DCA
DRUGS CONTROL ADMINISTRATION TELANGANA

Government of Telangana
DRUGS CONTROL ADMINISTRATION

L.Dis.No.1968/DD-I/Mfg/2023 **Dated: 22.06.2023**

To
M/s.Ichor Biologics Pvt. Ltd.,
Sy.No. 222P, Turkapally Village,
Shameerpet Mandal, Medchal –Malkajgiri District,
Telangana State- 500078, India.

Sir,

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder - Issue of World Health Organisation G.M.P. Certificate – Regarding.

Ref:
1. Your letter dated: 22.12.2022
2. Joint Inspection report dt: 15.03.2023 & 16.03.2023
3. Compliance submitted by the firm dt: 20.04.2023
4. Compliance verification report submitted by CDSCO, Hyderabad dt: 09.06.2023
5. Compliance submitted by the firm dt: 16.06.2023
6. Compliance verification report of Drugs Inspector, Shameerpet dt: 20.06.2023

-x-x-x-x

With reference to your application cited, I forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Inspection Report of the Officer of Drugs Control Administration, Telangana State vide reference 6th cited.

This Certificate is valid for a period from 20.06.2023 to 19.06.2026.

Deputy Director Drugs Control Administration Government Of Telangana HYDERABAD

Yours faithfully,

22/6/2023

Deputy Director-I,
Licensing and Certifying Authority

Contd...pg..2

ANDHRA CHAMBER OF COMMERCE SEC'BAD. (INDIA)

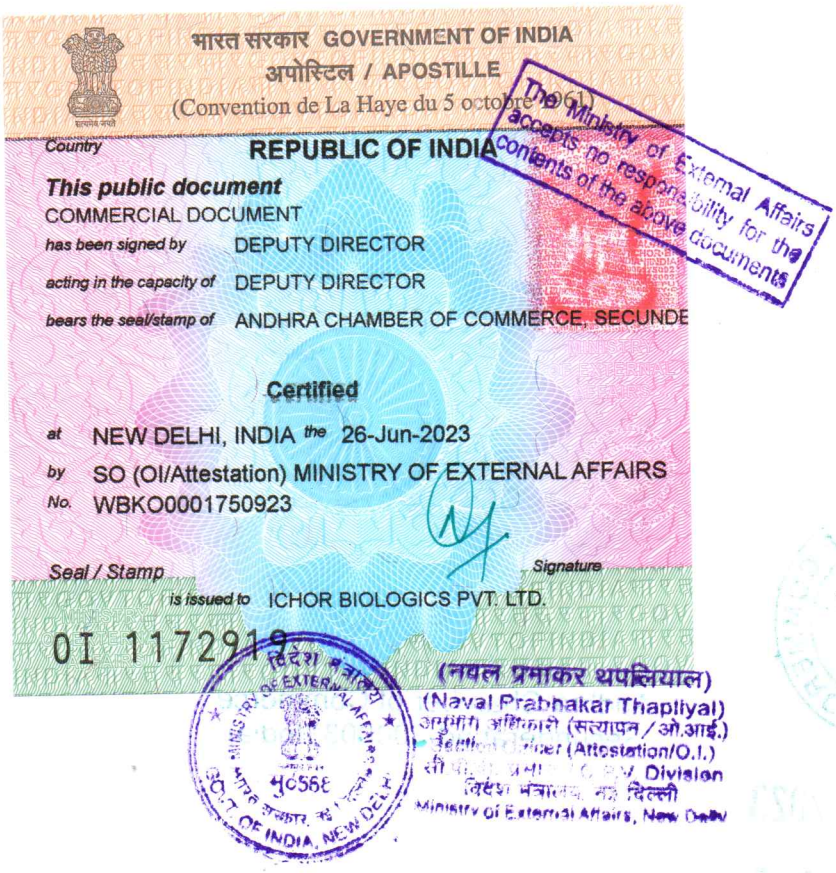
ATTESTED
K. SURYANARAYANA
Authorised Signatory
Andhra Chamber of Commerce
Secunderabad-500003 (India)

24 JUN 2023
No 0 1 3 0 9

M. SADA SIVA KUMAR REDDY ADVOCATE & NOTARY ENCLAVE, BHAGYANAGAR COLONY NOTARY Regn. No. 198 FIVE RUPEES NOTARIAL KUKATPALLY HYDERABAD

Digitally signed by Harea Stefan
Date: 2023.08.14 11:11:23 BST
Reason: MoldSign Signature
Location: Moldova

ATTESTED
24.6.2023
M. SADA SIVA KUMAR REDDY, B.Com., B.L.,
ADVOCATE & NOTARY
Appointed by Govt., India
G.O. Ms. No. 198, Rev (Regn-II), dt. 11.04.2000
102, Saraswathi Enclave, Bhagyanagar Colony,
Kukatpally, Hyderabad, T.S., India. (Ph: 98480 44395)



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 DEPUTY DIRECTOR

acting in the capacity of DEPUTY DIRECTOR

bears the seal/stamp of ANDHRA CHAMBER OF COMMERCE, SECUNDE

Certified

at NEW DELHI, INDIA the 26-Jun-2023

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. WBKO0001750923

Seal / Stamp Signature

is issued to ICHOR BIOLOGICS PVT. LTD.

