CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

No. of Certificate: Mfg/COPP/Opes/2019/ 1100 3366 1 10 3661
Exporting (Certifying) country: **INDIA**
Importing (requesting) country: **CHILE**

1. Name and dosage form of products: Prednisolone Acetate Opthalmic Suspension USP 1%W/v

1.1 Active ingredient (s) [2] and amount (s) per unit dose [3]: Composition:

Prednisolone Acetate USP	1%W/v
Benzethonium Chloride BP	0.006W/v
Aqueous Base	Q.S.

Excipients: Polysorbate-80 (Tween- 80) BP 0.100 %w/v, Boric Acid (AR Grade) BP 1.200 %w/v. Disodium Edetate (Inj.) BP 0.010 %w/v, Hypromellose (HPMC 5 CPS) BP 0.300 %w/v, Sodium Dihydrogen Phosphate Dihydrate BP 0.250 %w/v, Sodium Metabisulfite BP 0.200 %w/v, Sodium Chloride (Inj. Grade) BP 0.150 % w/v, Benzalkonium Chloride Solution BP 0.012% v/v, Sodium Citrate BP 1.000 %w/v and Water for Injections BP Q.S.

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 2 A and If the answer to 1.2 is no. Continue section 2 B [6]

2A.1 Number of product license [7] : And date of issue: **G/28A/6287-A** In Form No. **28A** And date of issue: **25/06/2019**	2B. 1 Applicant for certificate (name and address)N.A.
2A.2 Product license hol0der : (Name and address) **OPes Healthcare Private Limited Mfg. At: 11 Trimul Estate, Khatraj, Tal: Kalol Dist; Gandhinagar.**	2B. 2 Status of applicant: N.A. a ☒ b ☐ c ☐ 2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are
2A.3 Status of product – license Holder [8] : Manufacturer Of Dosage Form a ☐ b ☐ c ☐	2B.3 Why is marketing authorization lacking? N.A. Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are [9] : N.A.	2B. 4 Remarks : [13]
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	

NOTARY FIROZ AHMAD NCT DELHI Regd. No. 10636 GOVT. OF INDIA

COMMISSIONER FOOD & DRUGS CONTROL ADMINISTRATION सत्यमेव जयते GUJARAT STATE GANDHINAGAR

ATTESTED

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 Periodically of routine inspections (Years) Once in a year

3.2 Has the manufacture of this type of dosage form been inspected? Yes ☒ No ☐

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:

BHOPAL CHAMBER OF COMMERCE

19 MAY 2020

ATTESTED

NOTARY PUBLIC DELHI (INDIA)

21 MAY 2020

This Certificate Valid Up to **Two Years From The Date Of Issue**

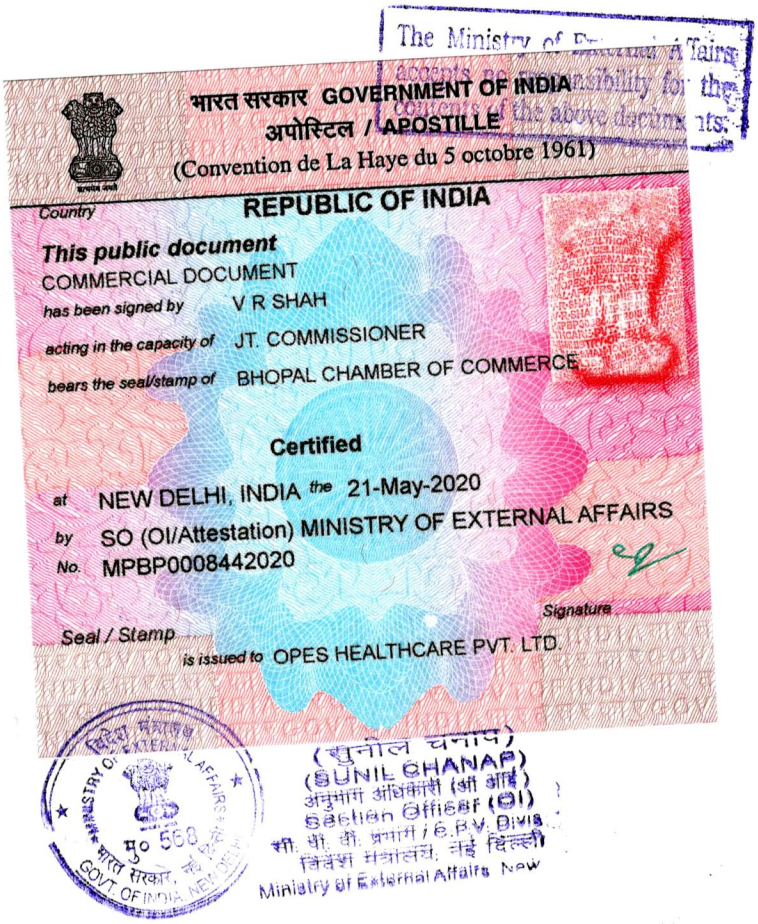
Address of certifying authority:
The Commissioner Food & Drug Control Administration
1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, INDIA
Tel: 91-79-232 53417 Fax: 91-79-232 53400

