State Institute For Drug Control

CERTIFICATE NUMBER: ***Sk/026V/2022***

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 Slovakia confirms the following:
The manufacturer: ***MSN Laboratories Private Limited***
Site address: ***Unit 04 Survey No 884 885 929 930 932 933 935 937-941 And 951, Mekaguda Village, Nandigama Mandal, Rangareddy District, Hyderabad, 509228***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011732*** / ***LOC-100073250***

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 ***2022-05-25***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[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.*

Digitally signed by Şarco Alexandru
Date: 2024.07.18 15:41:55 EEST
Reason: MoldSign Signature
Location: Moldova

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
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**
	1.6.3 Chemical/Physical

Clarifying remarks (for public users)

Remote assesment was carried out subsequently on 4.10.2022 and 13.10.2022. The validity of the GMP certificate is derived from last day of on-site inspection.

2022-12-05

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

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State Institute for Drug Control
Tel:***Confidential***
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