

7-5/2013/EU/WC-0165
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 22 JUL 2019

To,

**M/s. Swati Spentose Private Limited (Unit-I),
Plot No. A-1/2102 & 2103, Phase-III,
G.I.D.C Vapi-396195, Valsad, Gujarat, India**

SUB:- Written Confirmation of M/s. Swati Spentose Private Limited (Unit-I), Plot No. A-1/2102 & 2103, Phase-III, G.I.D.C Vapi-396195, Valsad, Gujarat, 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, Ahmedabad Zone office and the recommendation received from DDC(I), Ahmedabad Zonal office 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 conform 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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
01	10	08.07.2019	07.07.2022
02	03	22 JUL 2019	07.07.2022

Yours faithfully,



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

o/c S
12/7/19





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. Swati Spentose Private Limited (Unit-I),
Plot No. A-1/2102 & 2103, Phase-III,
G.I.D.C Vapi-396195, Valsad, Gujarat, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Prilocaine HCL EP/BP/USP	Manufacturing & Packing
2.	Diphenhydramine Hydrochloride EP/BP/USP	Manufacturing & Packing
3.	Granisetron Hydrochloride BP	Manufacturing & Packing

ITEM(S) Three (03) ONLY

The Written Confirmation remains valid until: 07.07.2022

Signature

012 18/7/19



Stamp of the authority and date

22 JUL 2019



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

Amended

CERTIFICATE NO. :

WC-0165

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. Swati Spentose Private Limited
2. **Manufacturer's License Number:** G/25/1884

The address of the manufacturer mentioned in the Written Confirmation Certificate (WC-0165) granted on date 08.07.2019 is hereby amended as follows:

In place of:

"M/s. Swati Spentose Private Limited (Unit-I), Plot No. A-1/2101 & 2103, Phase-III, GIDC Vapi-396195, Valsad, Gujarat, India"

Read as:

"M/s. Swati Spentose Private Limited (Unit-I), Plot No. A-1/2102 & 2103, Phase-III, G.I.D.C Vapi-396195, Valsad, Gujarat, India"

All other conditions of Written Confirmation Certificate will remain same.


Signature
18/7/19


18.7.19



Stamp of the authority and date



22 JUL 2019