Name of the Authorized Person: **Shri. V. R. Shah**

Signature:

Stamp and date:

Joint Commissioner
Food & Drugs Controls Administration
Gujarat State



भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country REPUBLIC OF INDIA

This public document

COMMERCIAL DOCUMENT

has been signed by V R SHAH

acting in the capacity of JT. COMMISSIONER

bears the seal/stamp of BHOPAL CHAMBER OF COMMERCE

Certified

at NEW DELHI, INDIA the 21-May-2020

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MPBP0008442020

Signature

Seal / Stamp

is issued to OPES HEALTHCARE PVT. LTD.

(सुनील घनाप)
(SUNIL GHANAP)
अनुभाग अधिकारी (ओ आई)
Section Officer (OI)
सी. पी. वी. प्रभाग / C.P.V. Divis
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs New

TRADUCCION CPP

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

No. of Certificate: Mfg/COPP/Opes/2019/ 1100 3366 1 10 3661
Exporting (Certifying) country: **INDIA**
Importing (requesting) country: **CHILE**

CERTIFICADO DE PRODUCTO FARMACEUTICO

Número de Certificado: Mfg:COPP/Opes/2019/103661

País exportador: India.

País importador: Chile.

1. Nombre y dosis de la forma farmacéutica del producto: Prednisolona Acetato Suspension oftálmica USP 1% W/v

1.1. Principio(s) activo(s) y cantidad(es) por unidad de dosis:

Prednisolona Acetato USP 1% W/v

Cloruro de bencetonio BP 0,006 W/v

Base acuosa c.s.

Excipientes: Polisorbato-80 (Tween-80) BP 0,100 %w/v; Acido Borico (Grado AR) BP 1,200 %w/v, EDTA (Iny.) BP 0,010 %w/v; Hipromelosa (HPMC 5 CPS) BP 0,300 %w/v, Fosfato de sodio dihidrogeno dihidratado BP 0,250 %w/v; Metabisulfito de sodio BP 0,200 %w/v; Cloruro de sodio (Iny. Grado) BP 0,150 %w/v, Solucion de cloruro de Benzalconio BP 0,012% v/v, Citrato de sodio BP 1.000 %w/v y agua para inyectables BP c.s.

1.2. ¿Está este producto autorizado para ser puesto en el mercado en el país exportador? SI

1.3 ¿Está este producto, realmente, en el mercado del país exportador? Sí.

2.A.1. Número de la autorización del producto y fecha de emisión:

Licencia No.: **G/28A/6287-A**, En forma No. **28A**

Fecha: **22/06/2019**

2.A.2. Titular de la autorización del producto:

Opes Healthcare Private Limited

Mgf. At. 11 Trimul Estate, Khatraj, Ta: Kalol Dist; Gandhinagar

2.A.3. Condición del titular de la autorización del producto

2.A.3.1. Para categoría b y c el nombre del Fabricante y dirección: No aplica.

