7-5/2013/EU/WC-0153
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 07 OCT 2019

To
M/s Sharon Bio Medicines Ltd,
Plot No. L-6, MIDC Taloja,Tal.Panvel
District-Raigad-410208,
Maharashtra, India.

SUB: Written Confirmation of M/s Sharon Bio Medicines Limited, Plot No. L-6, MIDC Taloja, Tal. Panvel, Dist-Raigad-410208, 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 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:-

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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards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	Validity
01	11	07 OCT 2019	02.07.2022

Yours faithfully,

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

08.10.19

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

WC-0153

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 Sharon Bio-Medicines Ltd,
Plot No. L-6, MIDC-Taloja,Tal.Panvel,
District: Raigad-410 208,
Maharashtra,India.

1. **Manufacturer's license Number: 25-KD/712**

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

As per list Annexed

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, in particular.

Date of Inspection of the plant 20th & 21st May 2019

The Written Confirmation remains valid until 02.07.2022

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

E-mail:
Telephone no. +91-11-23236965
Fax no.: +91-11-23236973

Signature

9/c 3.10.19

Stamp of the authority and date

07 OCT 2019

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

Annexure- 01

CERTIFICATE NO. : WC 0153

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 Sharon Bio Medicine Limited,**
Plot No. L-6,MIDC Taloja,Tal.Panvel,
District-Raigad-410208,
Maharashtra. India.

List of APIs:

Sl.No.	Active Substance(s)	Activitie(s)
1.	Aripiprazole USP	Manufacturing & Packing
2	Atomoxetine Hydrochloride USP	Manufacturing & Packing
3	Eperisone Hydrochloride JP	Manufacturing & Packing
4	Glimepiride USP	Manufacturing & Packing
5.	Ketoconazole EP	Manufacturing & Packing
6	Memantine Hydrochloride IH	Manufacturing & Packing
7	Miconazole Nitrate USP/BP	Manufacturing & Packing
8	Mosapride Citrate Dihydrate IH	Manufacturing & Packing
9	Nifedipine USP	Manufacturing & Packing
10	Trazodone Hydrochloride BP	Manufacturing & Packing
11	Trimetazidine Dihydrochloride EP/BP/JP	Manufacturing & Packing

ITEM(S) Elevan (11) Only

The Written Confirmation remains valid until 02.07.2022

Signature

Stamp of the authority and date

07 OCT 2019

D/C 3.10.19