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. Vinay Sapte
Director

Svizera Labs Pvt. Ltd.
Plot D-16/6 TTC Industrial Area, MIDC
Turbhe, Navi Mumbai 400 703, India

Ref: OGYÉI/12446-10/2019
Subject: GMP Certificate

25 February 2020

Dear Mr. Vinay Sapte,

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

Svizera Labs Pvt. Ltd.
Plot D-16/6 TTC Industrial Area, MIDC
Turbhe, Navi Mumbai 400 703, India

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

You are also requested to report the registration and distribution of the certified Active Pharmaceutical Ingredient in the EU and any event, which affects or may affect the GMP compliance.

Yours sincerely,

Dr Ferenc Lukács
Head of Inspectorate

Digitally signed by Chitic Vlad
Date: 2021.12.01 11:33:08 EET
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/12446-10/2019***

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: ***Svizera Labs Pvt. Ltd.***
Site address: ***Plot D-16/6 TTC Industrial Area, MIDC Turbhe, Navi Mumbai, Maharasthra, 400703, India***
DUNS Number: ***72-533-7690***

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 ***2019-12-09*** , 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 1.2.1.8 Other solid dosage forms: Single dose sachet(en) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: Single Dose Sachet(en) 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*

Any restrictions related to the scope of this certificate :

This GMP Certificate is valid up to 31 July 2021.

Clarifying remarks (for public users)

This GMP Certificate is valid up to 31 July 2021.

2020-02-26

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

Dr. Ferenc Lukacs
National Institute of Pharmacy and Nutrition
Tel: ***+36 1 8869300***
Fax: ***+36 1 8869463***