महाराष्ट्र शासन
आयुक्त
अन्न वा औषध प्रशासन , महा. राज्य
३४१ , वांद्रे - कुर्ला संकुल , रिजर्व बॅक
समोर, वांद्रे (पूर्व)
मुंबई - ४०० ०५१.

FOOD AND DRUG ADMINISTRATION

GOVERNMENT OF MAHARASHTRA
COMMISSIONER
Food and Drugs Administration (M.S.)
341, Bandra-Kurla Complex,
Opposite of RBI Buildings,
BAndra (E), Mumbai - 400 051
Tel : 022 - 26592362-65
E-Mail : comm.fda-mah@nic.in

क्र. NEW-WHO-GMP/CERT/KD/92111/2020/ 1872 /11 दिनांक. 24/07/2020

प्रति.
SVIZERA LABS PRIVATE LIMITED
THANE

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजुरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 92111

महोदय.

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ KD/92111 (एकूण प्रमाणपत्रे १) पाठवीण्यात येत आहेत

आपला

Digitally signed by Chitic Ecaterina
Date: 2021.09.01 18:54:46 EEST
Reason: MoldSign Signature
Location: Moldova

(जे. बी. मंत्री)
सहाय्यक आयुक्त (मुख्यालय) (डेस्क ११)
अन्न व औषध प्रशासन , म. राज्य.

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 21 JUL 2020

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).
Certificate No.: **NEW-WHO-GMP/CERT/KD/92111/2020/11/32612**

On the basis of the inspection carried out on **04.02.2020, 05.02.2020, 30.06.2020** ,we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **SVIZERA LABS PRIVATE LIMITED**
   Address : **PLOT NO. D-16/6, T.T.C. INDUSTRIAL AREA, M.I.D.C., TURBHE, THANE 400703 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD428 In Form 25, KD315 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Oral Powders	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 20 Jul 2023 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-2659236[illegible]
Fax: +91-22-2659195[illegible]
1IVS274921112020072[illegible]
SVIZERA LABS PRIVATE LIMITED - NEW-WHO-GMP/CERT/KD/92111/2020/11/32612

FOOD AND DRUG ADMINISTRATION COMMISSIONER MAHARASHTRA STATE

Name of the authorised person : **J. B. MANTRI**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:21 Jul 2020

Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.

2. The certification number should be traceable within the regulatory authority issuing the certificate.

3. Where the regulatory authority issues a licence for the site , this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.

4. Table 1
   List the dosage forms, starting materials, categories and activities. Examples are given below.

   Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

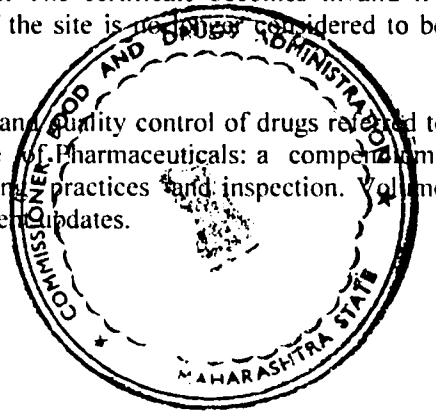
   Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

   Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

6. The requirements for good practices, the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials . Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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MAHARASHTRA STATE, INDIA

Drug License No : KD428 In Form 25,
KD315 In Form 28

Sr.No.	Name of the Product	Composition
1	Ethambutol Tablets BP 100 mg	Each Tablet Contains: Ethambutol Hydrochloride BP 100 mg
2	Rifampicin 75mg/ Isoniazid 50 mg / Pyrazinamide 150 mg Dispersible Tablets	Each uncoated Tablet Contains: Rifampicin BP 75 mg Isoniazid BP 50 mg Pyrazinamide BP 150 mg
3	Rifampicin 75mg/ Isoniazid 50 mg Dispersible Tablets	Each Dispersible Tablet Contains: Rifampicin BP 75 mg Isoniazid BP 50 mg
4	2 FDC LW Sachet	Each sachet contains: Rifampicin USP 300 mg Isoniazid USP 150 mg
5	2 FDC Sachet	Each sachet contains: Rifampicin USP 450 mg Isoniazid USP 225 mg
6	3 FDC LW Sachet	Each sachet contains: Rifampicin USP 300 mg Isoniazid USP 150 mg Ethambutol Hydrochloride USP 550 mg
7	3 FDC Sachet	Each sachet contains: Rifampicin USP 450 mg Isoniazid USP 225 mg Ethambutol Hydrochloride USP 825 mg
8	4 FDC LW Sachet	Each sachet contains Rifampicin USP 300 mg Isoniazid USP 150 mg Ethambutol Hydrochloride USP 550 mg Pyrazinamide USP 800 mg

