

7-5/2018/EU/WC/0422
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: **31 OCT 2019**

To

**M/s. Sai-Tech Pharmaceuticals Pvt. Ltd.,
Plot No. A-145/8, Khairane, M.I.D.C. Industrial Area,
Navi Mumbai - 400 705, Taluka – Koparkhairane,
District – Thane, Maharashtra, India**

Subject: Grant of Written Confirmation to M/s. Sai-Tech Pharmaceuticals Pvt. Ltd., Plot No. A-145/8, Khairane, M.I.D.C. Industrial Area, Navi Mumbai - 400 705, Taluka – Koparkhairane, District – Thane, 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, West Zone, Mumbai office and the recommendation received from DDC(I), West Zone, Mumbai 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:-

- 0/c
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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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.	02	08.06.2018	07.06.2021
2.	01	31 OCT 2019	07.06.2021

Yours faithfully,

Vh

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

etc

Encs
20/10/19

Pareek
25/10/19

[Signature]
25-10-19



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

Annexure - 02

CERTIFICATE NO. : WC-0422

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. Sai-Tech Pharmaceuticals Pvt. Ltd.,
Plot No. A-145/8, Khairane, M.I.D.C. Industrial Area,
Navi Mumbai - 400 705, Taluka - Koparkhairane,
District - Thane, Maharashtra, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Tolperisone Hydrochloride JP	Manufacturing & Packing

ITEM(S) One (01) ONLY

The Written Confirmation remains valid until: 07.06.2021

Signature

Stamp of the authority and date



31 OCT 2019

Narendra
25/10/19

9/11

SPCL
25/10/19

for
25-10-19