7-5/2019/EU/WC-0436

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 20 FEB 2025

To,
M/s. Lupin Manufacturing Solutions Limited.,
Plot No.130, Road No.11, Jawaharlal Nehru
Pharma City, Parawada(M), Anakapalli District-531019,
Andhra Pradesh, India

SUB:- Written Confirmation of M/s. Lupin Manufacturing Solutions Limited., Plot No.130, Road No.11, Jawaharlal Nehru Pharma City, Parawada(M), Anakapalli District-531019,Andhra Pradesh, 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/2024/8145 dated 12.03.2024 submitted to CDSCO, ADC(I), Visakhapatnam Sub Zone, and the recommendation received from ADC(I), Visakhapatnam Sub 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
-	-	20 FEB 2025	28.01.2028
01	09	20 FEB 2025	28.01.2028

Yours faithfully,

Chandrashekar 20/02/25

(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

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

CERTIFICATE NO. :

WC-0436

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. Lupin Manufacturing Solutions Limited.,**
Plot No.130, Road No.11, Jawaharlal Nehru
Pharma City, Parawada(M), Anakapalli District-531019,
Andhra Pradesh, India

2. Manufacturer's licence number: **02/VP/AP/2016/B/CC**

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 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: 11.11.2024 & 12.11.2024

The Written Confirmation remains valid until: **28.01.2028**

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: **Sh. Ranga Chandrashekar**,
Joint Drugs Controller (India)

E-mail: ranga.cs@cdsco.nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

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

20 FEB 2025

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

Annexure-01

CERTIFICATE NO. : WC-0436

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. Lupin Manufacturing Solutions Limited., Plot No.130, Road No.11, Jawaharlal Nehru Pharma City, Parawada(M), Anakapalli District-531019,Andhra Pradesh, India

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Darunavir Ethanolate IH	Manufacturing & Packing
2.	Fenofibrate USP	Manufacturing & Packing
3.	Linezolid USP	Manufacturing & Packing
4.	Sitagliptin Phosphate IH	Manufacturing & Packing
5.	Propranolol Hydrochloride USP	Manufacturing & Packing
6.	Raltegravir Potassium IH	Manufacturing & Packing
7.	Canagliflozin Hemihydrate IH	Manufacturing & Packing
8.	Pyrazinamide USP/IP	Manufacturing & Packing
9.	Empaglifozin IH	Manufacturing & Packing

ITEM(S) NINE (09) ONLY

The Written Confirmation remains valid until: 28.01.2028

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

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

20 FEB 2025

7-5/2019/EU/WC-0436
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated: 01 AUG 2025

To

M/s. Lupin Manufacturing Solutions Limited.,
Plot No.130, Road No.11, Jawaharlal Nehru Pharma City,
Parawada(M), Anakapalli District-531019,
Andhra Pradesh, India

Subject: - Written Confirmation of **M/s. Lupin Manufacturing Solutions Limited., Plot No.130, Road No.11, Jawaharlal Nehru Pharma City, Parawada(M), Anakapalli District-531019, Andhra Pradesh, 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 no. **WC/FR/2024/8114** submitted to CDSCO, ADC(I), Visakhapatnam Sub-Zone office, and the recommendation received from ADC(I), Visakhapatnam Sub-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.

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
--	--	20.02.2025	**28.01.2028**
01	09	20.02.2025	**28.01.2028**
02	04	01 AUG 2025	**28.01.2028**
03	03	01 AUG 2025	**28.01.2028**

Yours faithfully,

Chandrashekar
01/08/25

Ranga Chandrashekar
Joint Drugs Controller (India)

नियंत्रक (भारत) ... ller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन ... संघा महानिदेशालय
C.D.S.C.O(HQ) ... 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

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

CERTIFICATE NO. : **Annexure-02**
WC-0436

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. Lupin Manufacturing Solutions Limited,**
Plot No.130, Road No.11,
Jawaharlal Nehru Pharma City, Parawada(M),
Anakapalli District-531019, Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Bedaquiline Fumarate IH	Manufacturing & Packing
2.	Tolvaptan IH	Manufacturing & Packing
3.	Azilsartan Kamedoxomil IH	Manufacturing & Packing
4.	Dapagliflozin Propanediol IH	Manufacturing & Packing

ITEM(S) Four (04) ONLY

The Written Confirmation remains valid until: 28.01.2028

Chandrashekar
Signature 01/08/25

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
Ministry of Health & Family Welfare, Govt. of India

01 AUG 2025

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

CERTIFICATE NO. : **Annexure-03**
WC-0436

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. Lupin Manufacturing Solutions Limited,**
Plot No.130, Road No.11,
Jawaharlal Nehru Pharma City, Parawada(M),
Anakapalli District-531019, Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Cysteamine Bitartrate IH	Manufacturing & Packing
2.	Letermovir IH	Manufacturing & Packing
3.	Ivacaftor 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 substance(s) for the purpose of export only, as the above-mentioned active substance(s) are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 28.01.2028

Chandrashekar

Signature 01/08/25

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
Ministry of Health & Family Welfare, Govt. of India

0 1 AUG 2025