1 2 3 4 5 6 7 8 9

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Fax: +91-22-26591959

Name of the Authorised person : **J. B. MANTRI**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**21 Jul 2020**

1IVS2749211120200721
SVIZERA LABS PRIVATE LIMITED - NEW-WHO-GMP/CERT/KD/92111/2020/11/32612

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PLOT NO. D-16/6, T.T.C. INDUSTRIAL AREA,
M.I.D.C., TURBHE, THANE 400703
MAHARASHTRA STATE, INDIA

Drug License No KD328 In Form 25,
KD315 In Form 28

Sr.No.	Name of the Product	Composition
9	4 FDC Sachet	Eac Sachet Contains Rifampicin USP 450 mg Isoniazid USP 225 mg Ethambutol Hydrochloride USP 825 mg Pyrazinamide USP 1200 mg
10	ANTI-TB Schedule 1	Each Combipack Contains A. 1 Capsule of Rifampicin Capsules IP 450 mg Each Capsules Contains : Rifampicin IP 450 mg B. 2 Tablets of Isoniazid Tablets IP 300 mg Each uncoated tablet contains : Isoniazid IP 300 mg C. 2 Tablets of Pyrazinamide Tablets IP 750 mg Each uncoated tablet contains: Pyrazinamide IP 750 mg D. 2 Tablets of Ethambutol Tablets IP 600 mg Each uncoated tablet contains: Ethambutol Hydrochloride IP 600 mg
11	ANTI-TB Schedule 2	Each Combipack Contains A. 3 Capsules of Rifampicin Capsules IP 450 mg Each Capsule Contains: Rifampicin IP 450 mg B. 6 Tablets of Isoniazid Tablets IP 300 mg Each Uncoated Tablet Contains: Isoniazid IP 300 mg C. 4 Tablets of Pyridoxine Tablets IP 5 mg Each Uncoated Tablet Contains: Pyridoxine hydrochloride IP 5 mg
12	ANTI-TB Schedule 3	Each Combipack Contains: A. 3 Capsules of Rifampicin Capsules IP 450 mg Each Capsule Contains : Rifampicin IP 450 mg B. 6 Tablets of Isoniazid Tablets IP 300 mg Each uncoated tablet contains : Isoniazid IP 300 mg C. 4 Tablets of Pyridoxine Tablets IP 5 mg Each uncoated tablet contains: Pyridoxine Hydrochloride IP 5 mg D. 6 Tablets of Ethambutol Tablets IP 600 mg Each uncoated tablet contains: Ethambutol Hydrochloride IP 600 mg
13	CLOTRIMAZOLE VAGINAL TABLETS	Each vaginal tablet contains Clotrimazole BP 500 mg
14	DOXYCYCLINE TABLETS 100mg	Each tablet contains Doxycycline Monohydrate Ph. Eur equivalent to Doxycycline Ph.Eur 100 mg
15	Ethambutol 400mg / Isoniazid 150mg Tablets	Each Tablet Contains Ethambutol Hydrochloride BP 400 mg Isoniazid BP 150 mg
16	Ethambutol Tablets BP 400mg	Each Tablet Contains Ethambutol Hydrochloride BP 400 mg

1 2 3 4 5 6 7 8 9

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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Fax: +91-22-26591959
11VS2749211120200721
SVIZERA LABS PRIVATE LIMITED - NEW-WHO-GMP/CERT/KD/92111/2020/11/32612

Name of the Authorised person : J. B. MANTRI

Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai
Maharashtra State, India
Date 21 Jul 2020

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M.I.D.C., TURBHE, THANE 400703
MAHARASHTRA STATE, INDIA

Drug License No : KD428 In Form 25,
KD315 In Form 28

Sr.No.	Name of the Product	Composition
17	Ethambutol Tablets BP 800	Each Tablet Contains Ethambutol Hydrochloride BP 800 mg
18	Ethambutol Tablets IP 600mg	Each Uncoated Tablet Contains Ethambutol Hydrochloride IP 600 mg
19	FEBRINIL MAX (PARACETAMOL 1000 MG + PHENYLPHERINE HYDROCHLORIDE 12.2 MG ORAL POWDER SACHETS)	Each Sachet Contains: Paracetamol Ph.Eur 1000 mg Phenylepherine Hydrochloride Ph.Eur 12.2 mg
20	FEBRINIL MAX PLUS (PARACETAMOL 1000 MG + PHENYLPHERINE HYDROCHLORIDE 12.2 MG + GUAIFENESIN 200 MG ORAL POWDER SACHETS)	Each Sachet Contains: Paracetamol Ph.Eur 1000 mg Phenylepherine Hydrochloride Ph.Eur 12.2 mg Guaifenesin Ph.Eur 200 mg
21	FLUOXETINE CAPSULES 20mg	Each capsule contains Fluoxetine Hydrochloride EP 22.4 mg equivalent to Fluoxetine 20 mg
22	Gynotrim (Clotrimazole Vaginal Tablets 500 mg)	Each Vaginal Tablet Contains: Clotrimazole Ph.Eur 500 mg
23	Gynotrim Pessary (Clotrimazole Vaginal Tablets BP 500 mg)	Each Vaginal Tablet Contains: Clotrimazole BP 500 mg
24	Isoniazid Tablets BP 100mg	Each Tablet Contains Isoniazid BP 100 mg

