7-5/2013/EU/WC-0024
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated 08 JUL 2022

To

M/s. GRANULES INDIA LIMITED
Address: Plot No. 8, Jawaharlal Nehru Pharmacity,
Tadi (V) Paravada, Visakhapatnam-531019,
Andhra Pradesh India..

SUB:- Written Confirmation of M/s. Granules India Limited Address: Plot No. 8, Jawaharlal Nehru Pharmacity, Tadi (V) Paravada , Visakhapatnam-531019, Andhra Pradesh 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 no. WC/ED/2022/3897 submitted online to CDSCO, Zonal office, Hyderabad and the recommendation received from DDC(I), Zonal office, Hyderabad 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 The Written Confirmation will be withdrawn in the events of non compliance of Standards.

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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	28	08 JUL 2022	26.06.2025

Yours faithfully,

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

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

CERTIFICATE NO. : **WC-0024**

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. Granules India Limited,**
Plot No. 8,Jawaharlal Nehru Pharmacity,
Tadi (V) Paravada, Visakhapatnam-531019,
Andhra Pradesh India.

2. **Manufacturer's licence number**: 26/VP/AP/2007/B/CC/R & 19/VP/AP/2013/B/CC/R

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

As per List enclosed as Annexure-1

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: 23.05.2022 & 24.05.2022

The Written Confirmation remains valid until: 26.06.2025

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

Stamp of the authority and date

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

08 JUL 2022

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

CERTIFICATE NO. : **Annexure-1**

WC-0024

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. Granules India Limited Address: Plot No. 8, Jawaharlal Nehru Pharmacity, Tadi (V) Paravada , Visakhapatnam-531019, Andhra Pradesh India.**

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Abacavir Sulphate EP	Manufacturing & Packing
2.	Atazanavir Sulphate IH, EP	Manufacturing & Packing
3.	Azathioprine USP,EP	Manufacturing & Packing
4.	Azithromycin Anhydrous IH/USP	Manufacturing & Packing
5.	Brinzolamide IH,USP	Manufacturing & Packing
6.	Cetrizine Dihydrochloride EP	Manufacturing & Packing
7.	Clopidogrel Bisulphate USP	Manufacturing & Packing
8.	Darunavir Amorphous IH	Manufacturing & Packing
9.	Dimethyl Fumarate IH	Manufacturing & Packing
10.	Fexofinadine Hydrochloride USP	Manufacturing & Packing
11.	Fluconazole EP	Manufacturing & Packing
12.	Gabapentin EP, USP	Manufacturing & Packing
13.	Gliclazide IP,IH,BP,EP	Manufacturing & Packing
14.	Itraconazole IH,USP	Manufacturing & Packing
15.	Levocetirizine Dihydrochloride IH	Manufacturing & Packing
16.	Losartan Potassium EP	Manufacturing & Packing
17.	Metformin Hydrochloride IP,IH,BP,USP	Manufacturing & Packing
18.	Mycophenolate Mofetil USP, EP	Manufacturing & Packing
19.	Naproxen Sodium USP, EP	Manufacturing & Packing
20.	Olmesartan Medoxomil USP/Ph. Eur	Manufacturing & Packing
21.	Omeprazole Magnesium IH/USP	Manufacturing & Packing
22.	Pencillamine USP, EP	Manufacturing & Packing
23.	Pirfenidone IH, EP	Manufacturing & Packing
24.	Rifaximin EP	Manufacturing & Packing
25.	Tenegliptin Hydrobromide Hydrate IH	Manufacturing & Packing
26.	Tenofovir Disoproxil Succinate IH	Manufacturing & Packing
27.	Tizanidine Hydrochloride IP,USP,EP	Manufacturing & Packing
28.	Trazadone Hydrochloride IH/USP	Manufacturing & Packing

ITEM(S) Twenty Eight (28) ONLY

The Written Confirmation remains valid until: 26.06.2025

Signature

Stamp of the authority and date

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

08 JUL 2022

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