7-5/2020/EU/WC-0462
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:

26 JUN 2023

To

M/s Megafine Pharma (P) Limited.,
Plot No. 911-912, Phase-III, G.I.D.C,
Vapi-396195, Dist Valsad, Gujarat, India

SUB: Written Confirmation of M/s Megafine Pharma (P) Limited., 911-912, Phase-III, G.I.D.C, Vapi-396195, Dist Valsad, Gujarat, India as per requirement of EU for import of active substances imported into the European Union (EU) for edicinal 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 29.05.2023 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,

Rajeev Singh

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

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

Amended
WC-0462

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. 911-912, Phase-III, G.I.D.C,
Vapi-396195, Dist Valsad, Gujarat, India

2. Manufacturer's Licence Number: G/458 and G/209

The address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0462) along with annexure-01 granted on date 15.05.2023 is hereby amended as follows:

In place of:
M/s Megafine Pharma (P) Limited., Plot No. 911-912, Phase-III, G.I.D.C, Vapi-396196, Dist Valsad, Gujarat, India"

Read as:
"M/s Megafine Pharma (P) Limited., Plot No. 911-912, Phase-III, G.I.D.C, Vapi-**396195**, Dist Valsad, Gujarat, India"

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

Signature

Central Drugs Standard Control Organization

Stamp of the authority and date

20 JUN 2023

7-5/2020/EU/WC-462
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

20 JAN 2020

To

M/s Megafine Pharma (P) Ltd.,
Plot No. 911-912, III rd Phase, G.I.D.C.,
Vapi – 396195, Dist- Valsad, Gujarat, India

SUB:- Written Confirmation of M/s Megafine Pharma (P) Ltd., Plot No. 911-912, III rd Phase, G.I.D.C., Vapi – 396195, Dist- Valsad, Gujarat, 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, Ahmedabad Zone office, and the recommendation received from DDC(I), Ahmedabad 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.

Yours faithfully,

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

16/01/2020

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

CERTIFICATE NO. : WC-462

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) Ltd.,**
Plot No. 911-912, III rd Phase, G.I.D.C.,
Vapi – 396195, Dist- Valsad, Gujarat, India

2. Manufacturer's licence number: G/458 and G/209

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):

S. No.	Active substance(s)	Activity(ies)
1	Memantine HCl IP/USP	Manufacturing & Packing

ITEM(S) One (01) ONLY

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: 4th-5th July, 2019 & 12th September, 2019

The Written Confirmation remains valid until: Three Years from the 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

Drugs Standard Control Organization
सत्यमेव जयते
Ministry of Health & Family Welfare, Government of India

20 JAN 2020

7-5/2020/EU/WC-0462
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated: 30 SEP 2020

To

M/s. Megafine Pharma (P) Ltd.
911-912, III RD Phase, G.I.D.C.,
Vapi- 396 195, Dist- Valsad, Gujarat, India

Subject:- Written Confirmation of M/s. Megafine Pharma (P) Ltd., 911-912, III RD Phase, G.I.D.C., Vapi- 396 195, Dist- Valsad, Gujarat, 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, Ahmedabad Zone and the recommendation received from DDC(I), Ahmedabad 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	20.01.2020	**19.01.2023**
1	01	30 SEP 2020	**19.01.2023**

Yours faithfully,

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

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

Annexure-1

CERTIFICATE NO. : **WC-0462**

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

Name and address of site: **M/s. Megafine Pharma (P) Ltd.**
911-912, III RD Phase, G.I.D.C.,
Vapi- 396 195, Dist- Valsad, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Donepezil HCl USP/IP/IHS	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 19.01.2023

Signature

Stamp of the authority and date

30 SEP 2020

7-5/2020/EU/WC-0462
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated:

To

26 FEB 2021

M/s. Megafine Pharma (P) Ltd.
911-912, III RD Phase, G.I.D.C.,
Vapi- 396 195, Dist- Valsad, Gujarat, India

Subject:- Written Confirmation of M/s. Megafine Pharma (P) Ltd., 911-912, III RD Phase, G.I.D.C., Vapi- 396 195, Dist- Valsad, Gujarat, 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, Ahmedabad Zone and the recommendation received from DDC(I), Ahmedabad 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	20.01.2020	**19.01.2023**
1	01	30.09.2020	**19.01.2023**
2	01	26 FEB 2021	**19.01.2023**

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

CERTIFICATE NO. : **WC-0462**

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

Name and address of site: **M/s. Megafine Pharma (P) Ltd.**
911-912, III RD Phase, G.I.D.C.,
Vapi- 396 195, Dist- Valsad, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Quetiapine Fumarate USP/IP/Ph.Eur/IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 19.01.2023

Signature

Stamp of the authority and date

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

26 FEB 2021

7-5/2020/EU/WC-0462
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated:

21 MAR 2022

To

M/s. Megafine Pharma (P) Ltd.
911-912, III RD Phase, G.I.D.C.,
Vapi- 396 195, Dist- Valsad, Gujarat, India

Subject:- Written Confirmation of M/s. Megafine Pharma (P) Ltd., 911-912, III RD Phase, G.I.D.C., Vapi- 396 195, Dist- Valsad, Gujarat, 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/2022/2028 submitted to CDSCO, Ahmedabad Zone and the recommendation received from DDC(I), Ahmedabad 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	20.01.2020	**19.01.2023**
1	01	30.09.2020	**19.01.2023**
2	01	26.02.2021	**19.01.2023**
3	01	21 MAR 2022	**19.01.2023**

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. :

Annexure-3
WC-0462

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

Name and address of site: **M/s. Megafine Pharma (P) Ltd.**
911-912, III RD Phase, G.I.D.C.,
Vapi- 396 195, Dist- Valsad, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Rivaroxaban IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 19.01.2023

Signature

Stamp of the authority and date

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

21 MAR 2022

7-5/2020/EU/WC-0462
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA, Bhawan Kotla Road,
New Delhi-110002
Dated:

To

24 MAR 2022

M/s. Megafine Pharma (P) Ltd.
911-912, III RD Phase, G.I.D.C.,
Vapi- 396 195, Dist.- Valsad, Gujarat, India

Subject: - Written Confirmation of M/s Megafine Pharma (P) Ltd., 911-912, III RD Phase, G.I.D.C., Vapi- 396 195, Dist.- Valsad, Gujarat, 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/2022/1675 submitted to CDSCO, Ahmedabad Zone and the recommendation received from DDC(I), Ahmedabad 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	20.01.2020	19.01.2023
1	01	30.09.2020	19.01.2023
2	01	26.02.2021	19.01.2023
3	01	21.03.2022	19.01.2023
4	01	24 MAR 2022	19.01.2023

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. :

Annexure-4
WC-0462

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

Name and address of site: **M/s. Megafine Pharma (P) Ltd.**
911-912, III RD Phase, G.I.D.C.,
Vapi- 396 195, Dist- Valsad, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Vildagliptin IH	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 19.01.2023

Signature

Stamp of the authority and date

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

24 MAR 2022