Amended

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated

25 MAR 2021

To

M/s. Nuray Chemicals Pvt Ltd.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur-602003
Tamil Naidu, India

SUB:- Written Confirmation of M/s. Nuray Chemicals Pvt Ltd., Plot No. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur-602003 Tamil Naidu, 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, South Zone , Chennai and the recommendation received from DDC(I), South Zonal office 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	11	25 MAR 2021	06.12.2023
2	08	25 MAR 2021	06.12.2023

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-0416**

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. Nuray Chemicals Pvt Ltd.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur-602003
Tamil Naidu, India

2. Manufacturer's licence number: Form-25 TN 00003314 dated 25.03.2013
Form-28 TN 00003315 dated 25.03.2013

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 list enclosed in Annexures

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: 06th & 07th January, 2021

The Written Confirmation remains valid until: 06th December, 2023

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

Signature

Stamp of the authority and date

25 MAR 2021

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

Amended
Annexure-1
WC-0416

CERTIFICATE NO. :

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. Nuray Chemicals Pvt Ltd.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur-602003
Tamil Naidu, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Atropine Sulphate USP	Manufacturing & Packing
2.	Chlorzoxazone USP	Manufacturing & Packing
3.	Dapsone USP	Manufacturing & Packing
4.	Diazoxide USP	Manufacturing & Packing
5.	Dichlorphenamide USP	Manufacturing & Packing
6.	Oxandrolone USP	Manufacturing & Packing
7.	Parecoxib Sodium IH	Manufacturing & Packing
8.	Piribedil IH	Manufacturing & Packing
9.	Prazosin Hydrochloride USP	Manufacturing & Packing
10.	Ramelteon IH	Manufacturing & Packing
11.	Thiothixene USP	Manufacturing & Packing

ITEM(S) Eleven (11) ONLY

The Written Confirmation remains valid until: 06.12.2023

Signature

Stamp of the authority and date

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

25 MAR 2021

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

Amended Annexure-2

CERTIFICATE NO. : WC416

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. Nuray Chemicals Pvt Ltd.,**
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur-602003
Tamil Naidu, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Brivudine IH	Manufacturing & Packing
2.	Carglumic Acid IH	Manufacturing & Packing
3.	Fludrocortisone Acetate USP	Manufacturing & Packing
4.	Methyl Testosterone USP	Manufacturing & Packing
5.	Nitisinone IH	Manufacturing & Packing
6.	Stiripentol IH	Manufacturing & Packing
7.	Treprostinil Sodium	Manufacturing & Packing
8.	Trientine Hydrochloride USP	Manufacturing & Packing

ITEM(S) Eight (08) 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: 06.12.2023

Signature

Stamp of the authority and date

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

25 MAR 2021

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation (HQ)
(International Cell)

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

22 JUN 2021

To,

M/s. Nuray Chemicals Pvt. Ltd.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602 003,
Tamil Nadu, India

SUB:- Application for update of address in the Written Confirmation of M/s. Nuray Chemicals Pvt. Ltd., Plot No. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur – 602 003, Tamil Nadu, 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 17/06/2021 for the update in the Written Confirmation Certificate issued by this office.

In this regard, it is stated that your application has been considered. Kindly find the enclosed Written Confirmation Certificate with updated address. 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

CERTIFICATE NO. : **Amended**
WC-0416

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 of site:** M/s. Nuray Chemicals Pvt. Ltd.

2. **Manufacturer's License Number:** **Form-25 TN 00003314 dated 25.03.2013**
Form-28 TN 00003315 dated 25.03.2013

The address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0416) issued on date 15.03.2021 is hereby amended as follows:

In place of:
M/s. Nuray Chemicals Pvt. Ltd., Plot No. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur – 602 003, **Tamil Naidu**, India.

Read as:
M/s. Nuray Chemicals Pvt. Ltd., Plot No. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur – 602 003, **Tamil Nadu**, India.

All other conditions of Written Confirmation Certificate will remain same.

