महाराष्ट्र शासन
आयुक्त
अन्न वा औषध प्रशासन , महा. राज्य
३४१ , वांद्रे - कुर्ला संकुल , रिजर्व बँक
समोर, वांद्रे (पूर्व)
मुंबई - ४०० ०५१.

सत्यमेव जयते
FDA MAHARASHTRA
FOOD AND DRUG ADMINISTRATION

GOVERNMENT OF MAHARASHTRA
COMMISSIONER
Food and Drugs Administration (M.S.)
341, Bandra-Kurla Complex,
Opposite of RBI Buildings,
BAndra (E), Mumbai - 400 051
Tel : 022 - 26592362-65
E-Mail : comm.fda-mah@nic.in

क्र. NEW-WHO-GMP/CERT/KD/59725/2017/ 3654 /11 दिनांक. 25/10/2017

प्रति,
AARTI INDUSTRIES LTD
THANE

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजुरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 59725

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ KD/59725 (एकूण प्रमाणपत्रे 1) पाठवीण्यात येत आहेत

आपला

(नि मो गांधी)
सह आयुक्त्त (मुख्यालय) करीता
अन्न व औषध प्रशासन , म. राज्य.

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 25/10/2017

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/59725/2017/11/21193**

On the basis of the inspection carried out on **24/07/2017, 25/07/2017 and 22/09/2017** ,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 INDUSTRIES LTD**
   Address : **PLOT NO D-53 , PHASE II , M.I.D.C KALYANSHIL RD DOMBIVALI (EAST) THANE 421204 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD591 In Form 25, KD414 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 23 Oct 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
1RAA3825972520171024

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:24 Oct 2017

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

24 OCT 2017

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/59725/2017/11 /21193 **VALID UP TO :23 Oct 2019**

Name of Manufactring Firm : AARTI INDUSTRIES LTD
PLOT NO D-53 , PHASE II , M.I.D.C KALYANSHIL
RD DOMBIVALI (EAST) THANE 421204
MAHARASHTRA STATE, INDIA

Drug License No : KD591 In Form 25,
KD414 In Form 28

Sr.No.	Name of the Product	Composition
1	Bambuterol Hcl BP	Colour:white or almost white powder
2	Bambuterol Hcl EP	Colour:White or almost white powder
3	Bambuterol Hcl IP	Colour:white or almost white powder
4	Budesonide BP	Colour:white or almost white powder
5	Budesonide EP	Colour:white or almost white powder
6	Budesonide IP	Colour:white or almost white powder
7	Budesonide USP	Colour:white or almost white powder
8	Deferiprone	Colour:White to almost white powder

1 2 3 4

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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
1RAA3825972520171024

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:24 Oct 2017

24 OCT 2017

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/59725/2017/11 /21193 **VALID UP TO :23 Oct 2019**

Name of Manufactring Firm : AARTI INDUSTRIES LTD
PLOT NO D-53 , PHASE II , M.I.D.C KALYANSHIL
RD DOMBIVALI (EAST) THANE 421204
MAHARASHTRA STATE, INDIA

Drug License No : KD591 In Form 25,
KD414 In Form 28

Sr.No.	Name of the Product	Composition
9	Fluticasone Propionate BP	Colour:white or almost white powder
10	Fluticasone Propionate EP	Colour:white or almost white powder
11	Fluticasone Propionate IP	Colour:white or almost white powder
12	Fluticasone Propionate USP	Colour:white or almost white powder
13	Ipratropium Bromide BP	Colour:white or almost white powder
14	Ipratropium Bromide EP	Colour:white or almost white powder
15	Mometasone Furoate BP	Colour:white or almost white powder
16	Mometasone Furoate EP	Colour:white or almost white powder

1 2 3 4

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: +91-22-26591952
1RAA3825972520171024

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:24 Oct 2017

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

24 OCT 2017.

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/59725/2017/11 /21193 **VALID UP TO :23 Oct 2019**

Name of Manufactring Firm : AARTI INDUSTRIES LTD
PLOT NO D-53 , PHASE II , M.I.D.C KALYANSHIL
RD DOMBIVALI (EAST) THANE 421204
MAHARASHTRA STATE, INDIA

Drug License No : KD591 In Form 25,
KD414 In Form 28

Sr.No.	Name of the Product	Composition
17	Mometasone Furoate USP	Colour:white to off white powder
18	Perindopril Erbumine BP	Colour:white or almost white
19	Perindopril Erbumine EP	Colour:white or almost white powder
20	Phenylephrine HCL BP	Colour:white or almost white powder
21	Phenylephrine HCL EP	Colour:white to almost white powder
22	Phenylephrine HCl IP	Colour:white or almost white powder
23	Phenylephrine HCL USP	Colour:white or almost white powder
24	R Salbutamol Sulphate	Colour:white to off white powder

1 2 3 4

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
1RAA3825972520171024

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:24 Oct 2017

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

24 OCT 2017

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/59725/2017/11 /21193 **VALID UP TO :23 Oct 2019**

Name of Manufactring Firm : AARTI INDUSTRIES LTD
PLOT NO D-53 , PHASE II , M.I.D.C KALYANSHIL
RD DOMBIVALI (EAST) THANE 421204
MAHARASHTRA STATE, INDIA

Drug License No : KD591 In Form 25,
KD414 In Form 28

Sr.No.	Name of the Product	Composition
25	R Salbutamol Sulphate IP	Colour:white to off white powder
26	Ranolazine	Colour:white to off white powder
27	Triamcinolone Acetonide BP	Colour:white or almost white powder
28	Triamcinolone Acetonide EP	Colour:white or almost white powder
29	Triamcinolone Acetonide IP	Colour:white or almost white powder
30	Triamcinolone Acetonide USP	Colour:white or almost white powder
31	Venlafaxine HCl BP	Colour:white to off white powder
32	Venlafaxine Hcl EP	Colour:white to off white powder

1 2 3 4

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
1RAA3825972520171024

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:24 Oct 2017

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

24 OCT 2017