7-5/2014/EU/WC-0278
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

12 7 AUG 2021

To

M/s. Rusan Pharma Ltd.
Plot No 6406, GIDC Estate
Ankleshwar – 393 002 Dist Bharuch, Gujarat

SUB:- Written Confirmation of M/s Rusan Pharma Ltd., Plot No 6406, GIDC Estate, Ankleshwar – 393 002 Dist Bharuch, Gujarat 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, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	12	27 AUG 2021	10.06.2024
02	02	27 AUG 2021	10.06.2024

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-0278**

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. Rusan Pharma Ltd.
Plot No 6406, GIDC Estate
Ankleshwar – 393 002 Dist Bharuch, Gujarat

2. Manufacturer's licence number: G/1505 & G/1094

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: 09-10/09/2020

The Written Confirmation remains valid until: 10.06.2024

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.: +91-11-23236973

Signature

Stamp of the authority and date

27 AUG 2021

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

Annexure-01

CERTIFICATE NO. : WC-0278

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. Rusan Pharma Ltd.
Plot No 6406, GIDC Estate
Ankleshwar – 393 002, Dist-Bharuch, Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Buprenorphine Hydrochloride EP/BP	Manufacturing & Packing
2.	Buprenorphine EP/BP	Manufacturing & Packing
3.	Bisoprolol Fumarate EP/BP/USP	Manufacturing & Packing
4.	Naltrexone Hydrochloride EP/USP	Manufacturing & Packing
5.	Naloxone Hydrochloride EP/BP/USP	Manufacturing & Packing
6.	Apomorphine Hydrochloride USP/BP	Manufacturing & Packing
7.	Fentanyl Citrate USP/EP/BP	Manufacturing & Packing
8.	Fentanyl EP/BP	Manufacturing & Packing
9.	Methadone Hydrochloride BP/EP/USP	Manufacturing & Packing
10.	Naltrexone Base IH	Manufacturing & Packing
11.	Nalbuphine Hydrochloride IH	Manufacturing & Packing
12.	Eflornithine Hydrochloride Monohydrate IH	Manufacturing & Packing

ITEM(S) Twelve (12) ONLY

The Written Confirmation remains valid until: 10.06.2024

Signature

Stamp of the authority and date

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

27 AUG 2021

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

Annexure-02

CERTIFICATE NO. : WC-0278

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. Rusan Pharma Ltd.
Plot No 6406, GIDC Estate
Ankleshwar – 393 002, Dist- Bharuch, Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Nalmefene Hydrochloride IH	Manufacturing & Packing
2.	Promedol Hydrochloride IH	Manufacturing & Packing

ITEM(S) TWO (02) 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: 10.06.2024

Signature

Stamp of the authority and date

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

27 AUG 2021

7-5/2014/EU/WC-0278
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

15 MAR 2022

To,
M/s. Rusan Pharma Ltd.
Plot No 6406, GIDC Estate
Ankleshwar – 393 002 Dist Bharuch, Gujarat

SUB:- Application for amendment of the Written Confirmation of "M/s. Rusan Pharma Ltd., Plot No 6406, GIDC Estate, Ankleshwar – 393 002 Dist Bharuch, Gujarat" 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 14/03/2022 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)

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

Amended

CERTIFICATE NO. : WC-0278

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. Rusan Pharma Ltd., Plot No 6406, GIDC Estate, Ankleshwar – 393 002 Dist Bharuch, Gujarat"**

2. **Manufacturer's License Number:** G/1505 & G/1094

The address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0278) granted on date 27.08.2021 is hereby amended as follows:

In place of:

"M/s. Rusan Pharma Ltd., Plot No 6406, GIDC Estate, Ankleshwar – 393 002, Dist Bharuch, Gujarat"

Read as:

"M/s. Rusan Pharma Ltd., Plot No 6406, 6407 & 6411, GIDC Estate, Ankleshwar – 393 002, Dist Bharuch, Gujarat"

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

15 MAR 2022

7-5/2014/EU/WC-00278
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

03 JUN 2022

To

M/s. Rusan Pharma Ltd.
Plot No 6406, GIDC Estate
Ankleshwar – 393 002 Dist Bharuch, Gujarat

SUB:- Written Confirmation of M/s Rusan Pharma Ltd., Plot No 6406, GIDC Estate, Ankleshwar – 393 002 Dist Bharuch, Gujarat 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/2022/2228 submitted to CDSCO, Ahmedabad Zone office, and the recommendation received from DDC (I), Ahmedabad 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	12	27.08.2021	10.06.2024
2	02	27.08.2021	10.06.2024
3	02	03 JUN 2022	10.06.2024

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-0278**

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. Rusan Pharma Ltd.**
Plot No 6406, GIDC Estate
Ankleshwar – 393 002 Dist Bharuch, Gujarat

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Apomorphine Hydrochloride Hemihydrate EP	Manufacturing & Packing
2.	Buprenorphine Hydrochloride USP	Manufacturing & Packing

ITEM(S) Two (02) ONLY

The Written Confirmation remains valid until: 10.06.2024

Signature

Stamp of the authority and date

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

03 JUN 2022

7-5/2014/EU/WC-0278
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 23 JUN 2023

To

M/s. Rusan Pharma Ltd.,
Plot No 6406, 6407& 6411, GIDC Estate, Ankleshwar-393002
Dist- Bharuch, Gujarat, India

SUB:- Written Confirmation of M/s. Rusan Pharma Ltd., Plot No 6406, 6407& 6411, GIDC Estate, Ankleshwar-393002, Dist- Bharuch, Gujarat, 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/2023/7018 submitted to CDSCO, Ahmedabad office, and the recommendation received from DDC (I), Ahmedabad 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	12	27.08.2021	10.06.2024
2	02	27.08.2021	10.06.2024
3	02	03.06.2022	10.06.2024
4	01	23 JUN 2023	10.06.2024

Yours faithfully,

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

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

Annexure-4

CERTIFICATE NO. : **WC-0278**

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. Rusan Pharma Ltd., Plot No 6406, 6407& 6411, GIDC Estate, Ankleshwar-393002, Dist- Bharuch, Gujarat, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Sodium Oxybate IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance 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: 10.06.2024

Rajan Singh

Signature

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

Stamp of the authority and date

23 JUN 2023