OGYÉI
National Institute of
Pharmacy and Nutrition

H-1051 Budapest, Zrínyi u. 3.
1372 P.O. Box:450.
Tel: +36 1 88 69-300, Fax: +36 1 88 69 460
E-mail: ogyei@ogyei.gov.hu, Web: www.ogyei.gov.hu

Mr. M. Ch. Satyanarayana Raju
Head Quality Management

MSN Laboratories Pvt. Ltd. Formulation Division Unit II
Survey Nos. 1277&1329 to 1324, Nandigama,
Rangareddy - 509228
Telangana, India

Ref: OGYÉI/53685-6/2019
Subject: GMP Certificate
Date: 14 February 2020

Dear Mr. M. Ch. Satyanarayana Raju,

Please find attached the GMP certificate of your facility registered in EudraGMDP database.

MSN Laboratories Pvt. Ltd. Formulation Division Unit II
Survey Nos. 1277&1329 to 1324, Nandigama Village & Mandal
Rangareddy - 509228
Telangana, India

Please consider that major changes related to the GMP system are to be reported on yearly basis.

You are also requested to report the authorisation, manufacturing and distribution of a medicinal product in the EU, and any event, which may affect the GMP compliance.

Yours sincerely,

Dr. Mátyás Szentiványi
General Director

Digitally signed by Moraru Grigore
Date: 2023.10.09 09:20:13 EEST
Reason: MoldSign Signature
Location: Moldova

OGYÉI
National Institute of
Pharmacy and Nutrition

H-1051 Budapest, Zrínyi u. 3.
1372 P.O. Box:450.
Tel: +36 1 88 69-300, Fax: +36 1 88 69 460
E-mail: ogyei@ogyei.gov.hu, Web: www.ogyei.gov.hu

National Institute of Pharmacy and Nutrition

CERTIFICATE NUMBER: ***OGYÉI/53685-6/2019***

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 Hungary confirms the following:
The manufacturer: ***MSN LABORATORIES PRIVATE LIMITED FORMULATIONS DIVISION UNIT II***
Site address: ***SURVEY NOS. 1277 & 1319 TO 1324, NANDIGAMA VILLAGE & MANDAL, RANGA REDDY DISTRICT, TELANGANA, 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 .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-12-19*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [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. 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.

[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[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.*

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**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

The inspection covered the manufacturing of oncological oral solid dosage products in Block C and general oral solid dosage products in Block D.

2020-02-14

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

Mr. Matyas Szentivanyi
National Institute of Pharmacy and Nutrition
Tel: *+36 18869 300*
Fax: