7-5/2014/EU/WC-0294

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 29 MAY 2024

To,

M/s. Solara Active Pharma Sciences Limited,
120 A & B, 120P and 121, Industrial Area,
Baikampady, New Mangalore -575011, India

SUB:- Written Confirmation of **M/s. Solara Active Pharma Sciences Limited, 120 A & B, 120P and 121, Industrial Area, Baikampady, New Mangalore -575011, 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/2024/7995 submitted to CDSCO, DDC(I), CDSCO Bangalore Zone, and the recommendation received from DDC(I), CDSCO Bangalore 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
--	--	29 MAY 2024	**04.03.2027**
01	12	29 MAY 2024	**04.03.2027**
02	02	29 MAY 2024	**04.03.2027**

Yours faithfully,

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

WC-0294

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. Solara Active Pharma Sciences Limited, 120 A & B, 120P and 121, Industrial Area, Baikampady, New Mangalore -575011,**

2. Manufacturer's licence number: **KTK/25/500/2005 & KTK/28/382/2008**

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):

and as per list enclosed as Annexures

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: 02.11.2023 & 03.11.2023

The Written Confirmation remains valid until: **04.03.2027**

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. Rajeev Singh Raghuvanshi,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

29 MAY 2024

Signature

Stamp of the authority and date

Annexure -01

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

CERTIFICATE NO. : WC-0294

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. Solara Active Pharma Sciences Limited, 120 A & B, 120P and 121, Industrial Area, Baikampady, New Mangalore -575011,

List of API(s):

S. No.	Active substance(s)	Activity(ies)
1.	Praziquantel IP/BP/USP/Ph. Eur	Manufacturing & Packing
2.	Imiquimod USP	Manufacturing & Packing
3.	Hydralazine Hydrochloride IP/BP/USP/Ph. Eur	Manufacturing & Packing
4.	Citicoline Sodium IP	Manufacturing & Packing
5.	Flecainide Acetate USP/Ph. Eur	Manufacturing & Packing
6.	Mesna Ph. Eur/USP/BP	Manufacturing & Packing
7.	Etomidate Ph. Eur/USP/BP	Manufacturing & Packing
8.	Rifaximin BP/Ph. Eur	Manufacturing & Packing
9.	Methoxsalen USP	Manufacturing & Packing
10.	Oseltamivir Phosphate IP/BP/USP/Ph. Eur	Manufacturing & Packing
11.	Colchicine IH/USP/Ph. Eur.	Manufacturing & Packing
12.	Disulfiram IP/USP/Ph. Eur.	Manufacturing & Packing

ITEM(S) TWELVE (12) ONLY

The Written Confirmation remains valid until: 04.03.2027

29 MAY 2024

Signature

Stamp of the authority and date

Annexure-02

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

WC-0294

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. Solara Active Pharma Sciences Limited, 120 A & B, 120P and 121, Industrial Area, Baikampady, New Mangalore -575011,**

List of API(s):

S. No.	Active substance(s)	Activity(ies)
01	Suxamethonium Chloride BP/Ph. Eur.	Manufacturing & Packing
02	Succinylcholine Chloride IP/USP	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 for sale in India.

The Written Confirmation remains valid until: 04.03.2027

Signature

Stamp of the authority and date

2 3 MAY 2024

7-5/2013/EU/WC-0294

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 19 JUN 2024

To,

M/s. Solara Active Pharma Science Limited,
120 A & B, 120P and 121, Industrial Area,
Baikampady, New Mangalore- 575 011, Karnataka

SUB:- Grant of Written Confirmation of M/s. Solara Active Pharma Science Limited, 120 A & B, 120P and 121, Industrial Area, Baikampady, New Mangalore- 575 011, Karnataka, 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/2022/2658 dated 22.04.2022 submitted to DDC(I), CDSCO Zonal office, Bangalore and the recommendation received from DDC(I), CDSCO Zonal office, 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.

9. The manufacturer is required to comply to the provision 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
-----	---	29.05.2024	04.03.2027
01	12	29.05.2024	04.03.2027
02	02	29.05.2024	04.03.2027
03	03	19 JUN 2024	04.03.2027

Yours faithfully,

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

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

Annexure-03

CERTIFICATE NO. : WC-0294

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. Solara Active Pharma Science Limited, 120 A & B, 120P and 121, Industrial Area, Baikampady, New Mangalore- 575 011, Karnataka

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Buspirone Hydrochloride USP	Manufacturing & Packing
2.	Buspirone Hydrochloride Ph. Eur	Manufacturing & Packing
3.	Edaravone IH	Manufacturing & Packing

ITEM(S) THREE (03) ONLY

The Written Confirmation remains valid until: 04.03.2027

Signature

Stamp of the authority and date

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

19 JUN 2024