SERIAL NO CERTIFICATE OF A PHARMACEUTICAL PRODUCT 1 SERIAL NO Certificate conforms to the format recommended by the WORLD HEALTH ORGANISA (General instructions and explanatory notes attached)	TTON
(Conord instructions and ovnianatory notes attached)	ALLON
No. of Certificate: Mfg/WHO COPP/Swiss Parenterals/2019/ ASH Export Ind Certification Jountry: INDIA Valid Up to:	11/06/2021
Importing (requesting) country: MOLDOVA 1. Name and dosage form of products: MIDAZOLAM INJECTION BP 1 MG/ML, 5 ml	
- 5FEB 2019 1.1 Active ingredient (s) ² and amount (s) per unit dose ³ :	2
Each ml Contains:	ODI/EI
Midazolam BP (As Hydrochloride) 1 mg	ad a
Benzyl Alcohol BP 1% v/v	N /5/
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 🖂
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 A.1 Number of product license ⁷ : G/28/1078 2B. 1 Applicant for certificate (name a	
In Form No. 28 And date of issue: 04/03/2017	
2A.2 Product license holder: (Name and address) 2B. 2 Status of applicant: N.A. a b c c	
808,809 & 810, Kerala Industrial Estate ,GIDC, Nr. Bavla, City: Ahmedabad – 382 220, Dist. Ahmedabad, Gujarat State, India. 2B.2.1 For categories b and c the name address of the manufacturer producing form are	
2A.3 Status of product – license 2B.3 Why is marketing authorization la	
Holder ⁸ : Manufacturer Dosage Form a b c Not Not Under Required Requested Consideration	Refused
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are 9: N.A.	*NOT
2A. 4 Is summary basis of Approval appended? 10 Yes No	S ASHWIN W
2A.5 Is the attached officially approved product information complete and consonant with the license ?¹¹ Yes No Not Provided	Dist. Ahmed Regd. No 967/09
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 second control of the second	GUJAR
form is produced?	ne dosage
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	The section of the se
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organisal	ion? is
Yes No Not applicable ATTESTED	
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of manufacture of the product? 16 Yes No Not applicable that the product of Commerce Millennial India Internation (Chamber of Commerce) If no, explain:	national
Address of certifying authority: (2) 0.0 rcmamenof the Authorized Persons ShriyD:M:PAT	ture
The Commissioner Food & Drug Control Administration 1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan, Signature: GAURAV R	AVISH
1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State, INDIA Tel: 91-79-232 53417 Fax: 91-79-232 53400 Stamp and date:	ector
Deputy Commission	er
ASHVIN V. MODI Food & Drugs Controls Admini	
GOVT. OF GUJARAT FEB 2019 Gujarat State	

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Please refer to the guidelines for full instruction on how to complete this form and information on the implementation of the scheme. The forms are available for generation by computer. They should always be submitted as hard copy, with responses presented in type rather than hand written. Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

- 1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage form and different strength can vary.
- 2. Use, whenever possible, International Nonproprietary Names (INNS) or national nonproprietary names.
- The formula (complete composition) of the dosage form should be given on the certificate or be appended.
- 4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product-license holder.
- 5. When applicable, append details of any restriction applied to the sale, distribution, or administration of the product that is specified in the product license.
- 6. Section 2A and 2B are mutually exclusive.
- 7. Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
- 8. Specify whether the person responsible for placing the product on the market:
 - Manufactures the dosage form.
 - Packages and / or labels a dosage form manufactured by an independent company : or
 - Is involved in none of the above.
- 9. This information can be provided only with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed the in the License must be updated or it will cease to be valid.
- 10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
- 11. This refers to product information approved by the competent national regulator, authority, such as a Summary of Product Characteristics (SPC).
- 12. In this circumstance, permission for issuing the certificate is required from the product license holder. This permission must be provided to the author भारत सरकार GOVERNMENT OF INDIA
- 13. Please indicate the rea
 - The product ha a) in the count-to,

अपोस्टिल / APOSTILLE (Convention de La Haye du 5 octobre 1961)

arly tropical diseases - not endemic

This public document of the type

The product ha b)

COMMERCIAL DOCUMENT

is issued to

pical conditions.

c) The product ha country of imp

SWISS PARENTERALS LTD.

harmaceutical products in the

d) The product ha GAURAV RAVISH

in active ingredient.

e) Any other rea has been signed by

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

14. Not applicable means inspection is conducte

Certified by

15. The requirements for

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

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6. The Section is to

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above. It is of particular importance when foreign contractors are involved in the manufacture circumstances the applicant should supply the certifying authority with information to identify the consideration of manufacture of the finished dosage forms and the extent and hadron or an early of these parties. The property this Model Configurate is available on Disketts in Word Perfect. each of these parties. he layout for this Model Certificate is available on Diskette in Word Perfect World Health Organization, 1211 Geneva 27, Switzerland. Management and Policie

NOTARIAL.

NOTARIAL



SERIAL NO....

5 FEB 2019

SWISS PARENTERALS LTD.

QUALITATIVE AND QUANTITATIVE FORMULA

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

q. s to 1 ml

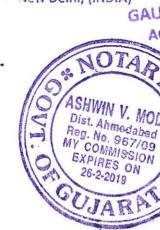


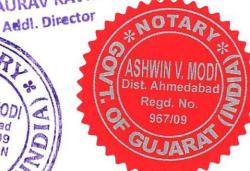
Authorized Signatory Millennial India Internationa

Chamber of Commerce Industry & Agriculture

New Delhi, (INDIA)









NOTARY GOVT. OF GUJARAY

- 5 FEB 2019



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

This public document of the type COMMERCIAL DOCUMENT

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



(Bhavana Sharma) अनुभाग अधिकारी (ओ आई) अनुमाग अतकार (आ आई) Section Officer (OI) सी. ची. कागग / C.P.V. Division विदेश मंत्रालय, नई दिल्ली Ministry of External Affairs, New Delhi