7-5/2013/EU/WC-0072
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 07 OCT 2019

To
M/s Symed Labs Limited,
Plot No: 25/B, Phase –III,IDA, Jeedimetla(v),
Quthbullapur(M), Medchal-Malkajgiri District-500055,
Telangana State,India.

SUB: Written Confirmation of M/s Symed Labs Limited, Plot No: 25/B, Phase –III, IDA, Jeedimetla (V), Quthbullapur(M), Medchal-Malkajgiri District-500055, Telangana State 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, Hyderabad Zone and the recommendation received from DDC (I), Hyderabad 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	Validity
01	20	09.09.2019	08.09.2022
01 (Amended)	20	07 OCT 2019	08.09.2022
02	02	07 OCT 2019	08.09.2022
03	01	07 OCT 2019	08.09.2022

Yours faithfully,

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

1.10.19.

01-10-19

01-10-19

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

(Amended)
Annexure- 01

CERTIFICATE NO. : WC 0072

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 Symed Labs Limited,
Plot No: 25/B, Phase –III, IDA,
Jeedimetla(V), Quthbullapur(M),
Medchal-Malkajgiri District 500055,
Telangana State, India

List of APIs:

Sl. No.	Name of the Active Substance (S)	Activity(ies)
1.	Agomelatine IH	Manufacturing & Packing
2.	Amisulpride IH/Ph.Eur	Manufacturing & Packing
3.	Brimonidine Tartarate IH	Manufacturing & Packing
4.	Carvedilol Ph.Eur.	Manufacturing & Packing
5.	Cinitapride Hydrogen Tartrate IH	Manufacturing & Packing
6.	Dapoxetine Hydrochloride IH	Manufacturing & Packing
7.	Dronedarone Hydrochloride IH	Manufacturing & Packing
8.	Eszopiclone IH/USP	Manufacturing & Packing
9.	Epalrestat IH	Manufacturing & Packing
10.	Hydroxyzine Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
11.	Iron Sucrose IH	Manufacturing & Packing
12.	Itopride Hydrochloride IH	Manufacturing & Packing
13.	Ketorolac Tromethamine USP/Ph.Eur	Manufacturing & Packing
14.	Lanthanum Carbonate IH	Manufacturing & Packing
15.	Levocetirizine Dihydrochloride IH/USP	Manufacturing & Packing
16.	Linezolid IH	Manufacturing & Packing
17.	Meclizine Hydrochloride Ph.Eur/USP	Manufacturing & Packing
18.	Mosapride Citrate Dihydrate IH/JP	Manufacturing & Packing
19.	Racecadotril Ph.Eur	Manufacturing & Packing
20.	Thalidomide USP	Manufacturing & Packing

ITEM(S) Twenty (20) Only

The Written Confirmation remains valid until: 08.09.2022

Signature

Stamp of the authority and date

07 OCT 2019

01-10-19

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

Annexure – 02

CERTIFICATE NO. : WC-072

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 Symed Labs Limited,
Plot No: 25/B, Phase –III, IDA,
Jeedimetla(V), Quthbullapur(M),
Medchal-Malkajgiri District 500055,
Telangana State, India.

List of APIs:

S. No.	Name of the Active substance(s)	Activity(ies)
1.	Phentermine Hydrochloride USP	Manufacturing & Packing.
2.	Phentermine Base 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: 08.09.2022

Signature VA

Stamp of the authority and date

07 OCT 2019

o/c 1.10.19

01-10-19

MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. Annexure- 03
WC 0072

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 Symed Labs Limited,
Plot No: 25/B, Phase –III, IDA,
Jeedimetla(V), Quthbullapur(M),
Medchal-Malkajgiri District 500055,
Telangana State,India

List of APIs:

Sl. No.	Name of the Active Substance (S)	Activity(ies)
1.	Meprobamate USP	Manufacturing & Packing

ITEM(S) One (01) Only

The Written Confirmation remains valid until: 08.09.2022

Signature

Stamp of the authority and date

07 OCT 2019

o/c 1.10.19.

01-10-19