



Tel. direct: +41 22 791 37 43
Fax direct: +41 22 791 47 30
E-mail : prequalinspection@who.int

In reply please
refer to: P5-447-3/IS/AGM/2

Your reference:

Mrs Gauri Sapte
Business Development Director
Svizera Labs Private Limited
Plot D 16/6, TTC Industrial Area
MIDC, Turbhe
Navi Mumbai – 400703
Inde

29 January 2018

Dear Mrs Sapte,

**WHO Prequalification of Medicines Programme
Closing of Inspection**

I refer to the inspection that was performed by Mrs Iveta Streipa, Mrs Tracy Moore and Mr Olivier Gross the details of which are outlined below:

Site name: Svizera Labs Private Limited
Address: Plot D 16/6, TTC Industrial Area MIDC, Turbhe, Navi, Mumbai – 400703, India
Date: 25 - 29 June 2017

Thank you for your email dated 19 December 2017 and the corrective actions to the observations listed in the inspection report. The actions taken or proposed to be taken in relation to the observations have been reviewed by the inspectors. In general, they are considered acceptable and their satisfactory implementation will be verified during future inspections.

On the basis of the findings of the inspection and these subsequent responses, the inspectors have recommended that the site can be considered to be compliant with the standards of GMP published by WHO for the scope activities listed below:

- Manufacture, blending / granulation, compression and packaging of solid unit dosage forms - tablets.
- Analytical and microbiological testing of drug substance and other raw materials associated intermediates and finished product.

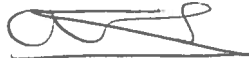
Furthermore the inspection findings and your response allow the Prequalification Inspection Services Group to recommend to the Prequalification Assessment Group that the site inspected may be continue to be named as a manufacturing site in the dossier for the following products:

PQT Number	Product	Strength	Dosage Form	Applicant
TB 189	Rifampicin /Isoniazid	150mg/75mg	Tablets	Svizera Europe (Almere)
TB192	Rifampicin/Isoniazid/ Ethambutol hydrochloride	150mg/75mg/275mg	Tablets	
TB 193	Rifampicin/ Isoniazid Ethambutol hydrochloride/ Pyrazinamide	150 mg/75 mg/275mg /400 mg	Tablets	

In addition, our office wishes to confirm that the Notice of Concern, dated 2 September 2015 published on 3 September 2015 will be removed as per the WHO PQT Inspections Services Group procedure "Notice of Lifting of a Notice of Concern".

Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the close out of this inspection.

Yours sincerely,



Dr Joey Gouws
Group Lead, Inspection Services
Prequalification Team
Regulation of Medicines and other Health Technologies