7-5/2013/EU/WC-0062
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 Unichem Laboratories Limited
Plot No. 197, Sector – I, Pithampur
Dist. Dhar, Madhya Pradesh

SUB:- Written Confirmation of M/s Unichem Laboratories Limited, Plot No. 197, Sector – I, Pithampur, Dist. Dhar, Madhya Pradesh 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, Indore Sub-Zone office, and the recommendation received from ADC (I), Indore Sub-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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.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	26	22 JUL 2019	Three years from date of issue
2	01	22 JUL 2019	Three years from date of issue

Yours faithfully,

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

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

WC-0062

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 Unichem Laboratories Limited
Plot No. 197, Sector – I, Pithampur
Dist. Dhar, Madhya Pradesh

2. Manufacturer's licence number: 25/7/2005

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

As per Annexure 1 & Annexure 2

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 to the EU.

Date of Inspection of the plant: 20.05.2019 & 21.05.2019

O/C **The Written Confirmation remains valid until**: Three years from date of issue

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. S Eswara Reddy,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date

22 JUL 2019

Annexure-1

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

CERTIFICATE NO. : WC-0062

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 Unichem Laboratories Limited
Plot No. 197, Sector – I, Pithampur
Dist. Dhar, Madhya Pradesh

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Amlodipine Besylate EP	Manufacturing & Packing
2.	Nateglinide IH/Ph. Eur.	Manufacturing & Packing
3.	Memantine Hydrochloride IH	Manufacturing & Packing
4.	Alfuzosin Hydrochloride EP	Manufacturing & Packing
5.	Eprosartan Mesylate IH	Manufacturing & Packing
6.	Lamotrigine EP	Manufacturing & Packing
7.	Zolpidem Tartrate EP	Manufacturing & Packing
8.	Telmisartan EP	Manufacturing & Packing
9.	Ranolazine IH	Manufacturing & Packing
10.	Phenylephrine Hydrochloride EP	Manufacturing & Packing
11.	Quetiapine Fumarate Ph. Eur.	Manufacturing & Packing
12.	Cinacalcet Hydrochloride IH	Manufacturing & Packing
13.	Tizanidine Hydrochloride EP/USP	Manufacturing & Packing
14.	Meloxicam EP/USP	Manufacturing & Packing
15.	Glipizide EP	Manufacturing & Packing
16.	Bumetanide Ph.Eur.	Manufacturing & Packing
17.	Milnacipran Hydrochloride IH	Manufacturing & Packing
18.	Tadalafil EP/USP	Manufacturing & Packing
19.	Atomoxetine Hydrochloride USP	Manufacturing & Packing
20.	Montelukast Sodium USP	Manufacturing & Packing
21.	Lacosamide IH	Manufacturing & Packing
22.	Phenytoin Sodium USP	Manufacturing & Packing
23.	Allopurinol USP	Manufacturing & Packing
24.	Fenofibrate USP	Manufacturing & Packing
25.	Metoprolol Succinate USP	Manufacturing & Packing
26.	Tolterodine Tartrate USP	Manufacturing & Packing

ITEM(S) TWENTY SIX (26) ONLY

The Written Confirmation remains valid until: Three years from date of issue

Signature

Stamp of the authority and date

22 JUL 2019

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

Annexure-2

CERTIFICATE NO. : WC-0062

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 Unichem Laboratories Limited
Plot No. 197, Sector – I, Pithampur
Dist. Dhar, Madhya Pradesh

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Quetiapine Hemifumarate IH	Manufacturing & Packing

ITEM(S) ONE (01) 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: Three years from date of issue

Signature

16-07-19

17-7-19

Stamp of the authority and date

22 JUL 2019