Signature

Stamp of the authority and date

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

22 JUN 2021

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

29 APR 2021

To

M/s. Nuray Chemicals Pvt. Ltd.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602 003
Tamil Nadu, India

SUB:- Written Confirmation of M/s. Nuray Chemicals Pvt. Ltd., Plot No. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur – 602 003, Tamil Nadu, 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, South Zone office, and the recommendation received from DDC (I), South 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	11	12.03.2021	06.12.2023
2	08	12.03.2021	06.12.2023
3	01	29 APR 2021	06.12.2023

Yours faithfully,

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

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

Annexure-3

CERTIFICATE NO. : **WC-0416**

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. Nuray Chemicals Pvt. Ltd.,**
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602 003
Tamil Nadu, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Betaine Anhydrous 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: 06.12.2023

Signature

Stamp of the authority and date

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

29 APR 2021

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

To

M/s. Nuray Chemicals Pvt. Ltd.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602 003
Tamil Nadu, India

13 MAY 2021

SUB:- Written Confirmation of M/s. Nuray Chemicals Pvt. Ltd., Plot No. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur – 602 003, Tamil Nadu, 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, South Zone office, and the recommendation received from DDC (I), South 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	11	12.03.2021	06.12.2023
2	08	12.03.2021	06.12.2023
3	01	29.04.2021	06.12.2023
4	07	13 MAY 2021	06.12.2023

Yours faithfully,

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

Annexure-4

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

CERTIFICATE NO. : WC-0416

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. Nuray Chemicals Pvt. Ltd.,**
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602 003
Tamil Nadu, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Methsuximide USP	Manufacturing & Packing
2.	Tafamidis	Manufacturing & Packing
3.	Tafamidis Meglumine	Manufacturing & Packing
4.	Phenoxybenzamine Hydrochloride USP	Manufacturing & Packing
5.	Alosetron Hydrochloride USP	Manufacturing & Packing
6.	Glycerol Phenylbutyrate	Manufacturing & Packing
7.	Atovaquone USP	Manufacturing & Packing

ITEM(S) SEVEN (07) 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: 06.12.2023

Signature

Stamp of the authority and date

13 MAY 2021

Amended

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

13 OCT 2021

To,
M/s. Nuray Chemicals Private Limited.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur,Thirvallur-602003
Tamil Nadu India

SUB:- Written Confirmation of M/s. Nuray Chemicals Private Limited., Plot No. 111, SIDCO Industrial Estate, Kakkalur,Thirvallur-602003 Tamil Nadu 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, South Zone and the recommendation received from DDC(I), South Zone office 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
01	11	25.03.2021	06.12.2023
02	08	25.03.2021	06.12.2023
03	01	29.04.2021	06.12.2023
04	07	13.05.2021	06.12.2023
05	01	13 OCT 2021	06.12.2023

Yours faithfully,

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

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

Amended
Annexure-05

CERTIFICATE NO. : **WC-0416**

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. Nuray Chemicals Private Limited.,**
Plot No. 111, SIDCO Industrial Estate,
Kakkalur,Thirvallur-602003
Tamil Nadu India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Peramivir 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 substance is not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 06.12.2023

Signature

Stamp of the authority and date

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

13 OCT 2021

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To,
M/s. Nuray Chemicals Private Limited.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur,Thirvallur-602003
Tamil **Nadu India**

08 JUN 2022

SUB:- Written Confirmation of M/s. Nuray Chemicals Private Limited., Plot No. 111, SIDCO Industrial Estate, Kakkalur,Thirvallur-602003 Tamil Nadu 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 online application no. WC/FR/2022/2299 submitted to CDSCO, South Zone and the recommendation received from DDC(I), South Zone office 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
01	11	25.03.2021	06.12.2023
02	08	25.03.2021	06.12.2023
03	01	29.04.2021	06.12.2023
04	07	13.05.2021	06.12.2023
05	01	13.10.2021	06.12.2023
06	01	08 JUN 2022	06.12.2023

Yours faithfully,

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

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

Annexure-06

CERTIFICATE NO. : WC-0416

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. Nuray Chemicals Private Limited.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thirvallur-602003
Tamil Nadu India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	L-Glutamine 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 substance is not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 06.12.2023

Signature

Stamp of the authority and date

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

08 JUN 2022

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

14 JUN 2022

To,
M/s. Nuray Chemicals Private Limited.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur,Thirvallur-602003
Tamil Nadu India

SUB:- Written Confirmation of M/s. Nuray Chemicals Private Limited., Plot No. 111, SIDCO Industrial Estate, Kakkalur,Thirvallur-602003 Tamil Nadu 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 online application no. WC/FR/2022/2299 submitted to CDSCO, South Zone and the recommendation received from DDC(I), South Zone office 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
01	11	25.03.2021	06.12.2023
02	08	25.03.2021	06.12.2023
03	01	29.04.2021	06.12.2023
04	07	13.05.2021	06.12.2023
05	01	13.10.2021	06.12.2023
06	01	08.06.2022	06.12.2023
07	01	14 JUN 2022	06.12.2023

Yours faithfully,

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

Annexure-07

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

WC-0416

CERTIFICATE NO. :

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. Nuray Chemicals Private Limited.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thirvallur-602003
Tamil Nadu India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Treprostinil Diolamine 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 substance is not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 06.12.2023

Signature

Stamp of the authority and date

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

14 JUN 2022

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

16 JUN 2022

To

M/s. Nuray Chemicals Pvt. Ltd.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602 003
Tamil Nadu, India

SUB:- Written Confirmation of M/s. Nuray Chemicals Pvt. Ltd., Plot No. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur – 602 003, Tamil Nadu, 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 online application No. WC/ED/2022/3834 submitted to CDSCO, South Zone office, and the recommendation received from DDC (I), South 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
01	11	12.03.2021	06.12.2023
02	08	12.03.2021	06.12.2023
03	01	29.04.2021	06.12.2023
04	07	13.05.2021	06.12.2023
05	01	13.10.2021	06.12.2023
06	01	08.06.2022	06.12.2023
07	01	14.06.2022	06.12.2023
08	01	15 JUN 2022	06.12.2023

Yours faithfully,

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

Annexure-08

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

CERTIFICATE NO. : WC-0416

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. Nuray Chemicals Pvt. Ltd.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602 003
Tamil Nadu, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Prucalopride Succinate 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: 06.12.2023

Signature V.K.S

16 JUN 2022

Stamp of the authority and date

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

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

15 MAY 2023

To,

M/s Nuray Chemicals Private Limited.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thirvallur-602003
Tamil Nadu India

SUB:- Written Confirmation of M/s. Nuray Chemicals Private Limited., Plot No. 111, SIDCO Industrial Estate, Kakkalur,Thirvallur-602003 Tamil Nadu 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 online application no. WC/ED/2023/6352 dated 24.01.2023 submitted to CDSCO, South Zone and the recommendation received from DDC(I), South Zone office 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
01	11	25.03.2021	06.12.2023
02	08	25.03.2021	06.12.2023
03	01	29.04.2021	06.12.2023
04	07	13.05.2021	06.12.2023
05	01	13.10.2021	06.12.2023
06	01	08.06.2022	06.12.2023
07	01	14.06.2022	06.12.2023
08	01	16.06.2022	06.12.2023
09	01	15 MAY 2023	06.12.2023

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Annexure-09

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

CERTIFICATE NO. : WC-0416

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. Nuray Chemicals Private Limited.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thirvallur-602003
Tamil Nadu India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Acebutolol Hydrochloride USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 06.12.2023

Signature

Stamp of the authority and date

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

15 MAY 2023

7-5/2017/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 06 JUL 2023

To,

M/s Nuray Chemicals Private Limited.,
Plot No. 111, SIDCO Industrial Estate,
Kakkalur,Thirvallur-602003
Tamil Nadu India

