Amended

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

01 SEP 2022

To

M/s Jubilant Pharmova Limited,
Plot No 18, 56, 57 & 58 KIADB Industrial area,
Nanjangud-571302, Mysore, Karnataka, India

SUB:- Written Confirmation of M/s Jubilant Pharmova Limited, Plot No 18, 56, 57 & 58 KIADB Industrial area, Nanjangud-571302 Mysore, Karnataka, Indiaas 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 office, and the recommendation received from DDC(I), Bangalore 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.

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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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	56	01 SEP 2022	04.11.2024
02	03	01 SEP 2022	04.11.2024

Yours faithfully,

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

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

Amended

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 Pharmova Limited,**
Plot No 18, 56, 57 & 58 KIADB Industrial area,
Nanjangud-571302, Mysore, Karnataka, India

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 List enclosed as Annexures

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: **30 September 2021 & 01 October 2021**

The Written Confirmation remains valid until: **04 November 2024**

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

Signature 01 SEP 2022

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

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

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Annexure-1

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 Pharmova Limited,**
Plot No 18, 56, 57 & 58 KIADB Industrial area,
Nanjangud-571302, Mysore, Karnataka, India

List of APIs:

Sr. No.	Active substance (s)	Activity(ies)
1.	AliskirenHemifumarate IH	Manufacturing & Packing
2.	Bosentan Monohydrate IH	Manufacturing & Packing
3.	Donepezil Hydrochloride IH	Manufacturing & Packing
4.	Esomeprazole Magnesium Dihydrate IH	Manufacturing & Packing
5.	Febuxostat IH	Manufacturing & Packing
6.	Ranolazine IH	Manufacturing & Packing
7.	Rivastigmine Tartrate IH	Manufacturing & Packing
8.	Rosuvastatin Calcium IH	Manufacturing & Packing
9.	Lacosamide IH	Manufacturing & Packing
10.	Sitagliptin Phosphate Monohydrate IH	Manufacturing & Packing
11.	Rivaroxaban IH	Manufacturing & Packing
12.	Alendronate Sodium Ph. Eur.	Manufacturing & Packing
13.	Aprepitant Ph. Eur.	Manufacturing & Packing
14.	Aripiprazole Ph. Eur.	Manufacturing & Packing
15.	Azithromycin Dihydrate Ph. Eur.	Manufacturing & Packing
16.	Azithromycin Monohydrate Ph.Eur.	Manufacturing & Packing
17.	Carbamazepine BP/Ph. Eur./USP	Manufacturing & Packing
18.	Cetirizine Dihydrochloride Ph. Eur./USP	Manufacturing & Packing
19.	Citalopram Hydrobromide Ph. Eur.	Manufacturing & Packing
20.	Darifenacine Hydrobromide IH	Manufacturing & Packing
21.	Deferasirox IH	Manufacturing & Packing
22.	Donepezil Hydrochloride USP	Manufacturing & Packing
23.	Escitalopram Oxalate USP	Manufacturing & Packing
24.	Eslicarbazepine Acetate IH	Manufacturing & Packing
25.	Esomeprazole Magnesium Ph. Eur./USP	Manufacturing & Packing
26.	Esomeprazole Magnesium Trihydrate Ph. Eur.	Manufacturing & Packing
27.	Esomeprazole Sodium IH	Manufacturing & Packing
28.	Galantamine Hydrobromide IH	Manufacturing & Packing
29.	Irbesartan Ph. Eur.	Manufacturing & Packing
30.	Lamotrigine Ph. Eur.	Manufacturing & Packing
31.	Levetiracetam Ph. Eur.	Manufacturing & Packing
32.	Losartan Potassium Ph. Eur.	Manufacturing & Packing
33.	Olanzapine Ph. Eur.	Manufacturing & Packing
34.	Olmesartan Medoxomil IH	Manufacturing & Packing

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Central Drugs Standard Control Organization • Ministry of Health & Family Welfare, Govt. of India •

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

CERTIFICATE NO. : **Amended 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

Name and address of site: **M/s Jubilant Pharmova Limited, Plot No 18, 56, 57 & 58 KIADB Industrial area, Nanjangud-571302, Mysore, Karnataka, India**

List of APIs:

35.	Oxcarbazepine IH/Ph. Eur.	Manufacturing & Packing
36.	Paliperidone IH	Manufacturing & Packing
37.	Pantoprazole Sodium Ph. Eur.	Manufacturing & Packing
38.	Pinaverium Bromide IH	Manufacturing & Packing
39.	Quetiapine Fumarate IH	Manufacturing & Packing
40.	Rabeprazole Sodium IH/USP	Manufacturing & Packing
41.	Risedronate Sodium USP	Manufacturing & Packing
42.	Risperidone Ph. Eur.	Manufacturing & Packing
43.	Rivastigmine Tartrate USP	Manufacturing & Packing
44.	Rizatriptan Benzoate Ph. Eur.	Manufacturing & Packing
45.	Sitagliptin Phosphate Monohydrate Ph. Eur.	Manufacturing & Packing
46.	Sitagliptin Phosphate USP	Manufacturing & Packing
47.	Solifenacin Succinate Ph. Eur.	Manufacturing & Packing
48.	Tadalafil Ph. Eur.	Manufacturing & Packing
49.	Terazosin Hydrochloride Ph. Eur.	Manufacturing & Packing
50.	Ticagrelor IH	Manufacturing & Packing
51.	Tramadol Hydrochloride Ph. Eur.	Manufacturing & Packing
52.	Valsartan Ph. Eur.	Manufacturing & Packing
53.	Varenicline Tartrate IH	Manufacturing & Packing
54.	Voriconazole Ph. Eur.	Manufacturing & Packing
55.	Zoledronic Acid IH	Manufacturing & Packing
56.	Zolmitriptan IH	Manufacturing & Packing

ITEM(S) Fifty Six (56) ONLY

The Written Confirmation remains valid until: 04.11.2024

Signature

01 SEP 2022

Stamp of the authority and date

Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare

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

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CERTIFICATE NO. : **Annexure-2**

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 Pharmova 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 USP	Manufacturing & Packing
2.	Citalopram Hydrochloride Ph. Eur.	Manufacturing & Packing
3.	Meclizine Hydrochloride 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: 04.11.2024

Signature

Stamp of the authority and date

Central Drugs Standard Control Organization
Ministry of Health & Family Welfare, Govt. of India

01 SEP 2022