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MAHARASHTRA STATE, INDIA

Drug License No : KD428 In Form 25,
KD315 In Form 28

Sr.No.	Name of the Product	Composition
25	Isoniazid Tablets BP 300mg	Each Tablet Contains Isoniazid BP 300 mg
26	Isoniazid Tablets IP 100mg	Each Uncoated Tablet Contains: Isoniazid IP 100 mg
27	Isoniazid Tablets IP 300mg	Each Uncoated Tablet Contains Isoniazid IP 300 mg
28	Loperamide Hydrochloride Capsules 2mg	Each capsule contains Loperamide Hydrochloride USP 2 mg
29	LOPERAMIDE HYDROCHLORIDE TABLETS USP 2 mg	Each tablet contains Loperamide Hydrochloride USP 2 mg
30	OXYBUTYNIN TABLETS 2.5mg	Each tablet contains Oxybutynin Hydrochloride Ph.Eur 2.5 mg
31	OXYBUTYNIN TABLETS 5mg	Each tablet contains Oxybutynin Hydrochloride Ph.Eur 5.00 mg
32	PDR 400 (Ethambutol Tablets BP 400 mg)	Each Film coated Tablet Contains Ethambutol Hydrochloride BP 400 mg

1 2 3 4 5 6 7 8 9

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SVIZERA LABS PRIVATE LIMITED - NEW-WHO-GMP/CERT/KD/92111/2020/11/32612

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MAHARASHTRA STATE, INDIA

Drug License No : KD428 In Form 25.
KD315 In Form 28

Sr.No.	Name of the Product	Composition
33	Pyrazinamide Tablets BP 400mg	Each Tablet Contains Pyrazinamide BP 400 mg
34	Pyrazinamide Tablets BP 500mg	Each Tablet Contains Pyrazinamide BP 500 mg
35	Pyrazinamide Tablets IP 750mg	Each Uncoated Tablet Contains Pyrazinamide IP 750 mg
36	PYRIDOXINE TABLETS IP 100 mg	Each uncoated tablet contains: Pyridoxine Hydrochloride IP 100 mg
37	Pyridoxine Tablets IP 5mg	Each Uncoated Tablet Contains: Pyridoxine Hydrochloride IP 5 mg
38	Rifampicin 150mg / Isoniazid 100mg Tablets	Each Tablet Contains Rifampicin BP 150 mg Isoniazid BP 100 mg
39	Rifampicin 150mg / Isoniazid 150mg Tablets	Each film coated tablet contains: Rifampicin BP 150 mg Isoniazid BP 150 mg
40	Rifampicin 150mg / Isoniazid 75mg / Ethambutol HCL 275mg Tablets	Each film coated tablet contains: Rifampicin BP 150 mg Isoniazid BP 75 mg Ethambutol HCL BP 275 mg

1 2 3 4 5 6 7 8 9

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

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MAHARASHTRA STATE, INDIA

Drug License No : KD428 In Form 25,
KD315 In Form 28

Sr.No.	Name of the Product	Composition
41	Rifampicin 150mg / Isoniazid 75mg / Pyrazinamide 400mg / Ethambutol HCL 275mg Tablets USP	Each film coated tablet contains Rifampicin USP 150 mg Isoniazid USP 75 mg Pyrazinamide USP 400 mg Ethambutol HCL USP 275 mg
42	Rifampicin 150mg / Isoniazid 75mg / Pyrazinamide 400mg Tablets	Each film coated tablet contains: Rifampicin BP 150 mg Isoniazid BP 75 mg Pyrazinamide BP 400 mg
43	Rifampicin 150mg / Isoniazid 75mg Tablets	Each film coated tablet contains: Rifampicin BP 150 mg Isoniazid BP 75 mg
44	Rifampicin 300 mg / Isoniazid 150 mg Tablets	Each Tablet Contains Rifampicin BP 300 mg Isoniazid BP 150 mg
45	Rifampicin 60mg / Isoniazid 30mg / Pyrazinamide 150mg Tablets	Each film coated tablet contains: Rifampicin BP 60 mg Isoniazid BP 30 mg Pyrazinamide BP 150 mg
46	Rifampicin 60mg / Isoniazid 30mg Tablets	Each film coated tablet contains: Rifampicin BP 60 mg Isoniazid BP 30 mg
47	Rifampicin 60mg / Isoniazid 60mg Tablets	Each film coated tablet contains: Rifampicin BP 60 mg Isoniazid BP 60 mg
48	Rifampicin Capsules BP 150mg	Each capsule contains Rifampicin BP 150 mg

