

CERTIFICATE OF A PHARMACEUTICAL PRODUCT ¹

SERIAL NO. 1342

This certificate conforms to the format recommended by the **WORLD HEALTH ORGANISATION**
(General instructions and explanatory notes attached)Valid Up to: **11/06/2021**

No. of Certificate: Mfg/WHO COPP/Swiss Parenterals/2019/

Exporting (Certifying) country: **INDIA**Importing (requesting) country: **MOLDOVA**1. Name and dosage form of products: **MIDAZOLAM INJECTION BP 1 MG/ML, 5 ml**

- 5 FEB 2019

1.1 Active ingredient (s) ² and amount (s) per unit dose ³:

Each ml Contains:

Midazolam BP (As Hydrochloride) 1 mg

Benzyl Alcohol BP 1% v/v

Water for Injection BP q.s.

Complete qualitative composition including excipients, see attached: Yes

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 ☐If the answer to 1.2 is yes, continue with section 2 A and If the answer to 1.2 is no. Continue section 2 B ⁶

2A.1 Number of product license ⁷ : G/28/1078 In Form No. 28 And date of issue: 04/03/2017	2B. 1 Applicant for certificate (name and address) N.A.
2A.2 Product license holder : (Name and address) M/s. SWISS PARENTERALS LTD 808,809 & 810, Kerala Industrial Estate ,GIDC, Nr. Bavla, City : Ahmedabad - 382 220, Dist. Ahmedabad, Gujarat State, India.	2B. 2 Status of applicant: N.A. a <input type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/> 2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are
2A.3 Status of product - license Holder ⁸ : Manufacturer Dosage Form a <input checked="" type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/>	2B.3 Why is marketing authorization lacking? N.A. Not <input type="checkbox"/> Not <input type="checkbox"/> Under <input type="checkbox"/> Refused <input type="checkbox"/> Required Requested Consideration
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are ⁹ : N.A.	2B. 4 Remarks : ¹³ N.A.
2A. 4 Is summary basis of Approval appended? ¹⁰ Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
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"/>	
2A. 6 Applicant for certificate if different from license holder ¹² : Not Applicable	

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?

Yes ☒ No ☐ Not applicable ¹⁴ ☐

If no or not applicable proceed to question 4

3.1 Periodically of routine inspections (Years) : Once in 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 the World Health Organisation? ¹⁵Yes ☒ No ☐ Not applicable ☐4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? ¹⁶Yes ☐ No ☐ Not applicable ☒

If no, explain:

Address of certifying authority:

The Commissioner Food & Drug Control Administration1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan,

Gandhinagar, Gujarat State, INDIA

Tel: 91-79-232 53417 Fax: 91-79-232 53400

Name of the Authorized Person: **SHRI. D.M. PATEL**

Signature:

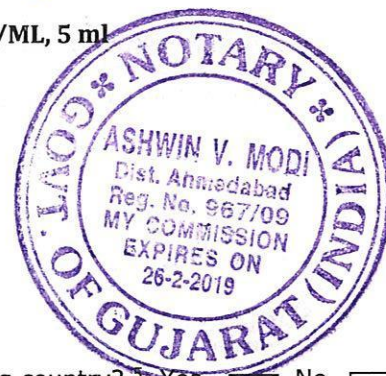
Stamp and date:

ASHVIN V. MODI
NOTARY
GOVT. OF GUJARAT

5 FEB 2019

Deputy Commissioner
Food & Drugs Controls Administration
Gujarat State

21 JAN 2019



ATTESTED

Authorized Signatory
Millennial India International
Chamber of Commerce

GAURAV RAVISH
Addl. Director

Explanatory notes

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SERIAL NO. 1346/2019

Ashwin V. Modi

ASHWIN V. MODI
NOTARY
GOVT. OF INDIA

SWISS PARENTERALS LTD.

QUALITATIVE AND QUANTITATIVE FORMULA

- 5 FEB 2019

NAME OF PRODUCT: MIDAZOLAM INJECTION BP 1 mg/ml, 5 ml

UNIT FORMULA:

Each ml contains:

ACTIVE:

Midazolam BP 1 mg

IN-ACTIVE:

Di Sodium Edetate BP 0.1 mg

Benzyl Alcohol BP 0.01 ml

Sodium Chloride BP 8.0 mg

Conc. Hydrochloride Acid BP q. s to pH

Water for Injections BP q. s to 1 ml

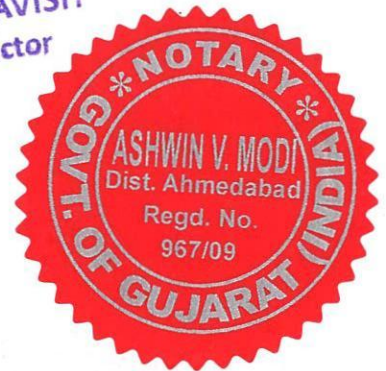
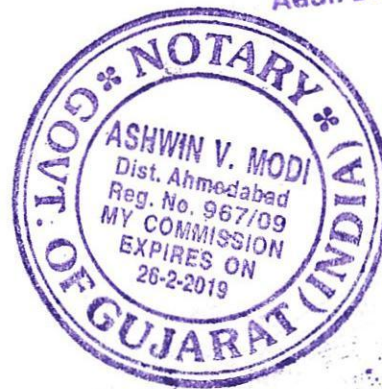


ATTESTED

Authorized Signatory
Millennial India International
Chamber of Commerce
Industry & Agriculture
New Delhi, (INDIA)



GAURAV RAVISH
Addl. Director



ATTESTED

Ashwin V. Modi

ASHVIN V. MODI
NOTARY
GOVT. OF GUJARAT

- 5 FEB 2019

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APOSTILLE

भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
INDIA

This public document of the type
COMMERCIAL DOCUMENT

is issued to SWISS PARENTERALS LTD.

has been signed by GAURAV RAVISH

with the seal / stamp of ADDL. DIRECTOR, MILLENNIAL INDIA
INTL. CHAMBER OF COMMERCE INDS & AGRICULTURE, ND

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 08-Feb-2019 at NEW DELHI, INDIA

with reference no. DLND0003092119

Signature
(Bhavana Sharma)
(Bhavana Sharma)
अनुभाग अधिकारी (ओ आई)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

The Ministry of External Affairs
accepts no responsibility for the
contents of the above documents.

International Chamber of Commerce Industry & Agriculture
08 FEB 2019

GOVT. OF INDIA, NEW DELHI
no 568