



सत्यमेव जयते

Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010Certificate No. : **20102278**

On the basis of the inspection carried out on 07-08/09/2020 & 12/10/2020 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1 Name & Address of site : **INTAS PHARMACEUTICALS LIMITED**
PLOT NO.496/1/A & B , SARKHEJ BAVLA HIGHWAY,
VILLAGE :- MATODA, TAL- SANAND
City : MATODA, DIST.- AHMEDABAD
GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/28E/1**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Blood Products such as Human Albumin Solution , Human Normal Immunoglobulin for Intravenous & Subcutaneous, Dried Human Anti haemophilic Factor VIII, Human Fibrinogen (Freeze Dried Powder)	Blood Products	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **15/10/2023**. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration, Block
 No. 8, 1ST floor, Dr. Jivraj Mehta Bhavan,
 Gandhinagar, Gujarat State, India. – Pin :
 382010

Name & function of : **(Dr. H.G. KOSHIA)**
 responsible person
 Commissioner

Email : **comfdca@gujarat.gov.in**

Phone : **91-79-23253417, Fax : 91-79-232-53400**

Date : **16/10/2020**





INTAS PHARMACEUTICALS LIMITED

Corporate House, Near Sola Bridge, S.G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, INDIA.
Ph. No. : 079-61577000, Website : www.intaspharma.com CIN - U24231GJ1985PLC007866

Plasma Fractionation Unit: Plot No: 496/1/A&B, Sarkhej - Bavla Highway, Vill: Matoda, Taluka - Sanand,
Ahmedabad - 382 213 Gujarat (India) Tel.: 02717 662103

LIST OF PRODUCTS FOR GRANT OF COPP AS PER WHO GMP GUIDELINES FOR EXPORT ONLY

DRUG MANUFACTURING LICENSE NO.: G/28E/1 ON FORM NO.: 28 E

FROM DATE: 16 OCT 2020

VALID UP TO: 15 OCT 2023

	NAME OF PRODUCTS	COMPOSITION
01	Human Normal Immunoglobulin for Intravenous Use EP, 5% Solution Pack Size : 10 ml, 20 ml, 50 ml & 100 ml	Each vial contains: Total Protein 50 g/L Immunoglobulin G $\geq 95\%$ Maltose (as stabilizer) 100 g/L IgA content ≤ 80 mg/L IgG subclass : Normal distribution
02	Human Normal Immunoglobulin for Intravenous Use EP, 10% Solution Pack Size : 10 ml, 20 ml, 50 ml & 100 ml	Each vial contains: Total Protein 100 g/L Immunoglobulin G $\geq 95\%$ Maltose (as stabilizer) 100 g/L IgA content ≤ 80 mg/L IgG subclass : Normal distribution
03	Human Normal Immunoglobulin for Intravenous Use EP, 5% Solution Brand Name: GLOBUCEL Pack Size : 10 ml, 20 ml, 50 ml & 100 ml	Each vial contains: Total Protein 50 g/L Immunoglobulin G $\geq 95\%$ Maltose (as stabilizer) 100 g/L IgA content ≤ 80 mg/L IgG subclass : Normal distribution
04	Human Normal Immunoglobulin for Intravenous Use EP, 10% Solution Brand Name: GLOBUCEL 10 Pack Size : 10 ml, 20 ml, 50 ml & 100 ml	Each vial contains: Total Protein 100 g/L Immunoglobulin G $\geq 95\%$ Maltose (as stabilizer) 100 g/L IgA content ≤ 80 mg/L IgG subclass : Normal distribution

For Intas Pharmaceuticals Limited


Authorized Signatory




For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar.