FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

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

No. of certificate : COPP/CERT/KD/76162/2018/11/24879/128809 Valid Upto :24 Jul 2021

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)[2] and amount (s) per unit dose [3]: Each gram contains :

Gentamicin Sulfate USP equivalent to Gentamicin 3 mg	Sterile Ointment base qs

For complete qualitative composition including excipients [4] As per Annexure

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 ☐

2A.1 Number of product license:[7] **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 [8]
A ☒ B ☐ C ☐

2A.4 For categories b and c the name and address of the manufacturer producing the dosage form is [9]

2A.4 Is summary basis of Approval appended ?[10]
Yes ☐ No ☒

2A.5 Is the attached officially approved product information complete and consonant with the license ?[11]
Yes ☐ No ☐ Not Provided ☒

2A.6 Applicant for certificate if different from License holder [12]
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[9]

2B.3. Why is marketing authorization lacking ?
☐ Not required ☐ Not requested ☐ Under Consideration ☐ Refused

2B.4 Remarks [13]

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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[14] ☐

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 ?[15]
Yes ☒ No ☐ Not Applicable [14] ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product ?[16]
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
GS1257616220180910059

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

NOTARY
RAMESH CHANDRA TIWARI
AREA - MAROL PIPELINE
ANDHERI (E), MUMBAI
STATE OF MAHARASHTRA
REGN. 3361
DATE OF EXP. 06-03-2021
GOVT. OF INDIA

NOTARY
RAMESH CHANDRA TIWARI
- MAROL, ANDHERI,
MUMBAI,
MAHARASHTRA
REGN. NO. 3361
GOVT. OF INDIA

IMC
CHAMBER OF COMMERCE AND INDUSTRY
14 SEP 2018
MUMBAI, INDIA

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 to the document prepared by some national regulatory authorities, that summarizes the on which
11. ... national regulatory authority, such as a summary
12. ... required from the product Licence holder. This
13. ... requesting registration:
    ... atment of conditions – particularly tropical
    ... its stability under tropical conditions:
    ... approved for use in pharmaceutical products
    ... num dosage limit for an active ingredient
14. ... a country other than that issuing the product
    ... of manufacture.
15. ... ality control of drugs referred to the certificate
    ... mmittee on specifications for Pharmaceutical
    ... 92 , Annex 1) Recommendations specifically
    ... the WHO Expert Committee on Biological
    ... , Annex 1).
16. ... der or applicant conforms to status (b) or (c) as
    ... when foreign contractors are involved in the
    ... ant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the nature and nature of any controls 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.

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

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 GALENTIC PHARMA (INDIA) PRIVATE LIMITED
has been signed by BIJU GEORGE
with the seal / stamp of CHAMBER OF COMMERCE AND INDUSTRY, MUMBAI
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 24-Sep-2018 at NEW DELHI, INDIA
with reference no. MHMC0030415518
(DEBABRATA PAUL)
Section Officer (O.I.)
Ministry of External Affairs

NOTARY GOVT. OF INDIA RAMESH CHANDRA TIWARI AREA-MAR.-IL PIPELINE ANDHERI (E) MUMBAI STATE OF MAHARASHTRA REGN.3361 DATE OF EXP.06-03-2021 NOTARIAL

A

FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

Annexure of Excipients

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

Sr.No.	Ingredients	Specification	Qty/Units
1	White Soft Paraffin	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
SLAG12576162201809100S9

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

IMC CHAMBER OF COMMERCE AND INDUSTRY
14 SEP 2018
MUMBAI, INDIA

10 SEP 2018