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MEDICINES AUTHORITY

IN012/12 Appendix 1 Version 2
Certificate No: **MT/002HM/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
The Malta Medicines Authority confirms the following:
The manufacturer **MSN Laboratories Private Limited**
Site address **Unit II Survey No. 1277 And 1319-1324, Nandigama Village, Kothur Taluka, Ranga Reddy 509228, India**
Additional details on units inspected C Block, D Block, G Block (excluding steriles)
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 7th December 2023 - 13th December 2023, it is considered that it complies with the Good Manufacturing Practice requirements[3] referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 .

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.

2nd July 2024 .....

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

[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 Interpretation of the Union format for GMP certificate.
[3] These requirements fulfil the GMP recommendations of WHO

Part 2

☐ Human 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)* 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packing
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:
Inspection covered C block for oncology solid dosage forms, D block for general solid dosage forms & G block for general solid dosage forms and for immunosuppressants in a dedicated area on the second floor. Packaging is limited to lines equipped with Pharmacode readers. This certificate is limited in scope to products intended for EU/EEA markets.

2nd July 2024 .....

Dr. Mark Cilia[1]
Director
Inspectorate & Enforcement Directorate
Malta Medicines Authority
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