7-5/2013/EU/WC-0027
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

02 MAY 2022

To

M/s. Nosch Labs Pvt. Ltd., Unit-II,
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

Subject:- Written Confirmation of M/s. Nosch Labs Pvt. Ltd., Unit-II, Sy. No. 14, Gaddapotharam Village, IDA, Kazipally, Jinnaram Mandal, Sangareddy Dist.-502319, Telangana, 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/RE/2022/1713 submitted to CDSCO, Hyderabad zone office and the recommendation received from DDC(I), Hyderabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	32	02 MAY 2022	**25/07/2025**

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. : WC-0027

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. Nosch Labs Pvt. Ltd., Unit-II,
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

2. Manufacturer's licence number: 42/MD/AP/2004/B/R

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

As per List enclosed as Annexure-1

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: 08/12/2021 to 10/12/2021

The Written Confirmation remains valid until: 25/07/2025

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

Signature

Stamp of the authority and date

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

0 2 MAY 2022

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

CERTIFICATE NO. : **Annexure-1**

WC-0027

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

Name and address of site: M/s. Nosch Labs Pvt. Ltd., Unit-II,
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Enalapril Maleate USP/BP/Ph.Eur	Manufacturing & Packing
2.	Itraconazole USP/BP/Ph.Eur	Manufacturing & Packing
3.	Lansoprazole USP/BP/Ph.Eur	Manufacturing & Packing
4.	Quetiapine Fumarate USP/Ph.Eur	Manufacturing & Packing
5.	Esomeprazole Magnesium USP	Manufacturing & Packing
6.	Olanzapine USP/Ph. Eur	Manufacturing & Packing
7.	Duloxetine Hydrochloride USP/Ph. Eur	Manufacturing & Packing
8.	Tamsulosin Hydrochloride USP/BP/Ph.Eur	Manufacturing & Packing
9.	Esomeprazole Magnesium Trihydrate BP/Ph.Eur	Manufacturing & Packing
10.	Pantoprazole Sodium Sesquihydrate BP/Ph.Eur/USP	Manufacturing & Packing
11.	Pantoprazole Sodium USP	Manufacturing & Packing
12.	Ketorolac Tromethamine USP	Manufacturing & Packing
13.	Ketorolac Trometamol BP/Ph.Eur	Manufacturing & Packing
14.	Moxifloxacin Hydrochloride USP/BP/Ph. Eur	Manufacturing & Packing
15.	Sumatriptan Succinate USP/BP/Ph. Eur	Manufacturing & Packing
16.	Omeprazole BP/ Ph. Eur	Manufacturing & Packing
17.	Omeprazole Sodium BP/Ph. Eur	Manufacturing & Packing
18.	Omeprazole magnesium USP/Ph.Eur	Manufacturing & Packing
19.	Doxazosin Mesylate USP/Ph.Eur/BP	Manufacturing & Packing
20.	Rizatriptan Benzoate USP	Manufacturing & Packing
21.	Pramipexole Dihydrochloride BP/Ph. Eur/USP	Manufacturing & Packing
22.	Donepezil Hydrochloride USP	Manufacturing & Packing
23.	Rasagiline Mesylate IH	Manufacturing & Packing
24.	Dexlansoprazole IH	Manufacturing & Packing
25.	Dapoxetine Hydrochloride IH	Manufacturing & Packing
26.	Esomeprazole Magnesium Dihydrate Ph. Eur	Manufacturing & Packing
27.	Dexrabeprazole Sodium IH	Manufacturing & Packing
28.	Amorolfine Hydrochloride Ph.Eur	Manufacturing & Packing
29.	Dabigatran Etexilate IH	Manufacturing & Packing
30.	Rabeprazole Sodium Hydrate Ph.Eur	Manufacturing & Packing

0/c 02 MAY 2022

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

CERTIFICATE NO. :

