7-5/2014/EU/WC-0295
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation (HQ)
(International Cell)

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

To,

M/s Aarti Pharmalabs Limited
D-53, Phase II, Kalyan Shill Road
Dombivli (E.), Dombivli – 421 204
Taluka: Dombivali City, District: Thane-Zone5

06 JAN 2023

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 02/11/2022 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-0295

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/591 & KD/414

The name of the manufacturer mentioned in the Written Confirmation Certificate (WC-0295) granted on date 18.08.2021 and 30.06.2021 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

7-5/2014/EU/WC-0295
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated:
18 AUG 2021

To

M/s Aarti Industries Limited,
Unit-1, Plot No D-53, Phase-II,
M.I.D.C., Kalyanshil Road, Dombivali (East)
Dist. Thane-421204, Maharashtra, India

Sub: Application for amendment in Written Confirmation certificate issued to M/s Aarti Industries Limited, Unit-1, Plot No D-53, Phase-II, M.I.D.C., Kalyanshil Road, Dombivali (East) Dist. Thane-421204, 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 02.07.2021 and recommendation received from CDSCO West Zone Mumbai vide letter Ref No 17-2/EU-GMP/WZ-2021/1797 dated 11.08.2021 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)

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

CERTIFICATE NO. :

Amended
Annexure-02

WC-0295

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 Limited,
Unit-1, Plot No D-53, Phase-II,
M.I.D.C., Kalyanshil Road, Dombivali (East)
Dist. Thane-421204, Maharashtra, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Deferiprone EP	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: 06/03/2024

Central Drugs Standard Control Organization

Stamp of the authority and date

Signature

18 AUG 2021

7-5/2014/EU/WC-0295
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated:
30 JUN 2021

To

M/s Aarti Industries Limited,
Unit-1, Plot No D-53, Phase-II,
M.I.D.C., Kalyanshil Road, Dombivali (East)
Dist. Thane-421204, Maharashtra, India

Sub: Written Confirmation M/s Aarti Industries Limited, Unit-1, Plot No D-53, Phase-II, M.I.D.C., Kalyanshil Road, Dombivali (East) Dist. Thane-421204, 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 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 event 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 up to
01	05	30 JUN 2021	06.03.2024
02	01	30 JUN 2021	06.03.2024

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. : WC-0295

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 Limited,
Unit-1, Plot No D-53, Phase-II,
M.I.D.C., Kalyanshil Road, Dombivali (East)
Dist. Thane-421204, Maharashtra, India

2. Manufacturer's licence number: KD 591 & KD 414 valid up to 22.12.2025

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 01 & 02

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: 17/03/2021 & 18/03/2021

The Written Confirmation remains valid until: 06/03/2024

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.: +91-11-2323697[illegible]

Signature

Stamp of the authority and date

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

30 JUN 2021

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

Annexure-01

CERTIFICATE NO. : **WC-0295**

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 Limited,**
Unit-1, Plot No D-53, Phase-II,
M.I.D.C., Kalyanshil Road, Dombivali (East)
Dist. Thane-421204, Maharashtra, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Bambuterol Hydrochloride (BP/Ph.Eur)	Manufacturing & Packing
2.	Perindropil Erbumine (BP/Ph.Eur)	Manufacturing & Packing
3.	Phenylephrine Hydrochloride (BP/Ph.Eur)	Manufacturing & Packing
4.	R-Salbutamol Sulphate (IH)	Manufacturing & Packing
5.	Fluticasone Furoate (IH)	Manufacturing & Packing

ITEM(S) Five (05) ONLY

The Written Confirmation remains valid until: 06/03/2024

Signature

Stamp of the authority and date

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

30 JUN 2021

Annexure-02

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

CERTIFICATE NO. : WC-0295

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 Limited,
Unit-1, Plot No D-53, Phase-II,
M.I.D.C., Kalyanshil Road, Dombivali (East)
Dist. Thane-421204, Maharashtra, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Deferiprone IH	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: 06/03/2024

Signature

Stamp of the authority and date

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

30 JUN 2021