National Authority Of Medicines And Health Products

CERTIFICATE NUMBER: ***FT068/MH/002/2024***

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 Portugal confirms the following:
The manufacturer: ***Jodas Expoim Private Limited***
Site address: ***Plot No 55 Phase III Biotech Park, Karkapatla Village, Markook Mandal, Siddipet District, Telangana, 502279, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100033666*** / ***LOC-100052844***

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, transposed in the following national legislation:Art.176.º n.º 4 of Decree-Law n.º 176/2006, 30 of August.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-07-07***, 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.*

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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 Special Requirements 7 Other: Oncologics(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: Oncologics and Pre-Filled Syringes in general(en) 1.1.1.6 Other: Dry powders for injection(en) Special Requirements 1 B-lactam Antibiotics
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids Special Requirements 7 Other: Contrast Media(en) 1.1.2.3 Small volume liquids Special Requirements 7 Other: Contrast Media, Oncologics and Pre Filled Seringes in general(en)
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

2024-04-10 Name and signature of the authorised person of the

Competent Authority of Portugal

Confidential
National Authority Of Medicines And Health Products
Tel:***Confidential***
Fax:***Confidential***

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