

F. No: 7-5/2013/EU/WC-0294
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(International Cell)

(Amended)

FDA Bhawan, Kotla Road,
New Delhi- 110 002.

Dated: 02 APR 2019

To,

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

Sub: - Written Confirmation of M/s Solara Active Pharma Sciences 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 application submitted to CDSCO, Bengaluru Sub Zonal office and the recommendation received from DDC (I), Bengaluru 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 The Written Confirmation will be withdrawn in the event of non-compliance of Standards.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 up to
01.	06	02 APR 2019	04 th March 2021
02.	01	02 APR 2019	04 th March 2021

Yours faithfully,



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

o/c


02-04-19


04/04/19



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 & 121, Industrial Area,
Baikampady, New Mangalore-575 011,
Karnataka, INDIA

2. Manufacturer's license number: KTK/25/500/2005 dt: 31.08.2018
KTK/28/382/2008 dt: 31.08.2018

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per List enclosed as Annexure- 01 & 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: **27th NOV 2017, 24th & 25th JAN 2019**

The Written Confirmation remains valid until: **04th March 2021.**

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

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

Signature
DR. S. ESWARA REDDY
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Stamp of the authority and date



9/c

02-04-19



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

(Amended)
Annexure- 01
WC 294

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 & 121, Industrial Area,
Baikampady, New Mangalore-575 011,
Karnataka, INDIA.

List of APIs:

S. No.	Active substance (s)	Activity (ies)
1.	Praziquantel (IP/BP/USP/EP)	Manufacturing & Packing
2.	Imiquimod (USP)	Manufacturing & Packing
3.	Oseltamivir Phosphate (IP/BP/USP/Ph.Eur)	Manufacturing & Packing
4.	Suxamethonium Chloride (Ph.Eur /BP)	Manufacturing & Packing
5.	Succinylcholine Chloride (IP/USP)	Manufacturing & Packing
6.	Hydralazine Hydrochloride (IP/BP/USP/Ph.Eur)	Manufacturing & Packing


ITEM(S) Six (06) Only

The Written Confirmation remains valid until: 04th March 2021


Dr. S. ESWARA REDDY
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Stamp of the authority and date




02.04.2019


02/04/19



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

(Amended)
CERTIFICATE NO. : Annexure - 02
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 &121, Industrial Area,
Baikampady, New Mangalore- 575 011
Karnataka, INDIA


List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Citicoline Sodium (IP)	Manufacturing & Packing

ITEM(S) One (01) ONLY

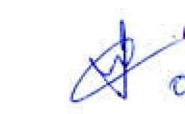

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 04th March 2021


Dr. S. ESWARA REDDY
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Stamp of the authority and date




02.04.2019


A/C