HELLENIC REPUBLIC
MINISTRY OF HEALTH & SOCIAL SECURITY
NATIONAL ORGANIZATION FOR MEDICINES
284, Mesogeion Avenue, 155 62 Holargos, Greece
www.eof.gr

REGISTERED MAIL

Holargos: 20-9-2023
Ref. No: 101827

Division : Division of Production and Distribution Control
Department : Inspections
Information : **Dr S. Giannakou**
Tel. / Fax : 210 6507338/ 210 6507405
Fax : 210 6549591
Email : sgiannakou@eof.gr

TO: *TITAN LABORATORIES Pvt. Ltd.*
Plot No. E27/1 & E27/2, M.I.D.C.
Mahad, Village-Jite, Dist. Raigad
Maharashtra State, Pin-402309
India

Subject: *TITAN LABORATORIES Pvt. Ltd.*

Dear Sirs,

Following the inspection of TITAN LABORATORIES Pvt. Ltd., please find attached the GMP certificate.

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY ★ 1836 ★ BOMBAY CHAMBER

A copy of this document / has been recorded with the Chamber

Authorised Signatory
Bombay Chamber of Commerce and Industry
Ref. No...BG/23/067366
Date.....20 OCT. 2023

DILIP GUPTA
Sr. Executive

DIMITRIOS FILIPPOU

President of Management Board
of the National Organization for Medicines

Pub.
Inspection Department

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ

ΒΕΒΑΙΩΝΕΤΑΙ ΓΙΑ ΤΗΝ ΑΚΡΙΒΕΙ
Η ΑΝΑΠΛΗΡΩΤΡΙΑ ΠΡΟΪΣΤΑΜΕΝΗ
ΓΕΝΙΚΗΣ ΓΡΑΜΜΑΤΕΙΑΣ

ΣΑΡΑΝΤΙΤΣΑ ΜΑΡΙΑ

Attached
GMP certificate.



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 AUTHORISED SIGANTORY

acting in the capacity of AUTHORISED SIGANTORY

bears the seal/stamp of BOMBAY CHAMBER OF COMMERCE AND INDUSTRY

Certified

at NEW DELHI, INDIA the 23-Oct-2023

by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

No. MHMC0003178623

Seal / Stamp

Signature

is issued to TITAN LABORATORIES PVT. LTD.

OI 1519940

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

(जगदीप कुमार मल्होत्रा)

(Jagdeep Kumar Malhotra)

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

MINISTRY OF EXTERNAL AFFAIRS GOVT. OF INDIA, NEW DELHI

National Organization For Medicines

CERTIFICATE NUMBER: ***84296/ 1-8-2023***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

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

The competent authority of Greece confirms the following:
The manufacturer: ***Titan Laboratories Private Limited***
Site address: ***Plot No E 27/1 And E 27/2, Midc Mahad Village Jite, Raigad, 402309, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100021420 / LOC-100030117***
DUNS Number: ***86-337-0948***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:
Δ.ΥΓ 3(α)/Γ.Π. 32221/29-4-2013, Art. 162(4)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-06-09***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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 EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate:

Other solid dosage forms include granules and pellets. The GMP Certificate is limited to Module II, Module III, Module IV & Module M of the building.

Clarifying remarks (for public users)

Other solid dosage forms include granules and pellets. The GMP Certificate is limited to Module II, Module III, Module IV & Module M of the building.

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY ★1836★ BOMBAY CHAMBER

2023-09-08

Name and signature of the authorised person of the Competent Authority of

Dimitrios Dimas
Tel:*+30 213 2040373*
Fax:*+30 213 2040563*

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY
BOMBAY CHAMBER
★1836★