FOOD & DRUG ADMINISTRATION, GUJARAT STATE, GANDHINAGAR
CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

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

No. of certificate : **CERT/BKRS**
Exporting (Certifying) country : **INDIA**
Importing (requesting) country : **OTHER THAN INDIA**
Name and dosage form of product :CLARI-BKRS (**CLARITHROMYCIN FOR INJECTION BP 500MG**)
1.1. Active ingredient (s) [2]and amount (s) [3]:
Composition: Each vial contains:
Clarithromycin BP.... 500mg

For complete qualitative composition including excipients[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 omit section 2B
If the answer to 1.2 is no, omit section 2A and continue section 2B[6]

2A

A.1 Number of product licence[7] and date of issue G/28A/5696-A Dated. 01/Jan/2019
A.2 Product license holder :
M/s BKRS PHARMA PVT LTD.
at 46/4-7, Dehgam, Road, Zak Village,
Tal. - Dehgam, Dist. Gandhinagar.
A.3. Status of product-license

Holder[8] a [√] b [ ] c [ ]

A.3. 1 For categories b & c the name and address of manufacturer producing the dosage Form are[9] : **Not applicable**
A.4 Is summary basis of Approval appended ?[10]

Yes [ ] No [√]

A.5 Is the attached, officially approved product Information complete and consonant with the license ? [11]

Yes [ ] No [ ] Not provided [√]

A.6 Applicant for certificate if different from license holder : [12] : **Not applicable**

2B

B.1 Applicant for certificate (name and address)

B.2 Status of applicant: a [ ] b [ ] c [ ]

B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are [9]

B.3 Why is marketing authorization lacking?

Not Required [ ] Not Requested [ ] Under Consideration [ ] Refused [ ]

B. 4 Remark: [13]

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 Periodicity 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 [ ] N.A [√]

If no, explain :

VALID UP TO: TWO YEARS FROM THE DATE OF ISSUE

Address of certifying authority:
The Commissioner of
Food & Drugs Control Administration,
Gujarat State, Jivraj Mehta Bhavan,
Block No. 8, 1st Floor, Old Sachivalaya,
GANDHINAGAR, GUJARAT, INDIA.

Name of the authorized person : **SHRI. R.L.VAISHYA**

Signature :

Joint Commissioner
Food & Drugs Control Administration
Gujarat State.

23 JUN 2020

Digitally signed by Chirtoacă Iurie
Date: 2022.01.05 14:24:49 EET
Reason: MoldSign Signature
Location: Moldova