AMENDED

7-5/2017/EU/WC-0395

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

0 8 APR 2024

To

M/s. Laurus Labs Limited., (UNIT-III)
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

SUB:- Written Confirmation of M/s. Laurus Labs Limited., (UNIT-III)., Plot No. 18, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District -531021, 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/2023/6706 submitted to CDSCO, Hyderabad Zone office, and the recommendation received from ADC (I), SEA Port Office Visakhapatnam 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
--	--	08 APR 2024	**22.03.2026**
01	19	08 APR 2024	**22.03.2026**
02	01	08 APR 2024	**22.03.2026**

Yours faithfully,

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

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

AMENDED
WC-0395

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-III)**
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

2. Manufacturer's licence number: **27/VP/AP/2014/B/CC/R**

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: 04.09.2023 & 05.09.2023

The Written Confirmation remains valid until: **22.03.2026**

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. Rajeev Singh Raghuvanshi,
Drugs Controller General (India)

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

08 APR 2024

Signature

Stamp of the authority and date

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

CERTIFICATE NO. :

AMENDED
Annexure-01
WC-0395

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-III)**
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Atazanavir Sulfate Ph.Eur.	Manufacturing & Packing
2.	Atorvastatin Calcium Trihydrate Ph.Eur/IH	Manufacturing & Packing
3.	Atorvastatin Calcium USP	Manufacturing & Packing
4.	Azacitidine IH	Manufacturing & Packing
5.	Clopidogrel Bisulfate IH	Manufacturing & Packing
6.	Clopidogrel Hydrogen Sulfate Ph.Eur	Manufacturing & Packing
7.	Empagliflozin IH	Manufacturing & Packing
8.	Emtricitabine IH/Ph.Int	Manufacturing & Packing
9.	Esomeprazole Magnesium Dihydrate Ph.Eur/IH	Manufacturing & Packing
10.	Hydroxychloroquine Sulphate Ph.Eur/USP/IH	Manufacturing & Packing
11.	Lamivudine Ph.Eur/Ph.int/USP/IH	Manufacturing & Packing
12.	Molnupiravir IH	Manufacturing & Packing
13.	Oseltamivir Phosphate USP	Manufacturing & Packing
14.	Pantoprazole Sodium Sesiquihydrate Ph.Eur	Manufacturing & Packing
15.	Pemetrexed Disodium Ph.Eur	Manufacturing & Packing
16.	Pirfenidone Ph.Eur/IH	Manufacturing & Packing
17.	Ritonavir USP/Ph.Eur/IH	Manufacturing & Packing
18.	Tenofovir Disoproxil Fumarate IH/Ph.Int	Manufacturing & Packing
19.	Valsartan IH/Ph.Eur	Manufacturing & Packing

ITEM(S) NINTEEN (19) ONLY

The Written Confirmation remains valid until: 22.03.2026

Signature

08 APR 2024

Stamp of the authority and date

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

CERTIFICATE NO. :

AMENDED
Annexure-02
WC-0395

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-III)**
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Felbamate USP	Manufacturing & Packing

ITEM(S) ONE (01) 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: 22.03.2026

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization

08 APR 2024

7-5/2017/EU/WC-0395

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 20 MAY 2024

To

M/s. Laurus Labs Limited., (UNIT-III)
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

SUB:- Written Confirmation of M/s. Laurus Labs Limited., (UNIT-III)., Plot No. 18, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District -531021, 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/2023/6706 submitted to CDSCO, Sub Zone Visakhapatnam office, and the recommendation received from ADC (I), Sub Zone Visakhapatnam 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
--	--	**27.03.2024**	**22.03.2026**
01	19	**27.03.2024**	**22.03.2026**
02	01	**27.03.2024**	**22.03.2026**
03	01	20 MAY 2024	**22.03.2026**

Yours faithfully,

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

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

CERTIFICATE NO. :

Annexure-03
WC-0395

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-III)**
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

List of APIs:

