

7-5/2019/EU/WC-0455  
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. Maithri laboratories Private Limited.,**  
**Sy No. 14, IDA Gaddapotharam, Gaddapotharam (V),**  
**Jinnaram (M), Sangareddy (D), Telangana State**

18 NOV 2022

**SUB:-** Written Confirmation of M/s. Maithri laboratories Private Limited., Sy No. 14, IDA Gaddapotharam, Gaddapotharam (V), Jinnaram (M), Sangareddy (D), Telangana State 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/2022/4109 submitted to CDSCO, Hyderabad Zonal office and the recommendation received from DDC(I), Hyderabad Zonal 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 conform 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	05	18 NOV 2022	30.09.2025
02	02	18 NOV 2022	30.09.2025

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-0455**

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. Maithri laboratories Private Limited.,  
Sy No. 14, IDA Gaddapotharam, Gaddapotharam (V),  
Jinnaram (M), Sangareddy (D), Telangana State**

**2. Manufacturer's licence number: 16/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

List of API(s):

**As per Annexure-01 & Annexure-02**

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: 29.08.2022 & 30.08.2022**

**The Written Confirmation remains valid until: 30.09.2025**

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: dcj@nic.in,**

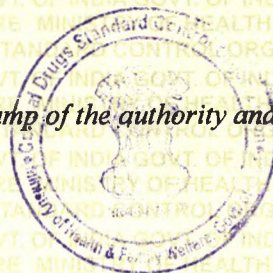
**Telephone no.: +91-11-23236965**

**Fax no.: +91-11-23236973**

Signature

18 NOV 2022

Stamp of the authority and date







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

Annexure-01

CERTIFICATE NO. :

WC-0455

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. Maithri laboratories Private Limited.,  
Sy No. 14, IDA Gaddapotharam, Gaddapotharam (V),  
Jinnaram (M), Sangareddy (D), Telangana State**

**List of APIs:**

Sr. No.	Active substance (s)	Activity(ies)
1.	Moxifloxacin Hydrochloride Ph.Eur	Manufacturing & Packing
2.	Ivabradine Hydrochloride IH	Manufacturing & Packing
3.	Telmisartan Ph.Eur/USP	Manufacturing & Packing
4.	Eliglustat Tartrate IH	Manufacturing & Packing
5.	Eliglustat Tartrate (Premix) IH	Manufacturing & Packing

**ITEM(S) Five (05) ONLY**

The Written Confirmation remains valid until: **30.09.2025**

Signature

Stamp of the authority and date



18 NOV 2022





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

Annexure-02

CERTIFICATE NO. :

WC-0455

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. Maithri laboratories Private Limited.,  
Sy No. 14, IDA Gaddapotharam, Gaddapotharam (V),  
Jinnaram (M), Sangareddy (D), Telangana State**

**List of APIs:**

Sr. No.	Active substance (s)	Activity(ies)
1.	Flucytosine USP/Ph.Eur	Manufacturing & Packing
2.	Fesoterodine Fumarate IH	Manufacturing & Packing

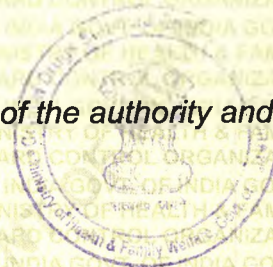
**ITEM(S) Two (02) ONLY**

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: **30.09.2025**

Signature

Stamp of the authority and date



18 NOV 2022



7-5/2019/EU/WC-0455  
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. Maithri laboratories Private Limited.,  
Sy No. 14, IDA Gaddapotharam, Gaddapotharam (V),  
Jinnaram (M), Sangareddy (D), Telangana State**

30 DEC 2022

**SUB:-** Written Confirmation of M/s. Maithri laboratories Private Limited., Sy No. 14, IDA Gaddapotharam, Gaddapotharam (V), Jinnaram (M), Sangareddy (D), Telangana States 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/2022/5693 submitted to CDSCO, Hyderabad Zonal office and the recommendation received from DDC(I), Hyderabad Zonal 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.

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	05	18.11.2022	30.09.2025
02	02	18.11.2022	30.09.2025
03	09	30 DEC 2022	30.09.2025
04	01	30 DEC 2022	30.09.2025

Yours faithfully,



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





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. Maithri laboratories Private Limited.,  
Sy No. 14, IDA Gaddapotharam, Gaddapotharam (V),  
Jinnaram (M), Sangareddy (D), Telangana State**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Azilsartan Kamedoxomil IH	Manufacturing & Packing
2.	Chlorpromazine Hydrochloride IH/USP/EP	Manufacturing & Packing
3.	Lurasidone Hydrochloride IH	Manufacturing & Packing
4.	Pyridostigmine Bromide USP/EP	Manufacturing & Packing
5.	Ranolazine IH	Manufacturing & Packing
6.	Tolterodine Tartrate USP/EP	Manufacturing & Packing
7.	Topiramate USP	Manufacturing & Packing
8.	Valganciclovir Hydrochloride USP	Manufacturing & Packing
9.	Vilazodone Hydrochloride IH	Manufacturing & Packing

ITEM(S) Nine (09) ONLY

The Written Confirmation remains valid until: 30.09.2025

Signature

Stamp of the authority and date



30 DEC 2022

30 DEC 2022





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

CERTIFICATE NO. :

Annexure-04  
WC-0455

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. Maithri laboratories Private Limited.,  
Sy No. 14, IDA Gaddapotharam, Gaddapotharam (V),  
Jinnaram (M), Sangareddy (D), Telangana State**

**List of APIs:**


Sr. No.	Active substance (s)	Activity(ies)
1.	Brivaracetam IH	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: **30.09.2025**

Signature 

Stamp of the authority and date  


30 DEC 2022

30 DEC 2022