7-5/2013/EU/WC-0087
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 Megafine Pharma (P) Limited.,
Plot No. 1 to 5, 31 to 35 & 48 to 51, 26 & K/201,
Village Lakhmapur, Taluka Dindori,
Dist. Nashik-422 202, Maharashtra, India.

02 AUG 2022

SUB:- Written Confirmation of M/s Megafine Pharma (P) Limited., Plot No. 1 to 5, 31 to 35 & 48 to 51, 26 & K/201, Village Lakhmapur, Taluka Dindori, Dist. Nashik-422 202, Maharashtra, Indiaas 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 received vide email dated 01.08.2022 on the subject cited above.

In this regard, please find the enclosed amended Written Confirmation Certificate. The condition of the 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,

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

Amended
WC-0087

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

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 of site: **M/s Megafine Pharma (P) Limited.,**
Plot No. 1 to 5, 31 to 35 & 48 to 51, 26 & K/201,
Village Lakhmapur, Taluka Dindori,
Dist. Nashik-422 202, Maharashtra, India.

2. Manufacturer's Licence Number: 25-NKD/54

The address of the manufacturer mentioned in the Certificate No WC-0087 along with annexure 01 & 02 of Written Confirmation Certificate granted on date 27.07.2022 is hereby amended as follows:

In place of:
"M/s Megafine Pharma (P) Limited, Plot No. 31 to 35, 48 to 51, 5, 26 & K/201, Village Lakhamapur, Taluka Dindori, Dist. Nashik-422 202, Maharashtra, India".

Read as:
"M/s Megafine Pharma (P) Limited, Plot No. 1 to 5, 31 to 35 & 48 to 51, 26 & K/201, Village Lakhmapur, Taluka Dindori, Dist. Nashik-422 202, Maharashtra, India."

All the other conditions of Written Confirmation Certificate will remain same.

Signature

02 AUG 2022

Stamp of the authority and date

7-5/2013/EU/WC-0087
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:
27 JUL 2022

To

M/s Megafine Pharma (P) Limited.,
Plot No. 31 to 35 & 48 to 51, 5, 26 & K/201,
Village Lakhamapur, Taluka Dindori,
Dist. Nashik-422 202,Maharashtra, India.

SUB: Written Confirmation of M/s Megafine Pharma (P) Limited.,Plot No. 31 to 35 & 48 to 51, 5, 26 & K/201, Village Lakhamapur, Taluka Dindori, Dist. Nashik-422 202 ,Maharashtra, 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/2022/4753 submitted to CDSCO, West Zone and the recommendation received from DDC (I), West Zone Mumbai 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	24	27 JUL 2022	21.07.2025
02	02	27 JUL 2022	21.07.2025

Yours faithfully,

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

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

WC-0087

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 Megafine Pharma (P) Limited .,
Plot No. 31 to 35, 48 to 51, 5, 26 & K/201,
Village Lakhamapur, Taluka Dindori,
Dist. Nashik-422 202,Maharashtra,India.

2.Manufacturer's license Number: 25-NKD/54

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: 13.01.2022 & 14.01.2022

The Written Confirmation remains valid until: 21.07.2025

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

Signature

27 JUL 2022

Stamp of the authority and date

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

Annexure-01
WC-0087

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 Megafine Pharma (P) Limited,
Plot No. 31 to 35 & 48 to 51, 5, 26 & K/201,
Village Lakhamapur, Taluka Dindori,
Dist. Nashik-422 202.

