Food & Drugs Control Administration

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

सत्यमेव जयते

Certificate No. : **23033935**

On the basis of the inspection carried out on **27-28/12/2022 & 27/02/2023** *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. 5 TO 14, PHARMEZ NEAR VILLAGE MATODA,
TAL - SANAND,
CITY : MATODA, DIST. – AHMEDABAD
GUJARAT STATE, INDIA

SR. No. 151 of 2024
NOTARY
16 JAN 2024

GIRISH S. PARMAR AHMEDABAD DIST. GUJARAT STATE REGD.No. 9646/2013 EXPIRY DATE 06/03/2028 NOTARY GOVT. OF INDIA

2 *Manufacturer's Licence number :* **G/25/1883** **G/28/1336**

3 *Table : 1*

Dosage Form (s)	*Category (ies)*	*Activity (ies)*
Tablet (Coated Uncoated), Capsule, Parenteral {S.V.P. Liquid,unit Lyophilized, Vial, PFS}	General	Manufacturer
Tablet (Coated Uncoated), Capsule, Parenteral {S.V.P. Liquid, unit Lyophilized, Vial, PFS}, Soft Gelatin Capsule	Cytotoxic	
Ointment (External preparation)	Sex hormone	

GUJARAT CHAMBER OF COMMERCE & INDUSTRY ESTD. 1949 AHMEDABAD

KIRTIKUMAR B. MODH
ASST. SECRETARY SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD

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 **27/02/2026** *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*

ATTESTED BY ME
GIRISH S. PARMAR
NOTARY
GOVT. OF INDIA
16 JAN 2024

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

Email : *comfdca@gujarat.gov.in*

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

Date : *28/02/2023*

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

COMMISSIONER FOOD & DRUGS CONTROL ADMINISTRATION GUJARAT STATE GANDHINAGAR

NOTARY GIRISH S. PARMAR AHMEDABAD DIST. GUJARAT STATE REGD NO 9646/13 GOVT. OF INDIA

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

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

Country REPUBLIC OF INDIA

This public document

COMMERCIAL DOCUMENT

has been signed by AUTHORISED SIGNATORY

acting in the capacity of AUTHORISED SIGNATORY

bears the seal/stamp of GUJARAT CHAMBER OF COMMERCE AND INDUSTRY, AHMEDABAD

Certified

at NEW DELHI, INDIA the 30-Jan-2024

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. GJAH0001945424

Seal / Stamp

Signature

is issued to INTAS PHARMACEUTICALS LTD.

0I 1760298

विदेश मंत्रालय MINISTRY OF EXTERNAL AFFAIRS भारत सरकार, नई दिल्ली GOVT. OF INDIA, NEW DELHI

M0568

(राजकुमार सिंह)

(RAJ KUMAR SINGH)

अनुभाग अधिकारी (सत्यापन / ओ.आई.)

Section Officer (Attestation / O.I.)

सी.पी.वी. प्रभाग / C.P.V. Division

विदेश मंत्रालय, नई दिल्ली

Ministry of External Affairs, New Delhi

CHIEF PHARMACEUTICAL INSPECTOR

2023 -07- 14

SR. No. 1470 of 2023

NOTARY

IWSF.405.63.2023.IP.1.1
WTC/0614_01_01/124

15 DEC 2023

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended

Chief Pharmaceutical Inspector
/the Competent Authority of Poland/

confirms the following:

the manufacturer

Intas Pharmaceuticals Limited
Plot Nos. 5 to 14, Pharmez, Near Village Matoda, Sarkhej-Bavla National Highway, No. 8-A, Taluka: Sanand, Ahmedabad, Gujarat 382213, India

NOTARY GIRISH S. PARMAR AHMEDABAD DIST. GUJARAT STATE REGD.No. 9646/2013 EXPIRY DATE 03/2028 GOVT. OF INDIA

site address

Intas Pharmaceuticals Limited
Plot Nos. 5 to 14, Pharmez, Near Village Matoda, Sarkhej-Bavla National Highway, No. 8-A, Taluka: Sanand, Ahmedabad, Gujarat 382213, India

has been inspected in connection with marketing authorization(s) listing manufacturer located outside of the European Economic Area in accordance with Art. 111(4), of Directive 2001/83/EC as amended, transposed in Pharmaceutical Law of 6th of September 2001 (Journal of Laws from 2022. Item 2301).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **27-31/03/2023**, it is considered that it complies with the Good Manufacturing Practice requirements laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

GUJARAT CHAMBER OF COMMERCE & INDUSTRY AHMEDABAD ESTD. 1949

GŁÓWNY INSPEKTORAT FARMACEUTYCZNY

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57

www.gif.gov.pl
gif@gif.gov.pl

Part 2

Human Medicinal Products

1	**MANUFACTURING OPERATIONS**
1.1	**Sterile Products**
	1.1.1 Aseptically prepared 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids **1.1.2 Terminally sterilised** 1.1.2.3 Small volume liquids
1.2	**Non-sterile products**
	1.2.1 Non-sterile products 1.2.1.1 Capsules, hard shell 1.2.1.2 Capsules, soft shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary packing 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.13 Tablets **1.5.2 Secondary packing**
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility **1.6.2 Microbiological: non sterility** **1.6.3 Chemical/Physical** **1.6.4 Biological**

16 DEC 2023

DIVYA P. JOSHI
ASST SECRETARY SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD

ATTESTED BY ME

GIRISH S. PARMAR
NOTARY
GOVT. OF INDIA

15 DEC 2023

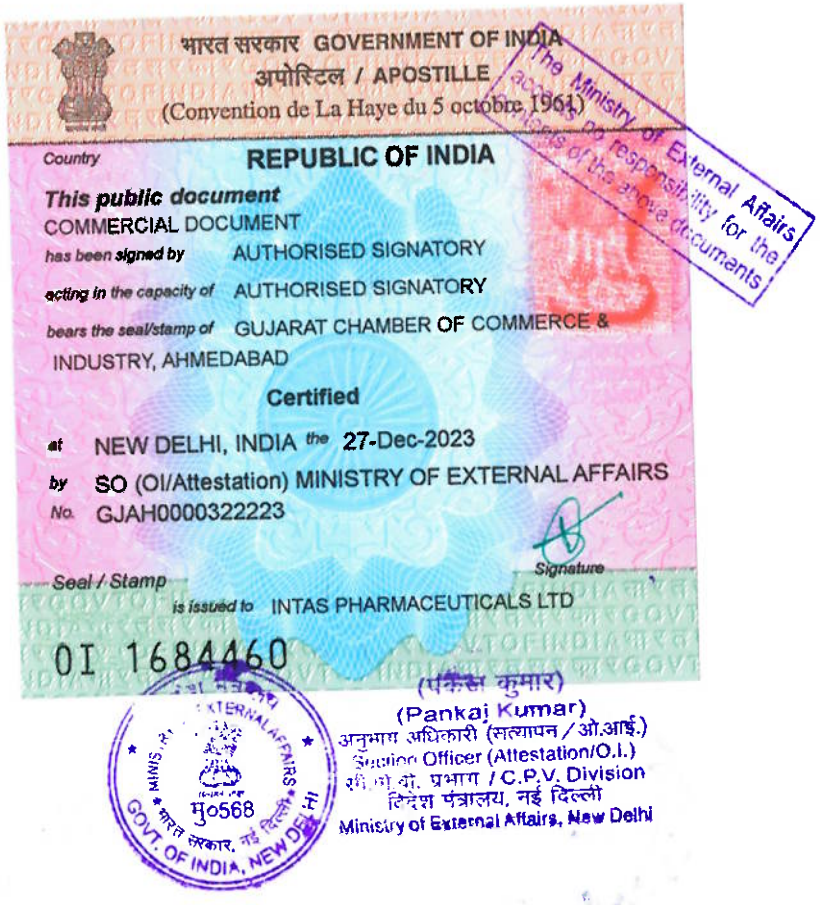
Any restrictions or clarifying remarks related to the scope of this certificate:

Points 1.1, 1.5, 1.6 concern medicinal products manufactured on production lines:
Block C (vial filling line 1, 2, 3, 4) Oncology Parenteral
and Block G (vial filling lines: 1, 2) (PFS Filling Line 3) General Parenteral.

Block B: points 1.2.1.1, 1.2.1.13, 1.5.1.1, 1.5.1.13;
Block C 2nd Floor Wing A: points 1.2.1.1, 1.2.1.2, 1.2.1.13, 1.5.1.1, 1.5.1.2, 1.5.1.13 also highly potent products;
Block G - only point 1.5

Chief Pharmaceutical Inspector
Ewa Krajewska

12 Senatorska str, 00-082 Warsaw, POLAND
phone 22 635 99 51
fax 22 635 99 57
www.gif.gov.pl
gif@gif.gov.pl



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Certified

at NEW DELHI, INDIA the 27-Dec-2023

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. GJAH0000322223

Seal / Stamp

Signature

is issued to INTAS PHARMACEUTICALS LTD

OI 1684460

MINISTRY OF EXTERNAL AFFAIRS * भारत सरकार, नई दिल्ली * GOVT. OF INDIA, NEW DELHI

MJ0568

(पंकज कुमार)

(Pankaj Kumar)

अनुभाग अधिकारी (सत्यापन / ओ.आई.)

Section Officer (Attestation/O.I.)

सी.पी.वी. प्रभाग / C.P.V. Division

विदेश मंत्रालय, नई दिल्ली

Ministry of External Affairs, New Delhi