1 2 3 4 5 6 7 8 9

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Drug License No : KD428 In Form 25,
KD315 In Form 28

Sr.No.	Name of the Product	Composition
49	Rifampicin Capsules BP 300mg	Each capsule contains: Rifampicin BP 300 mg
50	Rifampicin Capsules BP 450mg	Each capsule contains Rifampicin BP 450 mg
51	Rifampicin Capsules IP 150mg	Each capsule contains: Rifampicin IP 150 mg
52	Rifampicin Capsules IP 300mg	Each capsule contains: Rifampicin IP 300 mg
53	Rifampicin Capsules IP 450mg	Each Capsule Contains Rifampicin IP 450 mg
54	Rifampicin Tablets 150mg	Each Tablet Contains Rifampicin BP 150 mg
55	Rifampicin Tablets 300mg	Each Tablet Contains Rifampicin BP 300 mg
56	SCC-2 LLW Tablets (Rifampicin 150mg / Isoniazid 75mg Tablets)	Each Film coated Tablet Contains: Rifampicin BP 150 mg Isoniazid BP 75 mg

1 2 3 4 5 6 7 8 9

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Drug License No : KD428 In Form 25.
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Sr.No.	Name of the Product	Composition
57	SCC-3 LLW Tablets (Rifampicin 150mg / Isoniazid 75mg / Ethambutol Hydrochloride 275mg Tablets)	Each Film coated Tablet Contains Rifampicin BP 150 mg Isoniazid BP 75 mg Ethambutol Hydrochloride BP 275 mg
58	SCC-4 Tablets (Rifampicin 150mg / Isoniazid 75mg / Pyrazinamide 400mg / Ethambutol Hydrochloride 275mg Tablets USP)	Each Film Coated Tablet Conatins: Rifampicin USP 150 mg Isoniazid USP 75 mg Pyrazinamide USP 400 mg Ethambutol Hydrochloride USP 275 mg
59	SOTALOL HYDROCHLORIDE TABLETS 40mg	Each immediate release tablets contains Sotalol Hydrochloride EP 40 mg
60	TB-KIT (Rifampicin 150mg / Isoniazid 75mg Tablets)	Each film coated tablet contains: Rifampicin BP 150 mg Isoniazid BP 75 mg
61	TB-KIT 3 (Rifampicin 150mg / Isoniazid 75mg / Ethambutol Hydrocloride 275mg Tablets)	Each film coated tablet contains: Rifampicin BP 150 mg Isoniazid BP 75 mg Ethambutol Hydrochloride BP 275 mg
62	TB-KIT 4 (Rifampicin 150mg / Isoniazid 75mg / Pyrazinamide 400mg / Ethambutol HCl 275mg Tablets USP)	Each film coated tablet contains: Rifampicin USP 150 mg Isoniazid USP 75 mg Pyrazinamide USP 400 mg Ethambutol Hydrochloride USP 275 mg
63	TB-KIT Z (Rifampicin 150mg / Isoniazid 75mg / Pyrazinamide 400mg Tablets)	Each film coated tablet contains: Rifampicin BP 150 mg Isoniazid BP 75 mg Pyrazinamide BP 400 mg
64	TRAMADOL HYDROCHLORIDE CAPSULES 50mg	Each capsule contains Tramadol Hydrochloride BP 50 mg

1 2 3 4 5 6 7 8 9

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KD315 In Form 28

Sr.No.	Name of the Product	Composition
65	TUBACURE - FD TABLETS (Rifampicin 150mg / Isoniazid 75mg / Pyrazinamide 400mg / Ethambutol Hydrochloride 275mg Tablets USP)	Each coated tablet contains: Rifampicin USP 150 mg Isoniazid USP 75 mg Pyrazinamide USP 400 mg Ethambutol Hydrochloride USP 275 mg
66	TUBACURE-FD SACHET	Each Sachet Contains Rifampicin USP 450 mg Isoniazid USP 225 mg Ethambutol Hydrochloride USP 825 mg Pyrazinamide USP 1200 mg
67	ZUTOL (Ethambutol 400 mg and Isoniazid 150 mg Tablets)	Each Film coated Tablet Contains: Ethambutol Hydrochloride BP 400 mg Isoniazid BP 150 mg

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COMMISSIONER, FOOD AND DRUG ADMINISTRATION MAHARASHTRA STATE

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
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Name of the Authorised person : **J. B. MANTRI**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**21 Jul 2020**

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SVIZERA LABS PRIVATE LIMITED - NEW-WHO-GMP/CERT/KD/92111/2020/11/32612