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: 0 6 AUG 2021

To

M/s. Solara Active Pharma Sciences Ltd., 120 A & B, 120 P and 121, Industrial Area, Baikampady, New Mangalore 575 011, India

Subject:- Written Confirmation of M/s. Solara Active Pharma Sciences Ltd., 120 A & B, 120 P & 121, Industrial Area, Baikampady, New Mangalore 575 011, 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, Sub-Zone Bangalore office and the recommendation received from DDC(I), Sub-Zone 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).
- 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.

olc

- 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.

set to be a control desection one other taken of product to

Annexure No.	No. of Products	Date of Issue	Valid Upto
1	09	0 6 AUG 2021	04.03.2024
2	04 0 or 08	0 6 AUG 2021	04.03.2024
3	01	0 6 AUG 2021	04.03.2024

edicinal droducts for homes use in accombance

Yours faithfully,

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

> 108/22 03/08/22

010



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 Ltd., 120 A & B, 120 P and 121, Industrial Area, Baikampady, New Mangalore 575 011, India

2. Manufacturer's licence number: KTK/25/500/2005

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-1, 2 & 3

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;

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: 04.08.2020

The Written Confirmation remains valid until: 04.03.2024

The authenticity of this written confirmation may be verified with the issuing regulatory 010

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:

Telephone no.:

Fax no .:

dci@nic.in,

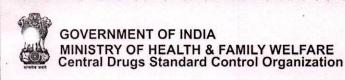
+91-11-23236965

+91-11-23236973

Stamp of the authority and date

6 AUG 2021

Signature



Annexure-1 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

Name and address of site:

M/s. Solara Active Pharma Sciences Ltd., 120 A & B, 120 P and 121, Industrial Area, Baikampady, New Mangalore 575 011, India

List of APIs:

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

ITEM(S) Nine (09) ONLY

The Written Confirmation remains valid until: 04.03.2024

Signature Ville

olc

O 6 AUG 2021

Stamp of the authority and date



Annexure-2 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

Name and address of site:

M/s. Solara Active Pharma Sciences Ltd., 120 A & B, 120 P and 121, Industrial Area, Baikampady, New Mangalore 575 011, India

List of APIs:

ole

S. No.	Active substance(s)	
1.	Suxamethonium Chloride Ph. Eur/BP	Activity(ies)
2.	Succinylcholine Chloride IP/USP	Manufacturing & Packing
3.	Disulfiram IP/Ph.Eur/USP	Manufacturing & Packing
4.	Colchicine IH/USP/Ph.Eur	Manufacturing & Packing
1313		Manufacturing & Packing

ITEM(S) Four (04) 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.

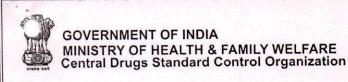
The Written Confirmation remains valid until: 04.03.2024

Signature Ville

13/08/1021

Stamp of the authority and date

0 6 AUG 2021



Annexure-3 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

Name and address of site:

M/s. Solara Active Pharma Sciences Ltd., 120 A & B, 120 P and 121, Industrial Area, Baikampady, New Mangalore 575 011, India

List of APIs:

olc

S. No.	Active substance(s)	Activity(ies)
1.	Oseltamivir Phosphate IP/BP/USP/Ph.Eur	
	N	manadaning a racking

ITEM(S) One (01) ONLY

This certificate is being issued subject to condition that the firm shall obtain prior approval from Drugs Controller General (India), in compliance with GSR 144(E) dated 17.02.2017

The Written Confirmation remains valid until: 04.03.2024

Signature VM

2/08/2021

Stamp of the authority and date