7-5/2019/EU/WC-0435
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
International Cell

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 17 JUN 2019

To

M/s. Surajlok Chemicals Pvt. Ltd,
Plot No. T-6, M.I.D.C, Tarapur Industrial Area,
Boisar, Dist- Thane -401506 Maharashtra, India.

SUB:- Written Confirmation of M/s. Surajlok Chemicals Pvt. Ltd, Plot No. T-6, M.I.D.C, Tarapur Industrial Area, Boisar, Dist- Thane -401506 Maharashtra, 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, Mumbai Zone office and the recommendation received from DDC(I), Mumbai 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
1	03	21.01.2019	20.01.2022
2	07	17 JUN 2019	20.01.2022
3	01	17 JUN 2019	20.01.2022

Yours faithfully,

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

o/c S 4/6/19

07/06/19

Annexure-2

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

CERTIFICATE NO. : WC-0435

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. Surajlok Chemicals Pvt. Ltd,**
Plot No. T-6, M.I.D.C, Tarapur Industrial Area,
Boisar, Dist- Thane -401506 Maharashtra, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Bupivacaine Hydrochloride IP/BP/USP	Manufacturing & Packing
2.	Vecuronium Bromide IP/BP	Manufacturing & Packing
3.	Methotrexate IP/BP/USP	Manufacturing & Packing
4.	Neostigmine Methylsulphate IP/BP/USP	Manufacturing & Packing
5.	Vincristine Sulphate IP/BP/USP	Manufacturing & Packing
6.	Cytarabine IP/BP/USP	Manufacturing & Packing
7.	Ropivacaine Hydrochloride BP/USP	Manufacturing & Packing

ITEM(S) Seven (07) ONLY

The Written Confirmation remains valid until: **20.01.2022**

Signature

O/C 4/6/19

07/06/19

Stamp of the authority and date

17 JUN 2019

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

Annexure-3

CERTIFICATE NO. : **WC-0435**

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. Surajlok Chemicals Pvt. Ltd,
Plot No. T-6, M.I.D.C, Tarapur Industrial Area,
Boisar, Dist- Thane -401506 Maharashtra, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Dacarbazine BP/USP	Manufacturing & Packing

ITEM(S) One (01) 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: <u>20.01.2022</u>

Signature
OIC 4/6/19

Stamp of the authority and date

17 JUN 2019