

**F.No: 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: 27 JUN 2019

To  
M/s Granules India Limited,  
Plot No.8, Jawaharlal Nehru Pharma City,  
Tadi Village, Parwada Mandal,  
Visakhapatnam District, Andhra Pradesh, India.

**SUB: Written Confirmation of M/s Granules India Limited, Plot No.8, Jawaharlal Nehru Pharma City, Tadi-Village, Parwada Mandal, Visakhapatnam District, 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 submitted to CDSCO, Hyderabad Zone and the recommendation received from DDC (I), Hyderabad 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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
01	17	27 JUN 2019	Three years from the date of issue

Yours faithfully,



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

26-06-2019

26-6-19

26/06/19





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

Annexure-01  
WC-0024

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 Granules India Limited,  
Plot No.8, Jawaharlal Nehru Pharma City,  
Tadi Village, Parwada Mandal,  
Visakhapatnam District,  
Andhra Pradesh, India.

List of APIs:

Sl.No.	Name of the Active Substances	Activitie(s)
1.	Abacavir Sulfate Ph.Eur	Manufacturing and Packing
2.	Atazanavir Sulfate IH	Manufacturing and Packing
3.	Azathioprine USP/EP	Manufacturing and Packing
4.	Cetirizine Dihydrochloride Ph.Eur	Manufacturing and Packing
5.	Clopidogrel Bisulfate USP	Manufacturing and Packing
6.	Dimethyl Fumarate (IH)	Manufacturing and Packing
7.	Fexofenadine Hydrochloride (USP)	Manufacturing and Packing
8.	Fluconazole Ph.Eur	Manufacturing and Packing
9.	Levocetirizine Dihydrochloride IH	Manufacturing and Packing
10.	Losartan Potassium Ph.Eur	Manufacturing and Packing
11.	Mycophenolate Mofetil USP/EP	Manufacturing and Packing
12.	Rifaximin Ph.Eur	Manufacturing and Packing
13.	Tenofovir Disoproxil Succinate IH	Manufacturing and Packing
14.	Tizanidine Hydrochloride IP/USP/EP	Manufacturing and Packing
15.	Brinzolamide IH/USP	Manufacturing and Packing
16.	Pirfenidone IH/Ph.Eur	Manufacturing and Packing
17.	Darunavir Amorphous IHS	Manufacturing and Packing

ITEM(S) Seventeen (17) Only

The Written Confirmation remains valid until: (03) Three years from the date of issue

Signature

Stamp of the authority and date



27 JUN 2019

26-06-2019  
26.6.19  
26/06/19





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 Granules India Limited,  
Plot No.8, Jawaharlal Nehru Pharma City,  
Tadi Village, Parwada Mandal,  
Visakhapatnam District, Andhra Pradesh, India.

2. Manufacturer's license Number: 26/VP/API/2007/B/CC

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 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 to the EU.

**Date of Inspection of the plant: 10<sup>th</sup> & 11<sup>th</sup> MAY 2019**

**The Written Confirmation remains valid until: (03)Three years from the 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:**

**Telephone no.:**

**Fax no.:**

dcic@nic.in,

+91-11-23236965

+91-11-23236973

Signature

Stamp of the authority and date



27 JUN 2019

dc 26-06-2019  
26-6-19  
26/06/19