7-5/2013/EU/WC-0099
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation (HQ)
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

06 JAN 2023

To,

M/s Aarti Pharmalabs Limited
Plot No.E-50, 50/1 and 59/1, Unit – IV
MIDC, Tarapur – 401506
Taluka: Palghar, District: Thane-Zone4

SUB:- Application for change in company name from M/s Aarti Industries Limited to M/s Aarti Pharmalabs Limited in the issued WC - Reg.

Ref.:
1. Your application vide email dated 13/10/2022 for change in company name from M/s Aarti Industries Limited to M/s Aarti Pharmalabs Limited

Sir,

Based on your application under reference (1) alongwith submitted documents please find enclosed Written Confirmation Certificate with updated company name. All the conditions of the Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India will remain same.

Please acknowledge the receipt.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Amended

CERTIFICATE NO. : WC-0099

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. **Name and address of site:** M/s Aarti Pharmalabs Limited
2. **Manufacturer's License Number:** KD/568 & KD/433

The name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0099) granted on date 24.08.2022 and 16.09.2022 is hereby amended as follows:

In place of:
M/s Aarti Industries Ltd.

Read as:
M/s Aarti Pharmalabs Limited

All other conditions of Written Confirmation Certificate will remain same.

06 JAN 2023

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India
सत्यमेव जयते

7-5/2013/EU/WC-0099
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

16 SEP 2022

To,

M/s Aarti Industries Ltd.
Plot No.E-50, 50/1 AND 59/1,Unit-IV, MIDC,
Tarapur – 401506, Dist- Palghar,
Maharashtra, India

SUB:- Application for amendment of the Written Confirmation of M/s Aarti Industries Ltd. Plot No.E-50, 50/1 AND 59/1,Unit-IV, MIDC, Tarapur – 401506, Dist-Palghar, Maharashtra, India as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your application submitted to this office vide email dated 08/09/2022 for the necessary correction in the Written Confirmation Certificate issued by this office.

In this regard, kindly find the enclosed amended Written Confirmation Certificate. The condition of the Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India will remain same.

Please acknowledge the receipt.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

7-5/2013/EU/WC-0099
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

24 AUG 2022

To

M/s Aarti Industries Ltd.
Plot No.E-50, Unit-IV, MIDC, Tarapur – 401506
Taluka: Palghar, District: Thane-Zone 4

SUB:- Written Confirmation of M/s Aarti Industries Ltd., Plot No.E-50, Unit-IV, MIDC, Tarapur – 401506 Taluka: Palghar, District: Thane-Zone 4 as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your online application no. WC/ED/2022/5240 submitted to CDSCO, West Zone office, and the recommendation received from DDC (I), West Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
1	44	24 AUG 2022	**29.07.2025**
2	01	24 AUG 2022	**29.07.2025**

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : **Amended**

WC-0099

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. **Name and address of site:** M/s Aarti Industries Ltd.
2. **Manufacturer's License Number:** KD/568 & KD/433

The address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0099) granted on date 24.08.2022 is hereby amended as follows:

In place of:
"M/s Aarti Industries Ltd.
Plot No.E-50, Unit-IV, MIDC, Tarapur – 401506
Taluka: Palghar, District: Thane-Zone 4"

Read as:
"M/s Aarti Industries Ltd.
Plot No.E-50, 50/1 AND 59/1,Unit-IV, MIDC, Tarapur – 401506
Dist- Palghar, Maharashtra, India"

All other conditions of Written Confirmation Certificate will remain same.

16 SEP 2022

Signature VL

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : **WC-0099**

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Aarti Industries Ltd.**
Plot No.E-50, Unit-IV, MIDC, Tarapur – 401506
Taluka: Palghar, District: Thane-Zone 4

2. Manufacturer's licence number: KD/568 & KD/433

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

As per Annexure 1 & Annexure 2

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 04/08/2022 & 05/08/2022

The Written Confirmation remains valid until: **29.07.2025**

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. V.G. Somani,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

24 AUG 2022

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-1

CERTIFICATE NO. : WC-0099

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Aarti Industries Ltd.**
Plot No.E-50, Unit-IV, MIDC, Tarapur – 401506
Taluka: Palghar, District: Thane-Zone 4

