7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated

14 OCT 2022

To

M/s R L Fine Chem Pvt. Ltd.
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208. Karnataka, India

SUB:- Written Confirmation of M/s R L Fine Chem Pvt. Ltd, Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208. Karnataka, 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/2022/5232 submitted to CDSCO, Bangalore office and the recommendation received from DDC(I), Bangalore 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	14	14 OCT 2022	28.07.2025
02	04	14 OCT 2022	28.07.2025

Yours faithfully,

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

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

WC-0445

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 R L Fine Chem Pvt. Ltd.**
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase,
Kudumalakunte Village, Gowribidanoor Taluk,
Chickkaballapura Dist.-561208. Karnataka, India

2. Manufacturer's license number: KTK/25/653/2016

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 enclosed as Annexure -01 & 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: 14.02.2022 & 15.02.2022

The Written Confirmation remains valid until: 28.07.2025

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

14 OCT 2022

Stamp of the authority and date

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

CERTIFICATE NO. :

Annexure- 01
WC -0445

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 R L Fine Chem Pvt. Ltd.**
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208. Karnataka, India

List of APIs

Sl.No	Name of the active substances	Activities
1.	Amitriptyline HCl – Ph.Eur/BP/USP	Manufacturing & Packing
2.	Duloxetine HCl - Ph.Eur/BP/USP	Manufacturing & Packing
3.	Orphenadrine Citrate - Ph.Eur/BP/USP	Manufacturing & Packing
4.	Nortriptyline HCl - Ph.Eur/BP	Manufacturing & Packing
5.	Chlorpromazine HCl - Ph.Eur/BP/USP	Manufacturing & Packing
6.	Doxepin HCl - Ph.Eur/BP/USP	Manufacturing & Packing
7.	Lorazepam - Ph.Eur/BP/USP	Manufacturing & Packing
8.	Pyrimethamine - Ph.Eur/BP/USP	Manufacturing & Packing
9.	Clomipramine HCl - Ph.Eur/USP/BP/JP	Manufacturing & Packing
10.	Imipramine HCl - Ph.Eur/BP/USP/JP	Manufacturing & Packing
11.	Trimipramine Maleate – BP/Ph.Eur	Manufacturing & Packing
12.	Diazepam – BP/Ph.Eur/USP	Manufacturing & Packing
13.	Alprazolam - Ph.Eur/BP	Manufacturing & Packing
14.	Clonazepam - Ph.Eur/BP/USP	Manufacturing & Packing

ITEM(S) FOURTEEN (14) ONLY

The Written Confirmation remains valid until:28.07.2025

Signature

Stamp of the authority and date

04 OCT 2022

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

CERTIFICATE NO. : Annexure- 02
WC -0445

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 R L Fine Chem Pvt. Ltd.**
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208. Karnataka, India

List of APIs

Sl.No	Name of the active substances	Activities
1.	Cyclobenzaprine HCl - USP	Manufacturing & Packing
2.	Doxylamine Succinate- USP	Manufacturing & Packing
3.	Doxylamine Hydrogen Succinate - Ph.Eur	Manufacturing & Packing
4.	Pitofenone HCl – IH	Manufacturing & Packing

ITEM(S) FOUR (04) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until:28.07.2025

Signature

Stamp of the authority and date

14 OCT 2022

7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated 03 FEB 2023

To

M/s R L Fine Chem Pvt. Ltd.
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208. Karnataka, India

SUB:- Written Confirmation of M/s R L Fine Chem Pvt. Ltd, Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208. Karnataka, 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/2022/6152 submitted to CDSCO, Bangalore office and the recommendation received from DDC(I), Bangalore 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	14	14.10.2022	28.07.2025
02	04	14.10.2022	28.07.2025
03	01	03 FEB 2023	28.07.2025

Yours faithfully,

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

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

Annexure- 03
WC -0445

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 R L Fine Chem Pvt. Ltd.**
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208. Karnataka, India

List of APIs

Sl.No	Name of the active substances	Activities
1.	Carbinoxamine Maleate USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until:28.07.2025

Signature

03 FEB 2023

Stamp of the authority and date

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

7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002
Dated

08 FEB 2023

To

M/s R L Fine Chem Pvt. Ltd.
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208. Karnataka, India

SUB:- Written Confirmation of M/s R L Fine Chem Pvt. Ltd, Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208. Karnataka, 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/2022/6148 submitted to CDSCO, Bangalore office and the recommendation received from DDC(I), Bangalore 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	14	14.10.2022	28.07.2025
02	04	14.10.2022	28.07.2025
03	01	03.02.2023	28.07.2025
04	01	08 FEB 2023	28.07.2025

