



FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051  
CERTIFICATE OF A PHARMACEUTICAL PRODUCT<sup>1</sup>

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

Valid Upto :24 Jul 2021

No. of certificate : COPP/CERT/KD/76162/2018/11/24879/128809  
Exporting Country : INDIA  
Importing Country : CHILE  
1. Name and dosage form of product : Bromycin Eye Ointment  
(Gentamicin Sulfate Ophthalmic Ointment USP 0.3%)

1.1 Active ingredient(s)<sup>2</sup> and amount (s) per unit dose<sup>3</sup>: Each gram contains :

Gentamicin Sulfate USP equivalent to Gentamicin 3 mg

Sterile Ointment base qs

For complete qualitative composition including excipients<sup>4</sup> As per Annexure

1.2 Is this product licensed to be placed on the market for use in the exporting country?<sup>5</sup> Yes ☒ No ☐

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

2A.1 Number of product license:<sup>7</sup> KD180 In Form 28  
and date of issue: 28 May 2003

2A.2 Product License holder (Name and address):

GALENTIC PHARMA (INDIA) PRIVATE LIMITED PLOT NO R 673  
TTC MIDC RABALE THANE BELAPUR ROAD NAVI MUMBAI  
THANE 400701 MAHARASHTRA STATE, INDIA

2A.3 Status of product-license Holder<sup>8</sup>

A ☒ B ☐ C ☐

2A.4 For categories b and c the name and address of the manufacturer  
producing the dosage form is:<sup>9</sup>

2A.4 Is summary basis of Approval appended<sup>10</sup>

Yes ☐ No ☒

2A.5 Is the attached, officially approved product information complete and  
consonant with the license?<sup>11</sup>

Yes ☐ No ☐ Not Provided ☒

2A.6 Applicant for certificate if different from License holder<sup>12</sup>  
Not Applicable

2B.1 Applicant for certificate (name and address):

2B.2 Status of applicant:  
A ☐ B ☐ C ☐

2B.2.1 For categories b and c the name and address of the manufacturer  
producing the dosage form is:<sup>9</sup>

2B.3. Why is marketing authorization lacking?

☐ ☐ ☐ ☐

Not required Not requested Under Consideration Refused

2B.4 Remarks:<sup>13</sup>

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?  
If no or not applicable proceed to question 4. Yes ☒ No ☐ Not Applicable<sup>14</sup> ☐

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?<sup>15</sup>  
Yes ☒ No ☐ Not Applicable<sup>14</sup> ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?<sup>16</sup>  
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  
COPP/76162/2018/0910059

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: 10 Sep 2018

10 SEP 2018  
ATTESTED

AUTHORISED SIGNATORY  
IMC CHAMBER OF COMMERCE AND INDUSTRY  
MUMBAI, INDIA

BIJU GEORGE  
Senior Manager





## GENERAL INSTRUCTION :

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 suitable for generation by computer. They should always be submitted as hard copy, with responses printed 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 forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNS) or national nonproprietary names.
3. 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-Licence 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 Licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the Licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market :
  - (a) manufactures the dosages form
  - (b) packages and / or labels a dosage form manufactured by an independent company : or
  - (c) is involved in none of the above .

9. This information can be provided only with the consent of the product - Licence 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 Licence. If the production site is changed the Licence must be updated or it will cease to be valid.

10. This form is the document prepared by some national regulatory authorities, that summarizes the on which
11. becomes national regulatory authority, such as a summary
12. of the above documents, required from the product Licence holder. This

13. **This public document of the type**  
COMMERCIAL DOCUMENT

is issued to **GALENTIC PHARMA (INDIA) PRIVATE LIMITED**

has been signed by **BIJU GEORGE**

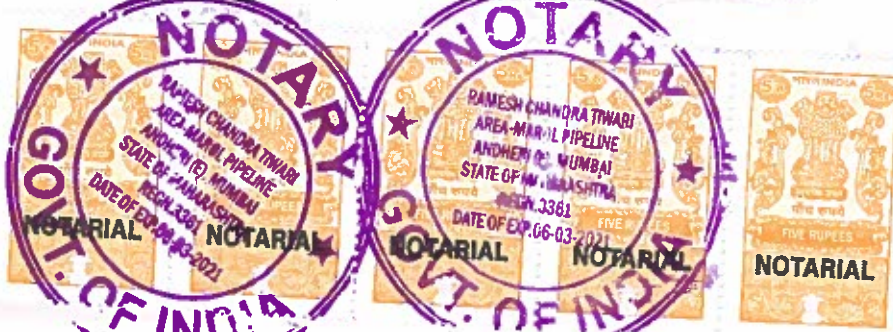
with the seal / stamp of **CHAMBER OF COMMERCE AND INDUSTRY, MUMBAI**

14. **Certified by**  
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS  
on 24-Sep-2018 at NEW DELHI, INDIA

with reference no. **MHMC0030415518**

16. See request for information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the nature of any control exercised over each of these parties

The layout for this Model Certificate is available on diskette in Word Perfect from the Division of Drug Management and Policies, World Health Organization, 1211 Geneva 27, Switzerland.



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CERTIFICATE OF A PHARMACEUTICAL PRODUCT<sup>1</sup>  
Annexure of Excipients

No. of certificate : COPP/CERT/KD/76162/2018/11/24879/128809 VALID UP TO : 24 Jul 2021  
Name of the : GALENTIC PHARMA (INDIA) PRIVATE LIMITED PLOT NO R 673 TTC MIDC  
Company : RABALE THANE BELAPUR ROAD NAVI MUMBAI THANE 400701  
MAHARASHTRA STATE, INDIA  
Name and dosage : Bromycin Eye Ointment  
form of product : (Gentamicin Sulfate Ophthalmic Ointment USP 0.3%)

Sr.No. Ingredients

1 White Soft Paraffin

Specification Qty/Units

USP q s to 100 00 %  
w/w

ATTESTED BY ME

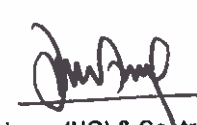
  
RAMESH CHANDRA TIWARI  
ADVOCATE & NOTARY  
GOVT. OF INDIA

Res. 129, A-Wing, Appli Ekta Hsg. Soc.  
Nav Pada, Marol Naka, A. K. Road,  
Andheri (E), Mumbai-400 059



Address of certifying authority :  
Food & Drug Administration, M.S.  
Bandra-kurla Complex,  
Bandra (E), Mumbai - 400 051.  
Maharashtra, INDIA.  
Tel: +91-22-26592363/64  
Fax: +91-22-26591959  
SLAG1257616220180910059

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: 10 Sep 2018

No 29203



10 SEP 2018