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Benazepril Hydrochloride Ph. Eur./USP	Manufacturing & Packing
2.	Levalbuterol Hydrochloride USP	Manufacturing & Packing
3.	Ramipril BP/ Ph. Eur. /USP	Manufacturing & Packing
4.	Quinapril Hydrochloride USP/ Ph. Eur.	Manufacturing & Packing
5.	Perindopril Erbumine BP/ Ph. Eur.	Manufacturing & Packing
6.	Lacidipine BP	Manufacturing & Packing
7.	RanolazineIH	Manufacturing & Packing
8.	Venlafaxine Hydrochloride Ph.Eur./USP	Manufacturing & Packing
9.	Ipratropium Bromide Ph. Eur. /BP	Manufacturing & Packing
10.	Quetiapine Fumarate IH/Ph. Eur./USP	Manufacturing & Packing
11.	Salmeterol Xinafoate Ph. Eur./BP/USP	Manufacturing & Packing
12.	Fluticasone Propionate Ph.Eur./BP/USP	Manufacturing & Packing
13.	Capecitabine USP	Manufacturing & Packing
14.	Bicalutamide Ph. Eur./USP	Manufacturing & Packing
15.	Azathioprine Ph. Eur. /BP/USP	Manufacturing & Packing
16.	Bupropion Hydrochloride USP	Manufacturing & Packing
17.	Cyclophosphamide (Non Sterile) Ph. Eur./BP/USP	Manufacturing & Packing
18.	Adapalene Ph.Eur./USP	Manufacturing & Packing
19.	Ifosfamide (Non Sterile) Ph. Eur./BP/USP	Manufacturing & Packing
20.	Mesna BP/ Ph. Eur./USP	Manufacturing & Packing
21.	Desonide IH	Manufacturing & Packing
22.	Mometasone Furoate Ph. Eur. /BP/USP	Manufacturing & Packing
23.	Mometasone Furoate Monohydrate IH/Ph. Eur.	Manufacturing & Packing
24.	Budesonide Ph. Eur./BP/USP	Manufacturing & Packing
25.	Loteprednol Etabonate IH	Manufacturing & Packing
26.	Ciclesonide Ph. Eur./IH	Manufacturing & Packing
27.	Mercaptopurine Ph. Eur /USP	Manufacturing & Packing
28.	Perindopril Arginine IH	Manufacturing & Packing

24 AUG 2022

Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-1

CERTIFICATE NO. : WC-0099

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Aarti Industries Ltd.**
Plot No.E-50, Unit-IV, MIDC, Tarapur – 401506
Taluka: Palghar, District: Thane-Zone 4

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
29.	Formoterol Fumarate Dihydrate Ph. Eur./BP	Manufacturing & Packing
30.	Formoterol Fumarate USP	Manufacturing & Packing
31.	Phenylephrine Hydrochloride Ph. Eur./BP/IP/USP	Manufacturing & Packing
32.	Fluticasone Furoate IH	Manufacturing & Packing
33.	Olopatadine Hydrochloride USP	Manufacturing & Packing
34.	Enzalutamide IH	Manufacturing & Packing
35.	Chlorzoxazone USP	Manufacturing & Packing
36.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
37.	Apixaban IH	Manufacturing & Packing
38.	Sitagliptin Hydrochloride IH	Manufacturing & Packing
39.	Sitagliptin Phosphate Anhydrous IH	Manufacturing & Packing
40.	Nilotinib Hydrochloride IH	Manufacturing & Packing
41.	Desonide USP	Manufacturing & Packing
42.	Ipratropium Bromide USP	Manufacturing & Packing
43.	Mercaptopurine BP	Manufacturing & Packing
44.	Adapalene BP	Manufacturing & Packing

ITEM(S) FORTY FOUR (44) ONLY

The Written Confirmation remains valid until: 29.07.2025

Signature 24 AUG 2022

Stamp of the authority and date

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-2

CERTIFICATE NO. : WC-0099

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s Aarti Industries Ltd.**
Plot No.E-50, Unit-IV, MIDC, Tarapur – 401506
Taluka: Palghar, District: Thane-Zone 4

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Diflunisal Ph. Eur /BP/USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 29.07.2025

Signature

Stamp of the authority and date

24 AUG 2022