0I 1172919

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

(नवल प्रभाकर थपलियाल)

(Naval Prabhakar Thapliyal)

अधिकारी (सत्यापन / ओ.आई.)

(Attestation/O.I.)

Division

विदेश मंत्रालय, नई दिल्ली

Ministry of External Affairs, New Delhi

L.Dis.No.1968/DD-I/Mfg/2023

Dated: 20.06.2023

LIST OF PRODUCTS APPROVED UNDER WHO-GMP CERTIFICATIONSCHEME FOR EXPORT PURPOSE

1. **Human Albumin Solution 20% EP 100 mL**
   Composition:
   Each vial contains:
   Total Protein -200 g/L
   Sodium Caprylate not less than - 0.08 mmol / g of protein
   N-Acetyltryptophan not more than - 0.08 mmol / g of protein
   Na+ content not more than - 160 mmol/L
   K+ content - <2 mmol/L
   Aluminium content - <200 µg/L
   Does not contain Preservative

2. **Normal Immunoglobulin for Intravenous Use 5% B.P. 100 mL**
   Composition:
   Each vial contains:
   Total Protein - 50 g/L
   Immunoglobulin G - NLT 95%
   Stabilizer Maltose - 10%
   IgA content - ≤ 30 mg/L
   IgG subclass distribution – Normal
   Does not contain Preservative

3. **Normal Immunoglobulin for Intravenous Use 5% B.P. 50 mL**
   Composition:
   Each vial contains:
   Total Protein - 50 g/L
   Immunoglobulin G - NLT 95%
   Stabilizer Maltose - 10%
   IgA content - ≤ 30 mg/L
   IgG subclass distribution - Normal
   Does not contain Preservative

Deputy Director Drugs Control Administration Government Of Telangana HYDERABAD

22/6/23

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ANDHRA CHAMBER OF COMMERCE SEC'BAD. (INDIA)

M. SADA SIVA KUMAR REDDY, ADVOCATE & NOTARY Regn. No. 198 SARASWATHI ENCLAVE, BHAGYANAGAR COLONY F-102, KUKATPALLY HYDERABAD T.S. INDIA

L.Dis.No.1968/DD-I/Mfg/2023 **Dated: 20.06.2023**

4. **Human Albumin Solution 20% EP 50 mL**
   Composition:
   Each vial contains:
   Total Protein - 200 g/L
   Sodium Caprylate not less than - 0.08 mmol / g of protein
   N-Acetyltryptophan not more than - 0.08 mmol / g of protein
   Na+ content not more than- 160 mmol/L
   K+ content not more than - 2 mmol/L
   Aluminium content not more than - 200 µg/L
   Does not contain Preservative

5. **Fibrin Sealant Kit 1 mL BP**
   Composition:
   Each Kit contains:
   1 vial for Fibrinogen Concentrate, Lyophilized, which after reconstitution gives 1 mL solution of
   Fibrinogen Clottable protein - Not less than 40 mg
   1 vial for Thrombin 500, lyophilized, (human) - 500 IU
   1 vial for Calcium chloride solution - 40 mmol $CaCl_2$/L

Manufacturer : M/s. Ichor Biologics Pvt. Ltd.,
Sy.No. 222P, Turkapally Village,
Shameerpet Mandal,
Medchal –Malkajgiri District,
Telangana State- 500078, India.

When applicable : Placing the product on the market as detailed above

It is certified that the above products had been authorized to be placed on the market for use in the Country and exporting countries.

Drug License No. : 02/RR/AP/2013/BP/CC, dated: 13-09-2013 in Form 28E, valid up to 31-03-2026.

Deputy Director Drugs Control Administration Government Of Telangana HYDERABAD

29/6/23

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ANDHRA CHAMBER OF COMMERCE SEC'BAD. (INDIA)

SARASWATHI ENCLAVE, BHAGYANAGAR COLONY, KUKATPALLY, HYDERABAD, T.S. INDIA. NOTARY Regn. No. 198

DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

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DRUGS CONTROL ADMINISTRATION

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It is also certified that (a) the manufacturing plant in which the product is produced is Subject to inspection at suitable intervals.

The Unit M/s. Ichor Biologics Pvt. Ltd., Sy.No. 222P, Turkapally Village, Shameerpet Mandal, Medchal –Malkajgiri District, Telangana State- 500078, India was inspected jointly by Mr.B.Praveen, Drugs inspector, Drugs Control Administration, Hyderabad, Ms.Heema Naik, Drugs Inspector, CDSCO, Hyderabad and Mr.Sravan Kumar, ADI, CDSCO, Hyderabad on 15.03.2023 & 16.03.2023.

(b) The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacturer and Quality Control (As recommended by the World Health Organisation) in respect of 05 (Five) product to be sold or distributed with in the Country or origin (or to be exported).

This Certificate is valid for a period form 20.06.2023 & 19.06.2026.

Deputy Director Drugs Control Administration Government Of Telangana HYDERABAD

Yours faithfully,

Deputy Director-I,
Licensing and Certifying Authority

ANDHRA CHAMBER OF COMMERCE SEC'BAD. (INDIA)

SIVA KUMAR REDDY, ADVOCATE, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY, NOTARY Regn. No 198