

7-5/2015/EU/WC-0318
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

09 MAR 2020

To
M/s. Malladi Drugs & Pharmaceuticals Ltd.,
Unit-5, Plot No. 49, 50, 55 & 56, IDA, Gajulamandyam,
Attur (P.O.), Renigunta- 517520 Chittoor Dist., Andhra Pradesh, India.

SUB: Written Confirmation of M/s. Malladi Drugs & Pharmaceuticals Ltd., Unit-5, Plot No. 49, 50, 55 & 56, IDA, Gajulamandyam, Attur (P.O.), Renigunta- 517520 Chittoor Dist., 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 application Ref. No. Nil dated 19.02.2020 for amendment in Annexure-1 of Written Confirmation Certificate-0318 issued dated 25.11.2019 w.r.t. the product Chlorphenamine Maleate Ph. Eur. (i.e. Chlorphenamine Maleate Ph. Eur. instead of Chlorpheniramine Maleate Ph. Eur.)

In this regard, it is to state that your application has been considered and amended Written Confirmation Certificate is enclosed herewith.

All other conditions of Written Confirmation Certificate shall remain same.

Yours faithfully,



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

o/c

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

Amended
Annexure- 1

CERTIFICATE NO. : WC- 0318

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. Malladi Drugs & Pharmaceuticals Ltd.,
Unit-5, Plot No. 49, 50, 55 & 56, IDA,
Gajulamandyam, Attur (P.O.), Renigunta- 517520
Chittoor Dist., Andhra Pradesh, India.

List of APIs:

Sl. No.	Name of the Active Substance (S)	Activity(ies)
1.	Metaminol Tartrate Ph.Eur/ BP	Manufacturing & Packing
2.	Dextromethorphan Hydrobromide Ph. Eur. /BP	Manufacturing & Packing
3.	Phenobarbital Ph.Eur/ BP	Manufacturing & Packing
4.	Chlorphenamine Maleate Ph.Eur.	Manufacturing & Packing

ITEM(S) Four (4) Only

The Written Confirmation remains valid until: 05th May, 2022

Signature

Stamp of the authority and date



09 MAR 2020

o/c