7-5/2019/EU/WC-0459
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

02 DEC 2022

To

M/s Laurus Labs Limited, Unit-4,
Plot No. 25, 25A to 25K, Atchutapuram,
Rambilli (M), Visakhapatnam-531011
Andhra Pradesh, India

SUB:- Written Confirmation of M/s Laurus Labs Limited, Unit-4, Plot No. 25, 25A to 25K, Atchutapuram, Rambilli (M), Visakhapatnam-531011 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/2022/5524submitted 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
01	12	02 DEC 2022	27.11.2025
02	03	02 DEC 2022	27.11.2025

Yours faithfully,

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

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

WC-0459

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 Laurus Labs Limited, Unit-4,**
Plot No. 25, 25A to 25K, Atchutapuram,
Rambilli (M), Visakhapatnam-531011
Andhra Pradesh, India

2. Manufacturer's license Number: 20/VSP/AP/2017/B/G

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 Annexed

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: 20/10/2021 & 21/10/2021

The Written Confirmation remains valid until: 27.11.2025

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

02 DEC 2022

Signature

Stamp of the authority and date

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

Annexure-01

CERTIFICATE NO. : WC-0459

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 Laurus Labs Limited, Unit-4, Plot No. 25, 25A to 25K, Atchutapuram, Rambilli (M), Visakhapatnam-531011 Andhra Pradesh, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Digoxin USP/Ph Int/Ph.Eur/IH/JP	Manufacturing & Packing
2.	Etoricoxib IH	Manufacturing & Packing
3.	Lopinavir USP/Ph Int/Ph.Eur/BP	Manufacturing & Packing
4.	Cyclopentolate Hydrochloride IH/USP/JP/Ph. Eur	Manufacturing & Packing
5.	Sitagliptin IH	Manufacturing & Packing
6.	Duloxetine Hydrochloride IH/BP/USP/Ph.Eur	Manufacturing & Packing
7.	Tenofovir Disoproxil Fumarate IH/Ph.Int.	Manufacturing & Packing
8.	Lamivudine BP/USP/Ph.Int./Ph.Eur	Manufacturing & Packing
9.	Pazopanib Hydrochloride IH	Manufacturing & Packing
10.	Clopidogrel Hydrochloride IH	Manufacturing & Packing
11.	Sitagliptin Phosphate Monohydrate IH/BP/USP/Ph. Eur	Manufacturing & Packing
12.	Vildagliptin IH	Manufacturing & Packing

ITEM(S) TWELVE (12) ONLY

The Written Confirmation remains valid until: 27.11.2025

Signature

Stamp of the authority and date

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

02 DEC 2022

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

Annexure-02

CERTIFICATE NO. : WC-0459

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 Laurus Labs Limited, Unit-4,
Plot No. 25, 25A to 25K, Atchutapuram,
Rambilli (M), Visakhapatnam-531011
Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Ivacaftor IH	Manufacturing & Packing
2.	Sitagliptin Hydrochloride Monohydrate IH	Manufacturing & Packing
3.	Sitagliptin Malate 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: 27.11.2025

Signature

Stamp of the authority and date

02 DEC 2022

7-5/2019/EU/WC-0459
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated
22 MAY 2023

To

M/s Laurus Labs Limited, Unit-4,
Plot No. 25, 25A to 25K, Atchutapuram,
Rambilli (M), Visakhapatnam-531011
Andhra Pradesh, India

SUB:- Written Confirmation of M/s Laurus Labs Limited, Unit-4, Plot No. 25, 25A to 25K, Atchutapuram, Rambilli (M), Visakhapatnam-531011 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/ED/2023/6861 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
01	12	02.12.2022	27.11.2025
02	03	02.12.2022	27.11.2025
03	01	22 MAY 2023	27.11.2025

Yours faithfully,

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

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

Annexure-03
WC-0459

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 Laurus Labs Limited, Unit-4,**
Plot No. 25, 25A to 25K, Atchutapuram,
Rambilli (M), Visakhapatnam-531011
Andhra Pradesh, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Amlodipine Besylate IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 27.11.2025

Rajeev Singh
Signature

Stamp of the authority and date

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

22 MAY 2023

7-5/2019/EU/WC-0459
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.
Dated: 26 JUN 2023

To,

M/s. Laurus Labs Limited,
Unit - 4, Plot No.25, 25A to 25K, Atchutapuram, Rambilli,
Visakhapatnam District-531011, Andhra Pradesh India.

