	
20	METFORMIN HYDROCHLORIDE EP	
21	METFORMIN HYDROCHLORIDE IP	
22	METFORMIN HYDROCHLORIDE USP	
23	PIOGLITAZONE HYDROCHLORIDE IP	
24	PIOGLITAZONE HYDROCHLORIDE USP	
123		

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Name of the Authorised person : O S SADHWANI

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Stamp and Date: Joint Commissioner (HQ) & Controlling Authority Food & Drug Administration, M.S.

> Bandra (E), Mumbai. Maharashtra State, India Date:17 Jun 2017