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: 11 FEB 2025

To,

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

SUB:- Written Confirmation of M/s. Rusan Pharma Limited, Plot No.6406, 6407 & 6411, GIDC Estate, Ankleshwar-393002, Dist- Bharuch 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/2024/8644 dated 01-Jul-2024 submitted to CDSCO, DDC(I), Ahmedabad Zone, 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.
9. The manufacturer is required to comply to the provision of GSR 20(E) dated 18.01.2022.

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
--	--	11 FEB 2025	09.06.2027
01	17	11 FEB 2025	09.06.2027
02	03	11 FEB 2025	09.06.2027

Yours faithfully,

11/02/25

(Ranga Chandrashekar)
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

WC-0278

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

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

2. Manufacturer's licence number: **G/25/1505**

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 as 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: 04.10.2023 & 05.10.2023

The Written Confirmation remains valid until: 09.06.2027

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: Ranga Chandrashekar,
Joint Drugs Controller (India)
E-mail: ranga.cs@cdsco.nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Chandrashekar
11/02/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

11 FEB 2025

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

Annexure-01
WC-0278

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

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Buprenorphine EP	Manufacturing & Packing
2.	Buprenorphine Hydrochloride Ph.Eur/BP/USP	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.	Naltrexone Base IH	Manufacturing & Packing
7.	Apomorphine Hydrochloride USP	Manufacturing & Packing
8.	Apomorphine Hydrochloride Hemihydrate EP	Manufacturing & Packing
9.	Fentanyl EP	Manufacturing & Packing
10.	Fentanyl Citrate EP/BP/USP	Manufacturing & Packing
11.	Methadone Hydrochloride EP/BP/USP	Manufacturing & Packing
12.	Nalbuphine Hydrochloride IH	Manufacturing & Packing
13.	Eflornithine Hydrochloride Monohydrate IH	Manufacturing & Packing
14.	Nalbuphine Base IH	Manufacturing & Packing
15.	Carbamazepine EP/USP	Manufacturing & Packing
16.	Clonazepam EP	Manufacturing & Packing
17.	Diazepam EP	Manufacturing & Packing

ITEM(S) Seventeen (17) ONLY

The Written Confirmation remains valid until: 09.06.2027

Chandrashekar 11/02/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

Central Drugs Standard Control Organisation
सत्यमेव जयते
Ministry of Health & Family Welfare, GOM. of India

11 FEB 2025

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

CERTIFICATE NO. : **Annexure-02**

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 Limited,**
Plot No.6406, 6407 & 6411, GIDC Estate,
Ankleshwar-393002, Dist- Bharuch

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Promedol Hydrochloride IH	Manufacturing & Packing
2.	Nalmefene Hydrochloride IH	Manufacturing & Packing
3.	Sodium Oxybate/Sodium Oxybutyrate IH	Manufacturing & Packing

ITEM(S) Three (03) 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: 09.06.2027

Chandrashekar

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

11 FEB 2025