List of APIs:

Sr. No	Name of the Active Substances	Activitie(s)
1.	Ambrisentan IH	Manufacturing and Packing
2.	Apixaban IH	Manufacturing and Packing
3.	Asenapine Maleate IH	Manufacturing and Packing
4.	Bosentan Monohydrate IH	Manufacturing and Packing
5.	Brinzolamide IH/EP/USP	Manufacturing and Packing
6.	Cinacalcet HydrochlorideIH	Manufacturing and Packing
7.	Darifenacine Hydrobromide IH	Manufacturing and Packing
8.	Desvenlafaxine Succinate Monohydrate IH	Manufacturing and Packing
9.	Donepezil Hydrochloride (Form I) IH/USP	Manufacturing and Packing
10.	Duloxetine Hydrochloride IH	Manufacturing and Packing
11.	Iloperidone IH	Manufacturing and Packing
12.	Memantine Hydrochloride IH/USP	Manufacturing and Packing
13.	Mirtazapine IP/USP/EP	Manufacturing and Packing
14.	Mirtazapine Hemihydrate IP/USP/EP	Manufacturing and Packing
15.	Paliperidone IH	Manufacturing and Packing
16.	Prasugrel Hydrochloride IH	Manufacturing and Packing
17.	Pyrantel Pamoate/Pyrante Embonate IP/USP/EP	Manufacturing and Packing
18.	Quetiapine Hemifumarate IH/EP/USP	Manufacturing and Packing
19.	Rivaroxaban IH	Manufacturing and Packing
20.	Solifenacin Succinate IH/EP	Manufacturing and Packing
21.	Venlafexine Hydrochloride USP/EP	Manufacturing and Packing
22.	Vildagliptin IH	Manufacturing and Packing
23.	Ziprasidone Hydrochloride Monohydrate USP/EP/IP	Manufacturing and Packing
24.	Lurasidone Hydrochloride IH	Manufacturing and Packing

ITEM(S) Twenty Four (24) Only

The Written Confirmation remains valid until: 21.07.2025

Signature Vkv

27 JUL 2022

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare

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

Annexure – 02

CERTIFICATE NO. : WC-0087

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 Megafine Pharma (P) Limited.,
Plot No. 31 to 35, 48 to 51, 5, 26 & K/201,
Village Lakhamapur, Tal- Dindori,
Dist. Nashik-422202,
Maharashtra,India.

List of APIs:

S. No.	Name of the Active substance(s)	Activity(ies)
1	Teriflunomide IH	Manufacturing & Packing.
2.	Mirabegron 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 or sale in India.

The Written Confirmation remains valid until: 21.07.2025

Signature

Stamp of the authority and date

27 JUL 2022

7-5/2013/EU/WC-0087
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 28 AUG 2023

To

M/s Megafine Pharma (P) Limited.,
Plot No. 1 to 5, 31 to 35 & 48 to 51, 5, 26 & K/201,
Lakhmapur, Taluka Dindori,
Dist. Nashik-422 202,Maharashtra,India.

SUB: Written Confirmation of M/s Megafine Pharma (P) Limited., Plot No. 1 to 5, 31 to 35 & 48 to 51, 5, 26 & K/201, Lakhmapur, Taluka Dindori, Dist. Nashik-422 202,Maharashtra, Indiaas per requirement of EU for import of active substances imported into theEuropean 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/2023/7051** submitted to CDSCO, West Zone and the recommendation received from DDC (I), West Zone Mumbai 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	24	27-07-2022	21.07.2025
02	02	27-07-2022	21.07.2025
03	02	28 AUG 2023	21.07.2025

Yours faithfully,

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

Annexure-03

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

CERTIFICATE NO. :

WC-0087

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 Megafine Pharma (P) Limited.,**
Plot No. 1 to 5, 31 to 35 & 48 to 51, 5, 26 & K/201,
Lakhmapur, Taluka Dindori,
Dist. Nashik-422 202, Maharashtra, India..

2. Manufacturer's licence number: **Form 25**: 25-NKD/54

List of APIs:

S. No.	Name of the Active substance(s)	Activity(ies)
1	Vortioxetine Hydrobromide IHS	Manufacturing & Packing.
2.	Apremilast IHS	Manufacturing & Packing.

ITEM(S) TWO (02) Only

The Written Confirmation remains valid until: 21.07.2025

Signature

Stamp of the authority and date

28 AUG 2023