

**7-5/2013/EU/WC-0139**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organisation**  
**(International Cell)**

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated: 05 AUG 2019

To  
M/s. R.L.Fine Chem Pvt Ltd.,  
No.15 ,KHB Industrial Area,  
Yelahanka, Bangalore-560064

**SUB: Written Confirmation of M/s. R.L.Fine Chem Pvt Ltd., No.15 ,KHB Industrial Area, Yelahanka, Bangalore-560064 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, Bangalore sub Zone 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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.

o/c

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	Validity
01	14	22.07.2019	21.07.2022
02	02	22.07.2019	21.07.2022
03	03	05 AUG 2019*	21.07.2022

Yours faithfully,



(Dr. S. Eswara Reddy)  
Drugs Controller General (India)

o/c

o/c 31.07.2019

for  
31.7.19  
with 31.7.19



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.,  
No.15 ,KHB Industrial Area,  
Yelahanka, Bangalore-560064.

List of APIs:

Sl. No.	Name of the Active Substance (S)	Activity(ies)
1	Trimipramine Maleate BP, Ph.Eur	Manufacturing & Packing
2	Doxylamine Succinate BP, Ph.Eur	Manufacturing & Packing
3	Trimipramine Mesylate IHS	Manufacturing & Packing

ITEM(S) Three (03) Only

The Written Confirmation remains valid until: 21.7.2022

  
Signature

Stamp of the authority and date



05 AUG 2019

o/c  31.7.2029

  
31.7.19

  
31/07/19