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:
28 NOV 2022

To,

M/s. Symed Labs Limited,
Unit-II, 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, Unit-II, 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 online application no. WC/RE/2022/4959 submitted to CDSCO, DDC(I), 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	Valid Upto
01	20	28 NOV 2022	08.09.2025
02	03	28 NOV 2022	08.09.2025

Yours faithfully,

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

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

WC-0072

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. Symed Labs Limited,**
Unit-II, Plot No.: 25/B, Phase-III, IDA, Jeedimetla (V),
Quthbullapur (M), Medchal-Malkajgiri District-500055,
Telangana state, INDIA.

2. Manufacturer's licence number: 26/RR/AP/2003/B/R

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):

As per list enclosed as Annexure-01 & Annexure-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: 27.01.2021, 28.01.2021 & 31.01.2021

The Written Confirmation remains valid until: **08.09. 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 V4L

28 NOV 2022

Stamp of the authority and date

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

Annexure-01

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

WC-0072

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. Symed Labs Limited, Unit-II, Plot No.: 25/B, Phase-III, IDA, Jeedimetla (V), Quthbullapur (M), Medchal-Malkajgiri District-500055, Telangana state, INDIA.

List of APIs:

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

ITEM(S) TWENTY (20) ONLY

The Written Confirmation remains valid until: 08.09.2025

Signature Vkr 28 NOV 2022 *Stamp of the authority and date*

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

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

Annexure-02

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,
Unit-II, Plot No.: 25/B, Phase-III, IDA, Jeedimetla (V),
Quthbullapur (M), Medchal-Malkajgiri District-500055,
Telangana state, INDIA.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Phentermine Hydrochloride USP	Manufacturing & Packing
2.	Phentermine Base IH	Manufacturing & Packing
3.	Meprobamate USP	Manufacturing & Packing

ITEM(S) THREE (03) 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: 08.09.2025

Signature

Stamp of the authority and date

28 NOV 2022

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: 14 AUG 2023

To,

M/s. Symed Labs Limited,
Unit-II, 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, Unit-II, 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 online application no. WC/FR/2023/7026 submitted to CDSCO, DDC(I), 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	Valid Upto
01	20	28.11.2022	08.09.2025
02	03	28.11.2022	08.09.2025
03	05	14 AUG 2023	08.09.2025

Yours faithfully,

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

GOVERNMENT OF INDIA
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,**
Unit-II, Plot No.: 25/B, Phase-III, IDA, Jeedimetla (V),
Quthbullapur (M), Medchal-Malkajgiri District-
500055, Telangana state, INDIA.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Brimonidine Tartrate USP / Ph.Eur	Manufacturing & Packing
2.	Carvedilol USP	Manufacturing & Packing
3.	Dronedarone Hydrochloride USP/Ph.Eur	Manufacturing & Packing
4.	Linezolid USP	Manufacturing & Packing
5.	Thalidomide IH	Manufacturing & Packing

ITEM(S) FIVE (05) ONLY

The Written Confirmation remains valid until: 08.09.2025

Signature

Stamp of the authority and date

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

14 AUG 2023

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 14 FEB 2025

To

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

SUB: - Written Confirmation of **M/s. Symed Labs Limited, Unit-II, Plot No.: 25/B, Phase -III, 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 online application no. WC/FR/2024/8777 submitted to DDC (I), CDSCO Hyderabad Zone office, and the recommendation received from DDC (I), CDSCO 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.

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
--	--	28.11.2022	**08.09.2025**
01	20	28.11.2022	**08.09.2025**
02	03	28.11.2022	**08.09.2025**
03	05	14.08.2023	**08.09.2025**
04	01	14 FEB 2025	**08.09.2025**

Yours faithfully,

(Ranga Chandrashekar)
Joint Drugs Controller (India)

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

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

CERTIFICATE NO. :

Annexure-04
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,**
Unit-II, Plot No.: 25/B, Phase -III, Jeedimetla(V),
Quthbullapur (M), Medchal -Malkajgiri
District -500055, Telangana State, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Levocetirizine Dihydrochloride Ph.Eur.	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

The Written Confirmation remains valid until: 08.09.2025

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुख्यालय), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एफ.डी.ए भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002

Stamp of the authority and date

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

14 FEB 2025