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

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 22.03.2026

Signature

Stamp of the authority and date

20 MAY 2024

7-5/2017/EU/WC-0395

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 12 SEP 2024

To

M/s. Laurus Labs Limited., (UNIT-III)
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

SUB:-Written Confirmation of M/s. Laurus Labs Limited., (UNIT-III), Plot No. 18, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District -531021, 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/2023/7412 submitted to CDSCO, Hyderabad Zone office, and the recommendation received from ADC (I), CDSCO, Sub Zone, Visakhapatnam 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
--	--	27.03.2024	**22.03.2026**
01	19	27.03.2024	**22.03.2026**
02	01	27.03.2024	**22.03.2026**
03	01	20.05.2024	**22.03.2026**
04	02	12 SEP 2024	**22.03.2026**

Yours faithfully,

Chandrashekar
12/09/24

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-04**
WC-0395

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-III), Plot No. 18, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District -531021, Andhra Pradesh, India**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Abiraterone Acetate IH	**Manufacturing & Packing**
02	Dolutegravir Sodium IH	**Manufacturing & Packing**

ITEM(S) TWO (02) ONLY

The Written Confirmation remains valid until: 22.03.2026

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

12 SEP 2024

7-5/2017/EU/WC-0395

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 24 APR 2025

To

M/s. Laurus Labs Limited., (UNIT-III)
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

SUB:- Written Confirmation of **M/s. Laurus Labs Limited., (UNIT-III)., Plot No. 18, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District -531021, 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/2024/8550 submitted to CDSCO, Sub Zone, Visakhapatnam, and the recommendation received from ADC (I), CDSCO, Sub Zone, Visakhapatnam 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.

10. The manufacturer shall obtain NOC from the respective CDSCO office on case to case basis for manufacture of active substance for export purpose, if active substance is falling under unapproved/Banned/ New drug in the country.

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
--	--	27.03.2024	**22.03.2026**
01	19	27.03.2024	**22.03.2026**
02	01	27.03.2024	**22.03.2026**
03	01	20.05.2024	**22.03.2026**
04	02	12.09.2024	**22.03.2026**
05	01	24 APR 2025	**22.03.2026**

Yours faithfully,

Ranga Chandrashekar
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
औषधि नियंत्रक (भारत) / Joint Dru
केंद्रीय मानक नियंत्रण संगठन (मुख्यालय)
C.D.S.C.O(HQ), Dte. General of
स्वास्थ्य एवं परिवार कल्याण मंत्रालय / Ministry of H
फ़ार्मा भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New

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

CERTIFICATE NO. :

Annexure-05
WC-0395

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-III)
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Apalutamide IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 22.03.2026

Chandrashekar 24/04/25

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

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

Stamp of the authority and date

24 APR 2025

7-5/2017/EU/WC-0395

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

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 09 JUL 2025

To

M/s. Laurus Labs Limited, (UNIT-III)
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

SUB:- Written Confirmation of **M/s. Laurus Labs Limited., (UNIT-III)., Plot No. 18, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District -531021, 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/FR/2025/9752 submitted to CDSCO, Sub-Zone Visakhapatnam and the recommendation received from ADC (I), CDSCO, Sub-Zone Visakhapatnam 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
--	--	27.03.2024	**22.03.2026**
01	19	27.03.2024	**22.03.2026**
02	01	27.03.2024	**22.03.2026**
03	01	20.05.2024	**22.03.2026**
04	02	12.09.2024	**22.03.2026**
05	01	24.04.2025	**22.03.2026**
06	01	09 JUL 2025	**22.03.2026**

Yours faithfully,

Chandrashekar
09/07/25

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

Annexure-06

CERTIFICATE NO. : WC-0395

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-III)**
Plot No. 18, Jawaharlal Nehru Pharma City,
Parawada Mandal, Anakapalli District -531021,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Venlafaxine Hydrochloride Ph.Eur.	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 22.03.2026

Chandrashekar
09/07/25

Signature

चंद्रशेखर राव/Chandrashekar Rao
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Control
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा म
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family
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

09 JUL 2025