7-5/2021/EU/WC-0494
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

26 FEB 2021

To

M/s Tagoor Laboratories Pvt. Ltd.,
(Unit-1), Sy No 29, Tupakulagudem (V),
Pochavaram Panchayat, Tallapudi (M),
West Godavari, Dist-534341, A.P, India

SUB:- Written Confirmation of M/s Tagoor Laboratories Pvt Ltd., (Unit-1), Sy No 29, Tupakulagudem (V), Pochavaram Panchayat, Tallapudi (M), West Godavari, Dist-534341, A.P, 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 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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 thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
1	09	26 FEB 2021	Three years from date of issue.

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-0494**

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 Tagoor Laboratories Pvt Ltd., (Unit-1), Sy No 29, Tupakulagudem (V), Pochavaram Panchayat, Tallapudi (M), West Godavari, Dist-534341, A.P, India**

2. Manufacturer's licence number: 08/WG/AP/2019/B/G in Form No 25

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 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: 02/07/2020 & 03/07/2020

The Written Confirmation remains valid until: Three years from date of issue

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 • सत्यमेव जयते

26 FEB 2021

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

Annexure-1

CERTIFICATE NO. :

WC-0494

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 Tagoor Laboratories Pvt Ltd., (Unit-1), Sy No 29, Tupakulagudem (V), Pochavaram Panchayat, Tallapudi (M), West Godavari, Dist-534341, A.P, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Domperidone IP/BP/Ph.Eur	Manufacturing & Packing
2.	Domperidone Maleate IP/BP/Ph.Eur	Manufacturing & Packing
3.	Pantoprazole Sodium Sesqui Hydrate IP/USP/Ph.Eur	Manufacturing & Packing
4.	Omeprazole IP/BP/Ph.Eur/USP	Manufacturing & Packing
5.	Esomeprazole Magnesium Tri-Hydrate IP/Ph.Eur	Manufacturing & Packing
6.	Esomeprazole Magnesium USP	Manufacturing & Packing
7.	Terbinafine Hydrochloride IP/BP/Ph.Eur/USP	Manufacturing & Packing
8.	Hydroxychloroquine Sulphate IP	Manufacturing & Packing
9.	Hydroxychloroquine Sulfate BP/Ph.Eur/USP	Manufacturing & Packing

ITEM(S) NINE (09) ONLY

The Written Confirmation remains valid until: Three years from date of issue

Signature

Stamp of the authority and date

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

26 FEB 2021

7-5/2021/EU/WC-0494
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

14 FEB 2023

To

M/s Tagoor Laboratories Pvt. Ltd.,
(Unit-1), Sy No 29, Tupakulagudem (V),
Pochavaram Panchayat, Tallapudi (M),
West Godavari, Dist-534341, A.P, India

SUB:- Written Confirmation of M/s Tagoor Laboratories Pvt Ltd., (Unit-1), Sy No 29, Tupakulagudem (V), Pochavaram Panchayat, Tallapudi (M), West Godavari, Dist-534341, A.P, 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/2022/5713 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 thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
1	09	26.02.2021	26.02.2024
2	02	14 FEB 2023	26.02.2024

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
WC-0494

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 Tagoor Laboratories Pvt Ltd., (Unit-1), Sy No 29, Tupakulagudem (V), Pochavaram Panchayat, Tallapudi (M), West Godavari, Dist-534341, A.P, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Losartan Potassium IP/BP/Ph.Eur/USP	Manufacturing & Packing
2.	Loratadine BP/Ph.Eur/USP	Manufacturing & Packing

ITEM(S) Two (02) ONLY

The Written Confirmation remains valid until: 26.02.2024

Signature Vkl

14 FEB 2023

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare

7-5/2021/EU/WC-0494
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 09 DEC 2024

To,

M/s. Tagoor Laboratories Pvt. Ltd.,
Unit-I, Sy. No: 29, Tupakulagudem (V),
Pochavaram Panchayat, Tallpudi (M),
East Godavari District- 534341, Andhra Pradesh, India

SUB:- Written Confirmation of **M/s. Tagoor Laboratories Pvt. Ltd., Unit-I, Sy. No: 29, Tupakulagudem (V), Pochavaram Panchayat, Tallpudi (M), East Godavari District-534341, 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/2023/7633 dated 18.10.2023 submitted to CDSCO, ADC(I), Vishakhapatnam Sub Zone, and the recommendation received from CDSCO, ADC(I), Vishakhapatnam 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
--	--	16.08.2024	26.02.2027
01	12	16.08.2024	26.02.2027
02	04	09 DEC 2024	26.02.2027

Yours faithfully,

(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-02

CERTIFICATE NO. : **WC-0494**

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. Tagoor Laboratories Pvt. Ltd.,**
Unit-I, Sy. No: 29, Tupakulagudem (V),
Pochavaram Panchayat, Tallpudi (M),
East Godavari District- 534341,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Molnupiravir IH	Manufacturing & Packing
2.	Desloratadine Ph.Eur/BP/USP	Manufacturing & Packing
3.	Alpha Lipoic Acid IP/USP	Manufacturing & Packing
4.	Thioctic Acid Ph.Eur/BP	Manufacturing & Packing

ITEM(S) Four (04) ONLY

The Written Confirmation remains valid until: 26.02.2027

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

09 DEC 2024