SR. No. 4197 OF 2023

NOTARY

15 DEC 2023

GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT

No : DCD/SPL.CEL/CR-173/2023-24
GSC No: DD008S230000049

Office of the Drugs Controller
For the State of Karnataka
P.B. No. 5377 ,Palace Road,
Bangalore - 560001
Date: 08/05/2023

WHO GMP CERTIFICATE

This one page certificate conforms to the format recommended by the World Health Organization

(General Instructions and explanatory notes are attached)

On the basis of the inspection carried out on M/s : SHILPA PHARMA LIFESCIENCES LIMITED 100% EOU we certify that the site indicated on this certificate complies with Good Manufacturing Practices(GMP) for the dosage form categories and activities listed on

Table 1

01.Name and Address of the site : SHILPA PHARMA LIFESCIENCES LIMITED 100% EOU

Plot No.,33, 33A, 40 to 47, Blocks C, D, E, H, I & AM, Raichur Industrial Growth Centre, Chicksugur - 584 134, Raichur District, Karnataka, India

02.Manufacturers Licence Numbers : KTK/25/564/2009 Dated 17/04/2009 Valid up to 16/04/2024

03.Table 1:

S. No.	Pharmaceutical Products / Dosage forms/ಔಷಧೀಯ ಉತ್ಪನ್ನಗಳು / ಡೋಸೇಜ್ ರೂಪಗಳು	Category(ies)/ವರ್ಗ	Activity(ies)/ಚಟುವಟಿಕೆ
1.	CAPECITABINE Ph.Eur	Anticancer	Synthesis, Purifications, Quality Control, Packing, Labelling
2.	CAPECITABINE USP	Anticancer	Synthesis, Purifications, Quality Control, Packing, Labelling
3.	CLOFARABINE	Anticancer	Synthesis, Purifications, Quality Control, Packing, Labelling
4.	DECITABINE	Anticancer	Synthesis, Purifications, Quality Control, Packing, Labelling
5.	DIMETHYL FUMARATE	Nrf2 activators	Synthesis, Purifications, Quality Control, Packing, Labelling
6.	ENZALUTAMIDE	Anticancer	Synthesis, Purifications, Quality Control, Packing, Labelling
7.	ERLOTINIB HCl	Anticancer	Synthesis, Purifications, Quality Control, Packing, Labelling
8.	FINGOLIMOD HCl USP	Sphingosine I-phosphate receptor modulators	Synthesis, Purifications, Quality Control, Packing, Labelling
9.	[illegible]	Sphingosine I-phosphate	Synthesis, Purifications, Quality

9.	FINGOLIMOD HCl Ph. Eur.	receptor modulators	Control, Packing, Labelling
10.	FINGOLIMOD HYDROCHLORIDE	Sphingosine I-phosphate receptor modulators	Synthesis, Purifications, Quality Control, Packing, Labelling

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

This certificate remains valid upto 12/03/2026 . It become invalid if the activities and or categories certified herewith are changed or if the site is on longer considered to be in compliance with GMP.

This certificate is issued as per WHO TRS No.908 of 2003.

Address of Certifying authority :Office of the Drugs Controller,For the State of Karnataka ,Palace Road,Bangalore - 560001,INDIA.

Name of the Authorized Person: Bhagoji T Khanapure

Email:dckarnataka@gmail.com

Signature valid
Digitally signed by Bhagoji T Khanapure
Date: 2023.05.08 [illegible]:19:24 IST

DRUGS CONTROLLER &
LICENCING AUTHORITY

GUJARAT CHAMBER OF COMMERCE & INDUSTRY
ESTD. 1949

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

Explanatory notes:

(1) This certificate, which is in the format recommeded by WHO,certifies the status of the Site listed in point 1 of the certificate.
(2) The certification number should be traceable within the regulatory authority issuing the certificate.
(3) Where the regulatory authority issues a licence for the site this number should be specified. Record "not applicable" in casewhere there is no legal framework for the issuing of a licence.
(4) Table 1
List the dosage forms, starting materials, categories and activities.
Examples give below.

Pharmaceutical	Category(ies)	Activity(ies)
Dosage form(s):		
Tablets	Cytotoxic	Packaging
	Hormone	Production, packaging,quality control
	Penicillin	Repackaging and labelling
Injectables	Cefalosporin	Aseptic preparation,packaging, labelling

Example 2

Pharmaceutical Product(s)2	Category(ies)	Activity(ies)
Starting material(s):3		
Paracetamol	Analgesic	Synthesis, purification,packing, labelling

2 Pharmaceutical Products: Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage for or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

3 Starting Materials: Any substance of a defined quality used in the production of alpharmaceutical product, but excluding packaging materials.Use, whenever available, International Nonproprietary Names
(INNs) or otherwise national nonproprietary names.

(5) The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
(6) The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

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

ATTESTED BY ME
GIRISH S. PARMAR
NOTARY
GOVT. OF INDIA
15 DEC 2023

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

16 DEC 2023
DIVYA P. JOSHI
ASST SECRETARY SERVICE CENTER
GUJARAT CHAMBER OF COMMERCE & INDUSTRY
AHMEDABAD

GUJARAT CHAMBER OF COMMERCE & INDUSTRY ESTD. 1949

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 documents

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 & INDUSTRY, AHMEDABAD

Certified

at NEW DELHI, INDIA *the* 27-Dec-2023

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. GJAH0000322623

Signature

Seal / Stamp

is issued to INTAS PHARMACEUTICALS LTD

0I 1684464

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

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(पंकज कुमार)

(Pankaj Kumar)

अनुभाग अधिकारी (सत्यापन / ओ.आई.)

Section Officer (Attestation/O.I.)

सं.रा.वे. प्रभाग / C.P.V. Division

विदेश मंत्रालय, नई दिल्ली

Ministry of External Affairs, New Delhi