2.A.4.¿Se adjuntan bases resumidas de la aprobación? No.

2.A.5. ¿Está la información del producto oficialmente aprobada y adjunta, completa y en concordancia con la licencia? No provisto

2.A.6. Solicitante del certificado, si difiere del titular de la licencia (nombre y dirección): No aplica

3 ¿La autoridad certificante coordina inspecciones periódicas de la planta farmacéutica en la que se produce la forma farmacéutica? Sí

3.1. Periodicidad en las inspecciones de rutina (años): Una vez al año.

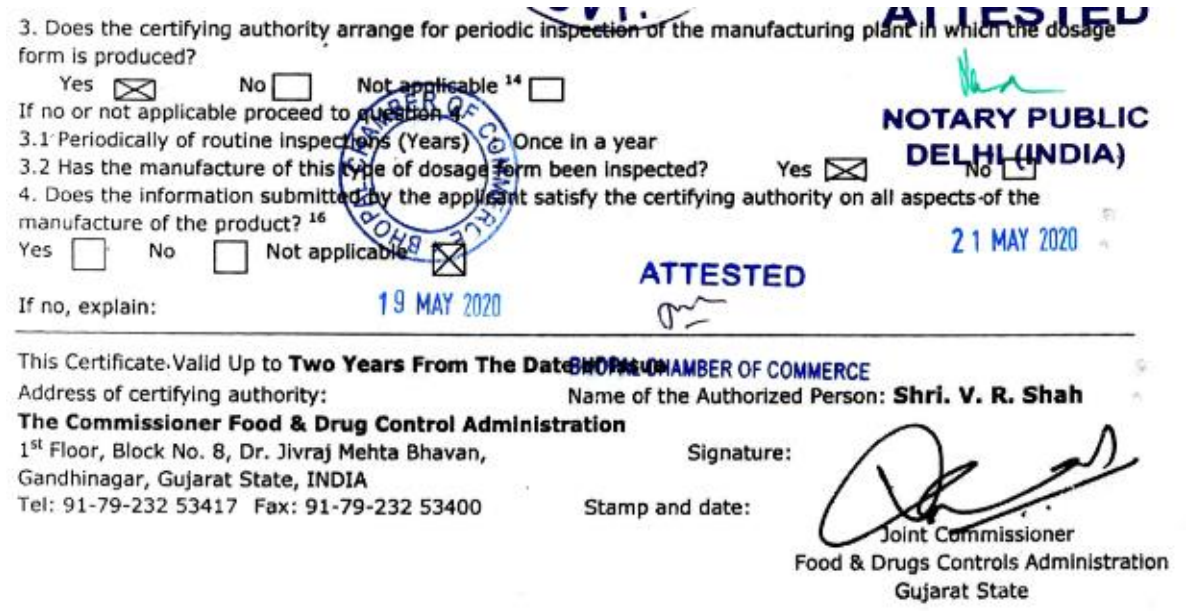
3.2. ¿Ha sido inspeccionado el fabricante de esta forma farmacéutica? Sí

3.3. ¿Cumplen las instalaciones y operaciones con las normas GMP recomendadas por la Organización Mundial de la Salud? Sí.

4. ¿La información proporcionada por el solicitante satisface a la autoridad certificante respecto de todos los aspectos de la manufactura del producto realizada por otra parte?

No aplica.

El certificado es válido por 2 años desde la fecha de emisión



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 Periodically of routine inspections (Years) Once in a year

3.2 Has the manufacture of this type of dosage form been inspected? Yes ☒ No ☐

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:

19 MAY 2020

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This Certificate Valid Up to **Two Years From The Date** BHOPAL CHAMBER OF COMMERCE

Address of certifying authority:

The Commissioner Food & Drug 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

Name of the Authorized Person: **Shri. V. R. Shah**

Signature:

Stamp and date:

Joint Commissioner

Food & Drugs Controls Administration

Gujarat State

APOSTILLA del 21 de Mayo 2020.

Traducido por:

QF. Patricio Iturra Diaz.