Annexure-1

WC-0027

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

Name and address of site: M/s. Nosch Labs Pvt. Ltd., Unit-II,
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
31.	Terconazole Ph.Eur	Manufacturing & Packing
32.	Rosuvastatin Calcium Ph.Eur	Manufacturing & Packing

ITEM(S) Thirty Two (32) ONLY

The Written Confirmation remains valid until: 25/07/2025

Signature

Stamp of the authority and date

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

02 MAY 2022

7-5/2013/EU/WC-0027
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. Nosch Labs Pvt. Ltd., Unit-II,
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

10 MAY 2022

Subject: - Written Confirmation of M/s. Nosch Labs Pvt. Ltd., Unit-II, Sy. No. 14, Gaddapotharam Village, IDA, Kazipally, Jinnaram Mandal, Sangareddy Dist.-502319, Telangana, 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/2022/1712 submitted to CDSCO, Hyderabad zone office and the recommendation received from DDC(I), Hyderabad 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	32	02/05/2022	25/07/2025
2	03	10 MAY 2022	25/07/2025

Yours faithfully,

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

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

Annexure-2

CERTIFICATE NO. : WC-0027

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

Name and address of site: **M/s. Nosch Labs Pvt. Ltd., Unit-II,**
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Naratriptan Hydrochloride USP	Manufacturing & Packing
2.	Pitavastatin Calcium IH	Manufacturing & Packing
3.	Sitagliptin Phosphate Monohydrate Ph.Eur	Manufacturing & Packing

ITEM(S) Three (03) ONLY

The Written Confirmation remains valid until: 25/07/2025

Signature

Stamp of the authority and date

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

10 MAY 2022

7-5/2013/EU/WC-0027
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA,BhawanKotla Road,
New Delhi-110002
Dated:

0 8 JUN 2022

To
M/s. Nosch Labs Pvt. Ltd., Unit-II,
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

Subject:- Written Confirmation of M/s. Nosch Labs Pvt. Ltd., Unit-II, Sy. No. 14, Gaddapotharam Village, IDA, Kazipally, Jinnaram Mandal, Sangareddy Dist.-502319, Telangana, 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/2022/3876 submitted to CDSCO, Hyderabad zone office and the recommendation received from DDC(I), Hyderabad 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.

o/c

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	32	02/05/2022	25/07/2025
2	03	10/05/2022	25/07/2025
3	01	08 JUN 2022	25/07/2025

Yours faithfully,

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

o/c

08.06.2022

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

Annexure-3

CERTIFICATE NO. : WC-0027

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

Name and address of site: M/s. Nosch Labs Pvt. Ltd., Unit-II,
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Rivaroxaban Ph.Eur	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 25/07/2025

Signature

o/c
08.06.2022
DI (KRS)

Stamp of the authority and date

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

08 JUN 2022

7-5/2013/EU/WC-0027

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

FDA,BhawanKotla Road,
New Delhi-110002
Dated:

15 JUN 2022

To
M/s. Nosch Labs Pvt. Ltd., Unit-II,
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

Subject:- Written Confirmation of M/s. Nosch Labs Pvt. Ltd., Unit-II, Sy. No. 14, Gaddapotharam Village, IDA, Kazipally, Jinnaram Mandal, Sangareddy Dist.-502319, Telangana, 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/2022/3734 submitted to CDSCO, Hyderabad zone office and the recommendation received from DDC(I), Hyderabad 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.

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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.

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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	32	02/05/2022	25/07/2025
2	03	10/05/2022	25/07/2025
3	01	08/06/2022	25/07/2025
4	01	15 JUN 2022	25/07/2025

Yours faithfully,

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

15.6.22

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

Annexure-4

CERTIFICATE NO. :

WC-0027

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

Name and address of site: M/s. Nosch Labs Pvt. Ltd., Unit-II,
Sy. No. 14, Gaddapotharam Village,
IDA, Kazipally, Jinnaram Mandal,
Sangareddy Dist.-502319, Telangana, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Linezolid USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 25/07/2025

O/C

Signature

15-06-2022

Stamp of the authority and date

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

15 JUN 2022