Yours faithfully,

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

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

CERTIFICATE NO. : Annexure- 04
WC -0445

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 R L Fine Chem Pvt. Ltd.
Plot No. IP No.27-29, Parts of Sy. No.s.18, 273, 274 & 313, KIADB Industrial Area, I Phase,
Kudumalakunte Village, Gowribidanoor Taluk,
Chickkaballapura Dist.-561208. Karnataka, India

List of APIs

Sl.No	Name of the active substances	Activities
1.	Flupentixol Decanoate B.P	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until:28.07.2025

Signature

Stamp of the authority and date

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

08 FEB 2023

7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:
09 OCT 2023

To,

M/s. R L Fine chem. Pvt.Ltd,
Plot No. IP No. 27-29, Parts of Sy.Nos. 18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village,
Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

SUB:- Written Confirmation of M/s. R L Fine chem. Pvt.Ltd, Plot No. IP No. 27-29, Parts of Sy.Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, 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/2023/6878 dated 23.03.2023 submitted to CDSCO, DDC(I), Sub-Zone Bangalore, and the recommendation received from DDC(I), Sub-Zone Bangalore 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	14	14.10.2022	28.07.2025
02	04	14.10.2022	28.07.2025
03	01	14.10.2022	28.07.2025
04	01	14.10.2022	28.07.2025
05	04	09 OCT 2023	28.07.2025

Yours faithfully,

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

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

Annexure-05

CERTIFICATE NO. :

WC-0445

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. R L Fine chem. Pvt.Ltd,
Plot No. IP No. 27-29, Parts of Sy.Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Alimemazine Hemitartrate Ph.Eur	Manufacturing & Packing
2.	Fenpiverinium Bromide IH	Manufacturing & Packing
3.	Orphenadrine Hydrochloride B.P.	Manufacturing & Packing
4.	Trimipramine Mesylate IH	Manufacturing & Packing

ITEM FOUR (04) 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 active substance 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: 28.07.2025

Rajan Singh

Signature

09 OCT 2023

Stamp of the authority and date

7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 16 OCT 2023

To,

M/s. R L Fine chem. Pvt.Ltd,
Plot No. IP No. 27-29, Parts of Sy.Nos. 18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village,
Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

SUB:- Written Confirmation of M/s. R L Fine chem. Pvt.Ltd, Plot No. IP No. 27-29, Parts of Sy.Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, 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/2023/7281 dated 30-JUN-2023 submitted to CDSCO, DDC(I), Sub-Zone Bangalore, and the recommendation received from DDC(I), Sub-Zone Bangalore 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	14	14.10.2022	28.07.2025
02	04	14.10.2022	28.07.2025
03	01	14.10.2022	28.07.2025
04	01	14.10.2022	28.07.2025
05	04	09.10.2023	28.07.2025
06	01	16 OCT 2023	28.07.2025

Yours faithfully,

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

Annexure-06

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

CERTIFICATE NO. : WC-0445

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. R L Fine chem. Pvt.Ltd, Plot No. IP No. 27-29, Parts of Sy.Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Oxazepam Ph.Eur	Manufacturing & Packing

ITEM ONE (01) ONLY

The Written Confirmation remains valid until: 28.07.2025

16 OCT 2023

Signature

Stamp of the authority and date

7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To

M/s. R L Fine Chem Pvt. Ltd.,
Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village,
Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

SUBJECT: - Written Confirmation of M/s. R L Fine Chem Pvt. Ltd., Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, 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/2023/7129, and WC/FR/2023/7470 submitted to CDSCO, Bangalore Sub-Zone office and the recommendation received from DDC (I), Bangalore 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.

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	14	14.10.2022	**28.07.2025**
02	04	14.10.2022	**28.07.2025**
03	01	14.10.2022	**28.07.2025**
04	01	14.10.2022	**28.07.2025**
05	04	09.10.2023	**28.07.2025**
06	01	16.10.2023	**28.07.2025**
07	03	28 NOV 2023	**28.07.2025**

Yours faithfully,

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

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

Annexure-7

CERTIFICATE NO. : WC-0445

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. R L Fine Chem Pvt. Ltd.,
Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Clozapine Ph. Eur	Manufacturing & Packing
2.	Vortioxetine Hydrobromide IHS	Manufacturing & Packing
3.	Sulfamethoxypyrazine IHS	Manufacturing & Packing

ITEM(S) Three (03) ONLY

The Written Confirmation remains valid until: 28.07.2025

Rajeev Singh
Signature

28 NOV 2023

Stamp of the authority and date

7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 26 DEC 2023

To

M/s. R L Fine Chem Pvt. Ltd.,
Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village,
Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

SUBJECT: - Written Confirmation of M/s. R L Fine Chem Pvt. Ltd., Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, 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/2023/7551 submitted to CDSCO, Bangalore Sub-Zone office and the recommendation received from DDC (I), Bangalore 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.

