FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-**09 Nov 2021**

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/NKD/103994/2021/11/37930**

On the basis of the inspection carried out on **05/08/2021 & 06/08/2021** ,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 of the Firm : **SUN PHARMACEUTICAL INDUSTRIES LTD**
   Address : **A-7/A-8, M.I.D.C, INDUSTRIAL AREA, AHMEDNAGAR 414111 MAHARASHTRA STATE, INDIA**
2. Licence No. : **NKD32 In Form 25, NKD39 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	Cytotoxics	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance
2	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance

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 08 Nov 2024 . 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.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1NUS744103994202111O9
SUN PHARMACEUTICAL INDUSTRIES LTD - NEW-
WHO-GMP/CERT/NKD/103994/2021/11/37930

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**09 Nov 2021**

Explanatory notes

1. This certificate which is in the format recommended 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 cases where there is no legal framework for the issuing of a licence.

4. Table 1
   List the dosage forms, starting materials, categories and activities. Examples are given below.

   Example -1

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

   Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

   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 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.

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/NKD/103994 /2021/11/37930 **VALID UP TO :08 Nov 2024**

Name of Manufacturing Firm : SUN PHARMACEUTICAL INDUSTRIES LTD
A-7/A-8, M.I.D.C, INDUSTRIAL AREA,
AHMEDNAGAR 414111 MAHARASHTRA STATE,
INDIA

Drug License No : NKD32 In Form 25,
NKD39 In Form 28

Sr.No.	Name of the Product	Composition
193	Temsirolimus IH	
194	Teriparatide IH	
195	Terlipressin Acetate IH	
196	Tetrabenazine IH	
197	Tramadol Hydrochloride EP	
198	Tramadol Hydrochloride IP	
199	Tramadol Hydrochloride USP	
200	Valproic Acid BP	

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SUN PHARMACEUTICAL INDUSTRIES LTD - NEW-WHO-GMP/CERT/NKD/103994/2021/11/37930

Name of the Authorised person : **D. R. GAHANE**

Signature:

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**09 Nov 2021**