MALTA MEDICINES AUTHORITY

Certificate No: MT/018HM/2023

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

The Medicines Authority of Malta confirms the following:

The manufacturer **Credo Life Sciences Private Ltd.**

Site address **No. 1613 Survey**
Nandigama Village
Rangareddy District,
Telangana State, 509228
India

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. 101A (10) of the Medicines Act (Chapter 458 of the Laws of Malta)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **30th March – 3rd April 2023**, it is considered that it complies with the Good Manufacturing Practice requirements[1] referred to in 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.

5th July 2023 .....

Dr. Mark Cilia[1]
Director Inspectorate & Enforcement Directorate
Malta Medicines Authority
Tel: 00356 234 39 119

1 The certificate referred to in paragraph 111(5) of Directive 2001/83/EC, is also applicable to importers.
2 Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.
3 These requirements fulfil the GMP recommendations of WHO

MALTA MEDICINES AUTHORITY

Part 2

☒ Human Medicinal Products* ☐ Human Investigational Medicinal Products*	
1 MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS *	
1.2	**Non-sterile products** *1.2.1 Non sterile products (processing operations for the following dosage forms)* 1.2.1.8 Other solid dosage forms (pellets for further processing)
1.6	**Quality Control testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate*:
The pellets are packaged in bulk for further processing.
This certificate is limited in scope to products intended for the EU/EEA markets and does not include the immunosuppressant block.

5th July 2023 .....

Dr. Mark Cilia[1]
Director Inspectorate & Enforcement Directorate
Malta Medicines Authority
Tel: 00356 234 39 119

[1] The signature, date and contact details should appear on each page of the certificate.