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

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

Dated 22 JUN 2023

To

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

SUB:- Application for amendment of the 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 vide letter dated 07.06.2023 on the subject cited above.

In this regard, please find the enclosed amended Annexure-01 of Written Confirmation Certificate. The condition of the 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 will remain same.

Please acknowledge the receipt.

Yours faithfully,

Rajeev Singh

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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

CERTIFICATE NO. :

Amended
Annexure-01

WC-0427

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), Visakhapatanam – 531019,
Andhra Pradesh, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Caspofungin Acetate IH	Manufacturing & Packing
2.	Dexmedetomidine Hydrochloride USP	Manufacturing & Packing
3.	Indomethacin Sodium USP	Manufacturing & Packing
4.	Fosphenytoin Sodium USP	Manufacturing & Packing
5.	Glatiramer Acetate IH	Manufacturing & Packing
6.	Isoproterenol Hydrochloride USP	Manufacturing & Packing
7.	Metaraminol Bitartrate BP	Manufacturing & Packing
8.	Neostigmine Methylsulfate USP	Manufacturing & Packing
9.	Paliperidone Palmitate (Sterile) IH	Manufacturing & Packing
10.	Plerixafor IH	Manufacturing & Packing
11.	Rocuronium Bromide USP	Manufacturing & Packing
12.	Levothyroxine Sodium USP	Manufacturing & Packing
13.	Atracurium Besylate USP	Manufacturing & Packing
14.	Dexrazoxane IH	Manufacturing & Packing
15.	Ziprasidone Mesilate Trihydrate Ph. Eur.	Manufacturing & Packing

ITEM(S) FIFTEEN (15) ONLY

The Written Confirmation remains valid until: 04.03.2025

Rajan Singh
Signature

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

Stamp of the authority and date

22 JUN 2023

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:

04 AUG 2022

To

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

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 online application No. WC/RE/2022/2499 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	15	04 AUG 2022	04.03.2025
02	05	04 AUG 2022	04.03.2025

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-0427**

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), Visakhapatanam – 531019,
Andhra Pradesh, India

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

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 -01 and 02

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: 29/11/2021 & 30/11/2021

The Written Confirmation remains valid until: **04.03.2025**

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

04 AUG 2022

Signature

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

Annexure-01

CERTIFICATE NO. : **WC-0427**

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), Visakhapatanam – 531019,
Andhra Pradesh, India.

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Caspofungin Acetate IH	Manufacturing & Packing
2.	Dexmedetomidine Hydrochloride USP	Manufacturing & Packing
3.	Indomethacin Sodium USP	Manufacturing & Packing
4.	Fosphenytoin Sodium USP	Manufacturing & Packing
5.	Glatiramer Acetate IH	Manufacturing & Packing
6.	Isoproterenol Hydrochloride USP	Manufacturing & Packing
7.	Metaraminol Bitartrate BP	Manufacturing & Packing
8.	Neostigmine Methylsulfate USP	Manufacturing & Packing
9.	Paliperidone Palmitate (Sterile) IH	Manufacturing & Packing
10.	Plerixafor IH	Manufacturing & Packing
11.	Rocuronium Bromide USP	Manufacturing & Packing
12.	Levothyroxine Sodium USP	Manufacturing & Packing
13.	Atracurium Besylate USP	Manufacturing & Packing
14.	Dexrazoxane IH	Manufacturing & Packing
15.	Ziprasidone Mesilate USP	Manufacturing & Packing

ITEM(S) FIFTEEN (15) ONLY

The Written Confirmation remains valid until: 04.03.2025

Signature

04 AUG 2022

Stamp of the authority and date

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

Annexure-02

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

CERTIFICATE NO. : **WC-0427**

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), Visakhapatanam – 531019,
Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
1.	Argatroban Monohydrate USP	Manufacturing & Packing
2.	Betamethasone Acetate (Sterile) USP	Manufacturing & Packing
3.	Doxycycline Hyclate USP	Manufacturing & Packing
4.	Foscarnet Sodium USP	Manufacturing & Packing
5.	Regadenoson IH	Manufacturing & Packing

ITEM(S) FIVE (05) 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: 04.03.2025

Signature

Stamp of the authority andDate

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

04 AUG 2022