7-5/2013/EU/WC-0092
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 15 JUL 2019

To

M/s. Jubilant Generics Limited
Plot No. 18, 56, 57 & 58, K.I.A.D.B. Industrial Area
Nanjangud – 571 302, Mysore District, Karnataka

SUB:- Written Confirmation of M/s. Jubilant Generics Limited, Plot No. 18, 56, 57 & 58, K.I.A.D.B. Industrial Area, Nanjangud – 571 302, Mysore District, Karnataka Sate 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, Bangalore Sub-Zone office, and the recommendation received from DDC (I), Bangalore 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.

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

WC-0092

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. Jubilant Generics Limited**
Plot No. 18, 56, 57 & 58, K.I.A.D.B. Industrial Area
Nanjangud – 571 302, Mysore District, Karnataka

2. Manufacturer's licence number: KTK/25/489/2003 & KTK/28/335/2003

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: 15/10/2018 & 16/10/2018

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

15 JUL 2019

Annexure-1

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

CERTIFICATE NO. : WC-0092

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. Jubilant Generics Limited
Plot No. 18, 56, 57 & 58, K.I.A.D.B. Industrial Area
Nanjangud – 571 302, Mysore District, Karnataka

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Alendronate Sodium Ph. Eur.	Manufacturing & Packing
2.	Aprepitant IH/Ph. Eur.	Manufacturing & Packing
3.	Aripiprazole IH/Ph. Eur.	Manufacturing & Packing
4.	Azithromycin Dihydrate Ph. Eur.	Manufacturing & Packing
5.	Azithromycin Monohydrate Ph.Eur./USP	Manufacturing & Packing
6.	Bupropion Hydrochloride USP	Manufacturing & Packing
7.	Carbamazepine Ph. Eur./USP/BP	Manufacturing & Packing
8.	Cetirizine Dihydrochloride Ph. Eur./USP	Manufacturing & Packing
9.	Citalopram Hydrobromide Ph. Eur./USP	Manufacturing & Packing
10.	Darifenacine Hydrobromide IH	Manufacturing & Packing
11.	Deferasirox IH	Manufacturing & Packing
12.	Donepezil Hydrochloride USP	Manufacturing & Packing
13.	Escitalopram Oxalate USP	Manufacturing & Packing
14.	Eslicarbazepine Acetate IH	Manufacturing & Packing
15.	Esomeprazole Magnesium Ph. Eur./USP	Manufacturing & Packing
16.	Esomeprazole Magnesium Trihydrate Ph. Eur.	Manufacturing & Packing
17.	Esomeprazole Sodium IH	Manufacturing & Packing
18.	Galantamine Hydrobromide IH	Manufacturing & Packing
19.	Lamotrigine Ph. Eur.	Manufacturing & Packing
20.	Levetiracetam USP/Ph. Eur.	Manufacturing & Packing
21.	Levocetirizine Dihydrochloride IH	Manufacturing & Packing
22.	Linezolid IH	Manufacturing & Packing
23.	Niacin USP/Nicotinic Acid Ph. Eur.	Manufacturing & Packing
24.	Olanzapine Ph. Eur./USP	Manufacturing & Packing
25.	Oxcarbazepine IH/Ph. Eur./USP	Manufacturing & Packing
26.	Paliperidone IH	Manufacturing & Packing
27.	Pantoprazole Sodium USP/Ph. Eur.	Manufacturing & Packing
28.	Paroxetine Hydrochloride Hemihydrate Ph. Eur./USP	Manufacturing & Packing
29.	Pinaverium Bromide IH	Manufacturing & Packing
30.	Quetiapine Fumarate IH	Manufacturing & Packing
31.	Rabeprazole Sodium IH/USP	Manufacturing & Packing

Annexure-1

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

CERTIFICATE NO. : WC-0092

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. Jubilant Generics Limited
Plot No. 18, 56, 57 & 58, K.I.A.D.B. Industrial Area
Nanjangud – 571 302, Mysore District, Karnataka

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
32.	Risedronate Sodium USP	Manufacturing & Packing
33.	Risperidone Ph. Eur.	Manufacturing & Packing
34.	Rivastigmine Tartrate USP	Manufacturing & Packing
35.	Rizatriptan Benzoate Ph. Eur./USP	Manufacturing & Packing
36.	Sitagliptin Phosphate Monohydrate Ph. Eur.	Manufacturing & Packing
37.	Sitagliptin Phosphate USP	Manufacturing & Packing
38.	Solifenacin Succinate IH/Ph. Eur.	Manufacturing & Packing
39.	Tadalafil Ph. Eur.	Manufacturing & Packing
40.	Telmisartan Ph. Eur.	Manufacturing & Packing
41.	Terazosin Hydrochloride Ph. Eur./USP	Manufacturing & Packing
42.	Tramadol Hydrochloride Ph. Eur.	Manufacturing & Packing
43.	Ticagrelor IH	Manufacturing & Packing
44.	Valacyclovir Hydrochloride USP	Manufacturing & Packing
45.	Varenicline Tartrate IH	Manufacturing & Packing
46.	Voriconazole USP/Ph. Eur.	Manufacturing & Packing
47.	Zoledronic acid IH	Manufacturing & Packing
48.	Zolmitriptan IH	Manufacturing & Packing

ITEM(S) FORTY EIGHT (48) ONLY

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

Signature

Stamp of the authority and date

15 JUL 2019

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

Annexure-2

CERTIFICATE NO. :

WC-0092

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. Jubilant Generics Limited
Plot No. 18, 56, 57 & 58, K.I.A.D.B. Industrial Area
Nanjangud – 571 302, Mysore District, Karnataka

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	Bupropion Hydrobromide IH	Manufacturing & Packing
2.	Citalopram Hydrochloride Ph. Eur.	Manufacturing & Packing
3.	Meclizine Hydrochloride USP/Ph. Eur.	Manufacturing & Packing

ITEM(S) THREE (03) 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

Stamp of the authority and date

15 JUL 2019