

CERTIFICATE OF A PHARMACEUTICAL PRODUCT¹

This certificate conforms to the format recommended by the **WORLD HEALTH ORGANISATION**
(General instructions and explanatory notes attached)

No. of Certificate: **MFG/WHO-COPP/SPARSH/2018**Valid Up to: **04.06.2021**Exporting (Certifying) Country: **INDIA**Importing (Requesting) Country: **PORTUGAL**

1. Name and dosage form of products: Ampicillin Oral Suspension BP 125 mg / 5 ml
AMPICILLIN VELVET MED 125MG

1.1 Active ingredient (s)² and amount (s) per unit dose³:

After reconstitution each 5 ml contains:

Ampicillin Trihydrate BP

Equivalent to Ampicillin.....125 mg

Excipients.....q.s.

Colour: Erythrosine FCF

Complete qualitative composition including excipients, see attached.⁴ **N.A.**

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 2A and If the answer to 1.2 is no, continue section 2B⁶

2A.1 Number of product license ⁷ : G/1174 And date of issue : 27.11.2017	2B.1 Applicant for certificate (name and address): N.A.
2A.2 Product license holder : (Name and address) SPARSH BIO-TECH PVT. LTD. Plot No. 1, Survey No. 242/243/244, Lakhavav, Jamnagar - 361006, Gujarat, India	2B.2 Status of applicant ⁸ : N.A. a <input type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/>
2A.3 Status of product - license Holder ⁹ : a <input checked="" type="checkbox"/> b <input type="checkbox"/> c <input type="checkbox"/> Manufactures the Dosage Forms	2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are ⁹ : N.A.
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are ⁹ : N.A.	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.4 Is summary basis of Approval appended? ¹⁰ Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2B.4 Remarks ¹³ : N.A.
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? ¹⁴
Yes ☒ No ☐ Not applicable ☐

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? ¹⁵

Yes ☒ No ☐ Not applicable ☐

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

Yes ☐ No ☐ **Not applicable** ☒

If no, explain:

Address of certifying authority:

The Commissioner Food & Drugs Control Administration**1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan,**
Gandhinagar, Gujarat State, INDIA

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

Date of Approval:

Name of the Authorized Person: **Mr. R. L. Vaishya**

Signature:

Stamp and date:

Joint Commissioner
Food & Drugs Controls Administration
Gujarat State

30 AUG 2018

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AMPICILLIN VELVET MED 250MG1.1 Active ingredient (s)² and amount (s) per unit dose³:**After reconstitution each 5 ml contains:**

Ampicillin Trihydrate BP

Equivalent to Ampicillin.....250 mg

Excipients.....q.s.

Colour: Erythrosine FCF

Complete qualitative composition including excipients, see attached.⁴ **N.A.**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 2A and if the answer to 1.2 is no, continue section 2B⁶

2A.1 Number of product license ⁷ : G/1174 And date of issue : 27.11.2017	2B.1 Applicant for certificate (name and address): N.A.
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2A.4 Is summary basis of Approval appended? ¹⁰ Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2B.4 Remarks ¹³ : N.A.
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?¹⁴
Yes ☒ No ☐ Not applicable ☐

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 & Drugs Control Administration1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, INDIA

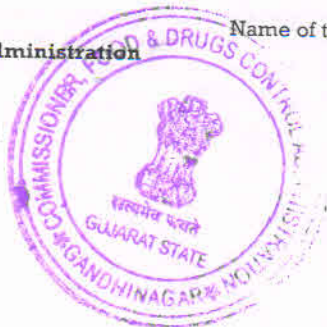
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AMPICILLIN VELVET MED 500MG1.1 Active ingredient (s)² and amount (s) per unit dose³:**Each hard gelatin capsule contains:****Ampicillin Trihydrate BP****Equivalent to Ampicillin.....500 mg****Excipients.....q.s.****Approved colours used in capsule shells.**Complete qualitative composition including excipients, see attached.⁴ **N.A.**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 2A and If the answer to 1.2 is no, continue section 2B⁶

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