

FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051
CERTIFICATE OF A PHARMACEUTICAL PRODUCT !

This certificate conforms to the format recommended by the World Health Organisation
 (General instructions and explanatory notes attached)

No. of certificate : **COPP/CERT/MD/84370/2019/11/28124/144261** Valid Upto : **27 Jun 2021**
 Exporting Country : **INDIA**
 Importing Country : **As per Annexure**
 1. Name and dosage form of product : **Pyridoxine Tablets BP 25 mg**

1.1 Active ingredient(s)² and amount (s) per unit dose³: Each uncoated Tablet Contains:

Pyridoxine Hydrochloride BP 25 mg

For complete qualitative composition including excipients :⁴ As per Annexure

1.2 Is this product licensed to be placed on the market for use in the exporting country ?⁵ Yes No

1.3 Is this product actually on the market in the exporting country ? Yes No Unknown

<p>2A.1 Number of product license:⁷ 4112A In Form 28A and date of issue: 16 Aug 2012</p> <p>2A.2 Product License holder (Name and address) : SVIZERA LABS PVT LTD PLOT NO 56/9 , GOVANDI MUMBAI 400043 Mfg At: MANEESH PHARMACEUTICALS LTD. PLOT NO. 40, ANCILLARY IND. PLOTS, GOVANDI, MUMBAI 400043 MAHARASHTRA STATE, INDIA</p> <p>2A.3 Status of product-license Holder :⁸ A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/></p> <p>2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is:⁹</p> <p>2A.4 Is summary basis of Approval appended ?¹⁰ Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>2A.5 Is the attached, officially approved product information complete and consonant with the license ?¹¹ Yes <input type="checkbox"/> No <input type="checkbox"/> Not Provided <input checked="" type="checkbox"/></p> <p>2A.6 Applicant for certificate if different from License holder ¹² Not Applicable</p>	<p>2B.1 Applicant for certificate (name and address) :</p> <p>2B.2 Status of applicant : A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/></p> <p>2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form is⁹</p> <p>2B.3. Why is marketing authorization lacking ? <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>Not required Not requested Under Consideration Refused</p> <p>2B.4 Remarks :¹³</p>
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3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage forms produced ?

if no or not applicable proceed to question 4. Yes No Not Applicable¹⁴

3.1 Periodicity of routine inspections(years) : **Once a year**

3.2 Has the manufacture of this type of dosage form been inspected ? Yes No

3.3 Do the facilities and operations conform to GMP as recommended by World Health Organisation ?¹⁵

Yes No Not Applicable ¹⁴

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?¹⁶

Yes No

If no. explain :

Address of certifying authority :
 Food & Drug Administration, M.S.
 Bandra-kurla Complex,
 Bandra (E), Mumbai – 400 051.
 Maharashtra,INDIA.
 Tel: +91-22-26592363/64/65
 Fax: +91-22-26591959
 51V54428437020190521059

Name of the Authorised person : **A. T. NIKHADE**

Signature : 
 Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
 Date: **21 May 2019**

Food & Drugs Administration, Maharashtra State, Mumbai 400051, India
Annexure to the Certificate of a Pharmaceutical Product

No. of Certificate : COPP/CERT/MD/84370/2019/11/28124/144261
 Name of the Product License Holder : MUMBAI 400043
 MANEESH PHARMACEUTICALS LTD. PLOT NO. 40,
 ANCILLARY IND. PLOTS, GOVANDI, MUMBAI 400043
 OWN License Holder : MAHARASHTRA STATE, INDIA
 Name of the Product :
 : Pyridoxine Tablets BP 25 mg