SUB:- Written Confirmation of M/s. Nuray Chemicals Private Limited., Plot No. 111, SIDCO Industrial Estate, Kakkalur,Thirvallur-602003 Tamil Nadu 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 online application no. WC/ED/2023/6361 dated 05.04.2023 submitted to CDSCO, South Zone and the recommendation received from DDC(I), South Zone office 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
01	11	25.03.2021	06.12.2023
02	08	25.03.2021	06.12.2023
03	01	29.04.2021	06.12.2023
04	07	13.05.2021	06.12.2023
05	01	13.10.2021	06.12.2023
06	01	08.06.2022	06.12.2023
07	01	14.06.2022	06.12.2023
08	01	16.06.2022	06.12.2023
09	01	15.05.2023	06.12.2023
10	01	06 JUL 2023	06.12.2023

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Annexure-10

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

CERTIFICATE NO. : **WC-0416**

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. Nuray Chemicals Pvt. Ltd.,**
Plot No. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602 003
Tamil Nadu, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Benazepril Hydrochloride USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 06.12.2023

Signature

DR. RAJEEV SINGH RAGHUVANSHI
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road,
New Delhi (India)

Stamp of the authority and date

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

06 JUL 2023

7-5/2013/EU/WC-0416

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To,

M/s. Nuray Chemicals Private Limited,
Plot no. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602003, Tamil Nadu, India

04 SEP 2023

SUB:- Written Confirmation M/s. Nuray Chemicals Private Limited, Plot no. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur – 602003, Tamil Nadu, 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 online application no.WC/ED/2022/5770 dated 04.11.2022submitted to CDSCO, DDC(I), South Zone, Chennai, Tamil Nadu and the recommendation received from DDC(I), South 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
01	11	25.03.2021	06.12.2023
02	08	25.03.2021	06.12.2023
03	01	29.04.2021	06.12.2023
04	07	13.05.2021	06.12.2023
05	01	13.10.2021	06.12.2023
06	01	08.06.2022	06.12.2023
07	01	14.06.2022	06.12.2023
08	01	16.06.2022	06.12.2023
09	01	15.05.2023	06.12.2023
10	01	06.07.2023	06.12.2023
11	01	04 SEP 2023	06.12.2023

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

CERTIFICATE NO. : **Annexure-11**

WC-0416

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. Nuray Chemicals Private Limited,**
Plot no. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602003, Tamil Nadu, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	"Pitolisant Hydrochloride 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 active substance 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: 06.12.2023

Signature

04 SEP 2023

Stamp of the authority and date

7-5/2013/EU/WC-0416
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 15 SEP 2023

To,

M/s. Nuray Chemicals Private Limited,
Plot no. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602003, Tamil Nadu, India

SUB:- Written Confirmation M/s. Nuray Chemicals Private Limited, Plot no. 111, SIDCO Industrial Estate, Kakkalur, Thiruvallur – 602003, Tamil Nadu, 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 online application no. WC/ED/2023/6841 dated 01-APR-2023 submitted to CDSCO, DDC(I), South Zone, Chennai, Tamil Nadu and the recommendation received from DDC(I), South 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
01	11	25.03.2021	06.12.2023
02	08	25.03.2021	06.12.2023
03	01	29.04.2021	06.12.2023
04	07	13.05.2021	06.12.2023
05	01	13.10.2021	06.12.2023
06	01	08.06.2022	06.12.2023
07	01	14.06.2022	06.12.2023
08	01	16.06.2022	06.12.2023
09	01	15.05.2023	06.12.2023
10	01	06.07.2023	06.12.2023
11	01	04.09.2023	06.12.2023
12	01	15 SEP 2023	06.12.2023

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

Annexure-12

CERTIFICATE NO. : WC-0416

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. Nuray Chemicals Private Limited,**
Plot no. 111, SIDCO Industrial Estate,
Kakkalur, Thiruvallur – 602003, Tamil Nadu, India

List of API(s):

Sr. No.	Active substance (s)	Activity(ies)
1.	Cevimeline Hydrochloride IHS	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 active substance 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: 06.12.2023

Signature

Stamp of the authority and date

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

15 SEP 2023