Regierung Von Oberbayern

CERTIFICATE NUMBER: ***DE_BY_04_GMP_2025_0075***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Germany confirms the following:
The manufacturer: ***Gland Pharma Limited***
Site address: ***Survey No 143 To 148 150 And 151, Near Gandimaisamma Cross Roads, D P Pally Dundigal Post, Medchal Malkajgiri District, Hyderabad, 500043***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011664*** / ***LOC-100018718***
DUNS Number: ***91-860-1238***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-06-07***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

EudraGMP

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids

Clarifying remarks (for public users)

Inspection is applicable for all products of dosage-forms mentioned under 1.1, manufactured on below mentioned production-lines. Following products were applied: Product 1: Zoledronsaeure beta 4 mg/5 ml concentrate for solution for infusion, Zoledronsaeure beta 5 mg/100 ml infusion solution Zoledronsaeure beta 4 mg/100 ml infusion solution Product 2: Fondaparinux-Natrium beta 2,5 m /0,5 ml, injection solution, prefilled syringe Fondaparinux-Natrium beta 5 mg/0,4 ml, injection solution, prefilled syringe Fondaparinux-Natrium beta 7,5 mg 0,6 ml, injection solution, prefilled syringe Fondaparinux-Natrium beta 10 mg/0,8 ml, injection solution, prefilled syringe Product 3: Palonosetron beta 250 microgramm injection solution Product 4 Levetiracetam Hospira 100 mg/ml, concentrate for solution for infusion Product 5 Daptomycin Fosun Pharma 350 mg, powder for solution for injection Building: Survey no: 143 - 148, 150 & 151, Domara pochampally Production Lines: (text missing)

2025-05-05

Name and signature of the authorised person of the Competent Authority of

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Regierung Von Oberbayern
Tel:***Confidential***
Fax:***Confidential***

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