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	14	14.10.2022	**28.07.2025**
02	04	14.10.2022	**28.07.2025**
03	01	14.10.2022	**28.07.2025**
04	01	14.10.2022	**28.07.2025**
05	04	09.10.2023	**28.07.2025**
06	01	16.10.2023	**28.07.2025**
07	03	28.11.2023	**28.07.2025**
08	01	26 DEC 2023	**28.07.2025**

Yours faithfully,

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

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

Annexure-8

CERTIFICATE NO. : WC-0445

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. R L Fine Chem Pvt. Ltd.,
Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Opipramol Dihydrochloride IH	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 28.07.2025

Rajeev Singh
Signature

26 DEC 2023

Stamp of the authority and date

7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 27 MAR 2024

To

M/s. R L Fine Chem Pvt. Ltd.,
Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village,
Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

SUBJECT: - Written Confirmation of M/s. R L Fine Chem Pvt. Ltd., Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, 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/2024/7851 submitted to CDSCO, Bangalore Sub-Zone office and the recommendation received from DDC (I), Bangalore 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
01	14	14.10.2022	**28.07.2025**
02	04	14.10.2022	**28.07.2025**
03	01	14.10.2022	**28.07.2025**
04	01	14.10.2022	**28.07.2025**
05	04	09.10.2023	**28.07.2025**
06	01	16.10.2023	**28.07.2025**
07	03	28.11.2023	**28.07.2025**
08	01	26.12.2023	**28.07.2025**
09	01	27 MAR 2024	**28.07.2025**

Yours faithfully,

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

Annexure-09
WC-0445

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 and address of site: M/s. R L Fine Chem Pvt. Ltd., Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Fluphenazine Decanoate Ph.Eur.	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 28.07.2025

Signature

Stamp of the authority and date

27 MAR 2024

7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

06 MAY 2024

To

M/s. R L Fine Chem Pvt. Ltd.,
Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village,
Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

SUBJECT: - Written Confirmation of M/s. R L Fine Chem Pvt. Ltd., Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, 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/2024/8013 submitted to CDSCO, Bangalore Sub-Zone office and the recommendation received from DDC (I), Bangalore 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
01	14	14.10.2022	**28.07.2025**
02	04	14.10.2022	**28.07.2025**
03	01	14.10.2022	**28.07.2025**
04	01	14.10.2022	**28.07.2025**
05	04	09.10.2023	**28.07.2025**
06	01	16.10.2023	**28.07.2025**
07	03	28.11.2023	**28.07.2025**
08	01	26.12.2023	**28.07.2025**
09	01	27.03.2024	**28.07.2025**
10	01	06 MAY 2024	**28.07.2025**

Yours faithfully,

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

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

Annexure-10
WC-0445

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. R L Fine Chem Pvt. Ltd., Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India**

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Nortriptyline Hydrochloride USP	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 28.07.2025

06 MAY 2024

Signature

Stamp of the authority and date

7-5/2019/EU/WC-0445
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

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

To

M/s. R L Fine Chem Pvt. Ltd.,
Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313,
KIADB Industrial Area, I Phase, Kudumalakunte Village,
Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

SUBJECT: -Written Confirmation ofM/s. R L Fine Chem Pvt. Ltd., Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, 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/2024/8133 submitted to CDSCO, Bangalore Sub-Zone office and the recommendation received from DDC (I), Bangalore 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
01	14	14.10.2022	**28.07.2025**
02	04	14.10.2022	**28.07.2025**
03	01	14.10.2022	**28.07.2025**
04	01	14.10.2022	**28.07.2025**
05	04	09.10.2023	**28.07.2025**
06	01	16.10.2023	**28.07.2025**
07	03	28.11.2023	**28.07.2025**
08	01	26.12.2023	**28.07.2025**
09	01	27.03.2024	**28.07.2025**
10	01	06.05.2024	**28.07.2025**
11	01	20 JUN 2024	**28.07.2025**

Yours faithfully,

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

Annexure-11
WC-0445

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 and address of site: M/s. R L Fine Chem Pvt. Ltd., Plot No. IP No. 27-29, Parts of Sy. Nos. 18, 273, 274 & 313, KIADB Industrial Area, I Phase, Kudumalakunte Village, Gowribidanoor Taluk, Chickkaballapura Dist.-561208, Karnataka, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Ambenonium Chloride 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: 28.07.2025

Signature

20 JUN 2024

Stamp of the authority and date