Valid up to: 27 Jun 2021

List of Countries For Export

Afghanistan	Bosnia and Herzegovina	Czechoslovakia	Grenada	Kosovo	Micronesia	Philippines	South Sudan	Turkey
Albania	Botswana	Denmark	Guatemala	Kurdistan	Moldova	Poland	Spain	Turkmenistan
Algeria	Brazil	Djibouti	Guinea	Kuwait	Monaco	Porte Rico	Sri Lanka	Turks and Calicos
Andorra	British Virgin	Dominica	Guinea-Bissau	Kyrgyzstan	Mongolia	Portugal	St. Kittics	Tuvalu
Anglia	Brunei	Dominican Republic	Guyana	LaO PDR	Monstserrat	Qatar	st. Kitties and Nevi	Uganda
Angola	Brunei Darussalam	DR Congo	Haiti	Laos	Montenegro	R.D. Congo	St. Lucia	Ukraine
Anguilla	Bulgaria	East Timor	Herzegovina	Latvia	Morocco	Rep. of Congo	St. Maarten	UNHCR
Antigua	Burkina Faso	Ecuador	Holland	Lebanon	Mozambique	Reunion	St. Vincent	UNICEF
Antigua and Barbuda	Burundi	Egypt	Holy See	Leone	Myanmar	RITES	St. Vincent and the Grenadines	United Arab Emirates
Argentina	Cabo Verde	El Salvador	Honduras	Lesotho	Namibia	Romania	Sudan	United Kingdom
Armenia	Cambodia	England	Hong-Kong	Liberia	Nauru	Russia	Sultanate of Oman	United State
Aruba	Cameroon	Equatorial Guinea	Hungary	Libya	Nepal	Rwanda	Suriname	UNOPS
Australia	Canada	Eritrea	Iceland	Liechtenstein	Netherlands	Samao	Swaziland	Uruguay
Austria	Cape Verde	Estonia	India	Lithuania	New Zealand	San Marino	Sweden	Uzbekistan
Azerbaijan	Cayman Island	Ethiopia	Indonesia	Luxembourg	Nicaragua	Sao Tome and Principe	switzerland	Vanuata
Bahamas	Central African Republic	Fiji	Iran	Macau	Niger	Saudi Arabia	Syria	Vatican City
Bahrain	Chad	Fiji Island	Iraq	Macedonia	Nigeria	Senegal	Taiwan	Venezuela
Bangladesh	Chile	Finland	Ireland	Madagascar	North Korea	Serbia	Tajikistan	Victiane
Barbados	China	France	Israel	Malawi	Norway	Seychelles	Tanzania	Vietnam
Belarus	Colombia	French Guiana	Italy	Malaysia	Oman	Sierra Leone	Tchad	Western Samoa
Belgium	Comoros	Gabon	Ivory Coast	Maldives	PAHO	Singapore	Thailand	WIIO
Belize	Congo	Gambia	Jamaica	Mali	Pakistan	Slovakia	The Netherlands	Yemen
Belorussia	Costa Rica	Georgia	Japan	Malta	Palau	Slovenia	Timor Leste	Yugoslavia
Benin	Croatia	Germany	Jordan	Marshal Island	Palestine	Solomom Island	Togo	Zaire
Bermuda	Cuba	Ghana	Kazakhstan	Mauritania	Panama	Somalia	Tongo	Zambia
Bhutan	Curacao	Global Fund	Kenya	Mauritius	Papua New Guinea	South Africa	Trinidad & Tobago	Zanzibar
Bolivia	Cyprus	Grand Cayman	Kiribati	MCGM	Paraguay	South Korea	Tunisia	Zimbabwe
Bosnia	Czechia	Guatemala	Nicaragua	Mexico	Peru			

Address of certifying authority : Maharashtra State, Mumbai 400051, India
 Name of the Authorised person : A. T. NIKHADE

Food & Drug Administration, M.S.
 Bandra-kurla Complex,
 Bandra (E), Mumbai - 400051,
 Maharashtra, INDIA.
 Tel: +91-22-26592369
 Fax: +91-22-26591939
 51V54428437020190521052

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
 Food & Drug Administration, M.S.
 Bandra (E), Mumbai.
 Maharashtra State, India
 Date: 21 May 2019



FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT ¹

Annexure of Excipients

No. of certificate : COPP/CERT/MD/84370/2019/11/28124/144261 VALID UP TO :27 Jun 2021
Name of the : SVIZERA LABS PVT LTD PLOT NO 56/9 , GOVANDI MUMBAI 400043
Company : Mfg At: MANEESH PHARMACEUTICALS LTD. PLOT NO. 40, ANCILLARY
IND. PLOTS, GOVANDI, MUMBAI 400043 MAHARASHTRA STATE, INDIA
Name and dosage : Pyridoxine Tablets BP 25 mg
form of product

Sr.No. Ingredients

- 1 Lactose
- 2 Maize Starch
- 3 Methyl Paraben
- 4 Polyvinyl Pyrrolodone
- 5 Maize Starch
- 6 Propyl Paraben
- 7 Magnesium Stearate
- 8 Sodium Starch Glycolate
- 9 Talcum (Purified)

Specification Qty/Units

- | | |
|-----------|-----------|
| IP/BP/USP | 71.0 mg |
| IP/BP/USP | 15.005 mg |
| IP | 0.100 mg |
| IP/BP/USP | 4.00 mg |
| IP/BP/USP | 10.0 mg |
| IP/BP | 0.02 mg |
| IP/BP/USP | 1.50 mg |
| IP/BP | 10.0 mg |
| IP/BP/USP | 1.50 mg |



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Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai.

Maharashtra State, India

Date:21 May 2019