Subject :- Written Confirmation M/s. Laurus Labs Limited, Unit - 4, Plot No.25, 25A to 25K, Atchutapuram, Rambilli, Visakhapatnam District-531011, Andhra Pradesh 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-Regarding.

Sir,

Please refer to your online application no. WC/ED/2023/6903 submitted to CDSCO, Hyderabad zone office and the recommendation received from DDC (I), 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 event 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 up to
01	12	02.12.2022	27.11.2025
02	03	02.12.2022	27.11.2025
03	01	22.05.2023	27.11.2025
04	01	26 JUN 2023	27.11.2025

Yours faithfully,

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

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

Annexure-04

CERTIFICATE NO. : WC-0459

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. Laurus Labs Limited,
Unit - 4, Plot No.25, 25A to 25K, Atchutapuram, Rambilli,
Visakhapatnam District-531011, Andhra Pradesh India.

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Tropicamide USP/Ph.Eur	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 27/11/2025.

Signature Rajeev Singh 26 JUN 2023

Stamp of the authority and date

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

7-5/2019/EU/WC-0459
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
15 JAN 2024

To,

M/s. Laurus Labs Limited,
Unit-4 ,Plot No.25, 25A To 25K,
Atchutapuram, Rambilli Mandal,
Visakhapatnam Distric-531011, Andhra Pradesh India.

SUB:- Written Confirmation of M/s. Laurus Labs Limited, Unit-4 ,Plot No.25, 25A To 25K,Atchutapuram, Rambilli Mandal,Visakhapatnam Distric-531011, 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/ED/2023/7451 submitted to CDSCO, Hyderabad Zone 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 there under as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
01	12	02 .12. 2022	27.11.2025
02	03	02 .12. 2022	27.11.2025
03	01	22.05.2023	27.11.2025
04	01	26.06.2023	27.11.2025
05	01	5 JAN 2024	27.11.2025

Yours faithfully,

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

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

Annexure-05

CERTIFICATE NO. : WC-0459

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. Laurus Labs Limited, Unit-4 ,Plot No.25, 25A To 25K,Atchutapuram, Rambilli Mandal,Visakhapatnam Distric-531011, Andhra Pradesh India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Raltegravir potassium USP/ Ph.eur	Manufacturing & Packing

Item(s) One (01) Only

The Written Confirmation remains valid until: 27.11.2025

Signature

15 JAN 2024

Stamp of the authority and date

7-5/2019/EU/WC-0459
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 25 MAR 2025

To

M/s. Laurus Labs Limited,
Unit-IV, Plot No. 25, 25A to 25K,
APSEZ De-Notified Area, Lalamkoduru Village,
Rambilli Mandal, Anakapalli District -531011,
Andhra Pradesh, India

SUB:- Written Confirmation of M/s. Laurus Labs Limited, Unit-IV, Plot No. 25, 25A to 25K, APSEZ De-Notified Area, Lalamkoduru Village, Rambilli Mandal, Anakapalli District - 531011, 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/ED/2025/9980** submitted to CDSCO, ADC(I), Visakhapatnam Sub-Zone office, 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 with the provisions 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
--	--	02.12.2022	27.11.2025
01	12	02.12.2022	27.11.2025
02	03	02.12.2022	27.11.2025
03	01	22.05.2023	27.11.2025
04	01	26.06.2023	27.11.2025
05	01	15.01.2024	27.11.2025
06	01	25 MAR 2025	27.11.2025

Yours faithfully,

Chandrashekar 25/03/25

(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. :

Annexure-06

WC-0459

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. Laurus Labs Limited,**
Unit-IV, Plot No. 25, 25A to 25K,
APSEZ De-Notified Area, Lalamkoduru Village,
Rambilli Mandal, Anakapalli District -531011,
Andhra Pradesh, India.

List of API(s):

S.No.	Active Substance(s)	Activity(ies)
01	4-((2R,3S,4S,5R)-3-(3,4-difluoro-2-methoxyphenyl)-4,5-dimethyl-5-(trifluoromethyl)tetrahydrofuran-2-carboxamido) picolinamide (VX-548)	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

This WC for the above drug substance is approved subject to the condition that the stability data shall be continued to be generated on the validation batches and should be submitted to CDSCO periodically & the above drug substance should be sold to the M/s Vertex Pharmaceuticals (Europe) Ltd., United Kingdom only.

The Written confirmation remains valid until: 27.11.2025

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

25 MAR 2025