## 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/55627/2017/11/18415/94984** **Valid Upto :06 May 2018**

**Exporting Country** : INDIA

**Importing Country** : **CHILE**

1. Name and dosage form of product : **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: **18 Feb 2013**

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.3.1 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]

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 :

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

NOTARY RAJESH CHANDRA MISRA AREA-MAROL PIPELINE ANDHERI (E), MUMBAI STATE OF MAHARASHTRA REGN. 3361 GOVT. OF INDIA No 51679

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
5LAG125562720170304059

Name of the Authorised person : **O S SADHWANI**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
**Food & Drug Administration, M.S.**
**Bandra (E), Mumbai.**
**Maharashtra State, India**
**Date:04 Mar 2017**

INDIAN MERCHANTS' CHAMBER 07 MAR 2017 MUMBAI-INDIA

04 MAR 2017

ATTESTED
AUTHORISED SIGNATORY
INDIAN MERCHANTS' CHAMBER
MUMBAI-INDIA.
ROHIT YADAV
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 refers to the document, prepared by some national regulatory authorities, that summarizes the on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as a summary of product characteristics (SPC).
12. In this circumstance, permission for issuing the certificate is required from the product Licence holder. This permission must be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration:
    (a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export:
    (b) the product has been reformulated with a view to improving its stability under tropical conditions:
    (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import:
    (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient
    (e) any other reason, please specify.
14. Not applicable means that the manufacture is
    certificate and Inspection is conducted under th
15. The requirements for good practices in the m
    are those included in the thirty- second report
    Preparations (WHO Technical Report Serie
    applicable to biological products have been
    Standardization (WHO Technical Report Serie
16. The Section is to be completed when the prod
    described in note 8 above. It is of particul
    manufacture of the product . In these circums
    information to identify the contracting parties
    form and the extent and nature of any controls

*The layout for this Model Certificate is available*
*Policies. World Health Organization, 1211 Geneva*

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) PVT. LTD.
has been signed by ROHIT YADAV
with the seal / stamp of MANAGER, INDIAN MERCHANTS CHAMBER, MUMBAI-INDIA
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 14-Mar-2017 at NEW DELHI, INDIA
with reference no. MHMC0008044717
Seal / Stamp
Signature
(PUSHPA RANJAN)
Section Officer (Attestation)
C.P.V. Division
Ministry of External Affairs
New Delhi

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

INDIAN MERCHANTS CHAMBER
07 MAR 2017
MUMBAI-INDIA

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

## FOOD & DRUG ADMINISTRATION MAHARASHTRA STATE, MUMBAI 400 051
## CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]
### Annexure of Excipients

| | | |
|---|---|---|
| No. of certificate | : | COPP/CERT/KD/55627/2017/11/18415/94984 VALID UP TO :06 May 2018 |
| 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 | : | Gentamicin Sulfate Ophthalmic Ointment USP 0.3% |

| Sr.No. | Ingredients | Specification | Qty/Units |
|---|---|---|---|
| 1 | White Soft Paraffin | USP | q.s. to 1000 mg |

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

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

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Address of certifying authority :
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Name of the Authorised person : O S SADHWANI

Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:04 Mar 2017

NO 51679

ATTESTED BY ME 04 MAR 2017

INDIAN MERCHANTS' CHAMBER 07 MAR 2017 MUMBAI-INDIA

RAMESH CHANDRA TIWARI
ADVOCATE & NOTARY
GOVT. OF INDIA
Flat No.129 A-Wing, Appli Elite Hsg. Soc
Near Pada, Marol Naka, A.K. Road
Andheri (E), Mumbai-400 059
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