

7-5/2018/EU/WC-0427
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 05 MAR 2019

To

M/s. Gland Pharma Limited,
Plot No.49 & 50, J.N. Pharma City,
Parawada (M), Visakhapatanam – 531019, Andhra Pradesh

SUB: - Written Confirmation of M/s. Gland Pharma Limited, Plot No.49 & 50, J.N. Pharma City, Parawada (M), Visakhapatanam – 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 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 The Written Confirmation will be withdrawn in the events of non-compliance of Standards.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	06	05 MAR 2019	Three Years from the Date of Issue
02	02	05 MAR 2019	

Yours faithfully,

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

Handwritten notes in blue ink:
7. 8/2/19
26/02/19
f. 5
27-2-19
Wd
27/02/19



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. Gland Pharma Limited,
Plot No.49 & 50, J.N. Pharma City,
Parawada (M), Visakhapatnam – 531019,
Andhra Pradesh, India

2. Manufacturer's licence number: 7/VP/AP/2014/B/G and 20/VSP/AP/2016/B/G

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 Annexure -1 and 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: 13/07/2017 & 14/07/2017

The Written Confirmation remains valid until: 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: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973


Signature


Stamp of the authority and date


7C 8706
26/01/19
27-2-19
28/2/19

05 MAR 2019



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. Gland Pharma Limited,
Plot No.49 & 50, J.N. Pharma City,
Parawada (M), Visakhapatnam – 531019,
Andhra Pradesh, India.

List of APIs:

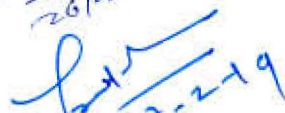
S. No.	Active substance(s)	Activity(ies)
1	Atracurium Besylate USP	Manufacturing & Packing
2	Cis Atracurium Besylate IH	Manufacturing & Packing
3	Dexmedetomidine HCl IH	Manufacturing & Packing
4	Dexrazoxane IH	Manufacturing & Packing
5	Tigecycline IH	Manufacturing & Packing
6	Ziprasidone Mesilate Trihydrate EP	Manufacturing & Packing

ITEM(S) Six (06) ONLY

The Written Confirmation remains valid until: Three Years from the Date of Issue


Signature

dc epca
26/02/19


27-2-19


27/02/19

Stamp of the authority and date



05 MAR 2019



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. Gland Pharma Limited,
Plot No.49 & 50, J.N. Pharma City,
Parawada (M), Visakhapatnam – 531019,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1	Argatroban Monohydrate IH	Manufacturing & Packing
2	Regadenoson IH	Manufacturing & Packing

ITEM(S) Two (02) ONLY

This certificate is being issued subject to condition that the firm shall obtained NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substance for the purpose of export only, as the above mentioned active substance is not approved for manufacture for sale in India

The Written Confirmation remains valid until: Three Years from the Date of Issue

Signature

9/ EDC
28/12/14
f. 27-2-19

27/02/14



Stamp of the authority and date

05 MAR 2019