BY REGD. POST

L. Dis. No. 16478/D1/4/2021

Office of the Director of Drugs Control,
Tamil Nadu, Chennai – 600 006.
Dated: 05.01.2022.

Sub: Drugs – Drugs and Cosmetics Act, 1940 and Rules made there under – M/s. Sun Pharmaceutical Industries Ltd., Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamil Nadu – 603303 - Applied for Revalidation of WHO – GMP Certificate in Form 25 and Form 28 – Request for the issue of Under Process Certificate – Reg.

Ref: Application Dated: 29.12.2021 of M/s. Sun Pharmaceutical Industries Ltd., Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamil Nadu – 603303.

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The Under Process Certificate requested in the reference cited is furnished herewith.

DIRECTOR OF DRUGS CONTROL

05/01/2022

To
M/s. Sun Pharmaceutical Industries Ltd.,
Sathammai Village, Karunkuzhi Post,
Madhuranthagam Taluk, Kancheepuram District,
Tamil Nadu – 603303.

L. Dis. No. 16478/D1/4/2021

Office of the Director of Drugs Control,
Tamil Nadu, Chennai – 600 006.
Dated: 05.01.2022.

CERTIFICATE

This is to Certify that M/s. Sun Pharmaceutical Industries Ltd., Sathammai Village, Karunkuzhi Post, Madhuranthagam Taluk, Kancheepuram District, Tamil Nadu – 603303 are having manufacturing licences in Form 25 & Form 28 bearing nos. **777/93 & 605/95** both dated: 27.02.2002. They have WHO GMP Certificate valid upto 31.12.2021 and they have applied for a further revalidation period from 01.01.2022 to 31.12.2024 and their application is under process in this Directorate.

DIRECTOR OF DRUGS CONTROL

05/01/2022

K. SIVABALAN B.Pharm
Director of Drugs Control
359, Anna Salai, Chennai - 600 006.

DIRECTORATE OF DRUGS CONTROL
TRUTH ALONE TRIUMPHS
CHENNAI-6

DEPARTMENT OF FOOD SAFETY AND DRUGS CONTROL ADMINISTRATION
GOVERNMENT OF TAMILNADU
359, Anna Salai, Chennai - 600 006, Tamil Nadu.

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

Certificate No: **K Dis. No: 17264/D1/4/2018, Dated: 01.04.2019**

On the basis of the inspection carried out on 08.01.2019, 09.01.2019 and 25.03.2019 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 and address of site: **M/s. Sun Pharmaceutical Industries Ltd.,**
Sathammai Village, Karunkuzhi Post,
Madhuranthagam Taluk,
Kancheepuram District, TamilNadu – 603 303,
India.

2 Manufacturer's licence number: Form 25 Bearing No: 777/93, Dated: 27.02.2002.
Form 28 Bearing No: 605/95, Dated: 27.02.2002.

3 Table 1:

Dosage form(s)	Category(ies)	Activity(ies)
Active pharmaceutical ingredients (Vide List Attached)	General (Other Than Betalactum, sex hormones & cytotoxic)	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 31.12.2021 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.

Name and function of responsible person: K.Sivabalan, B.Pharm.,

Director of Drugs Control

Director of Drugs Control
Chennai-600 006

Email:tndcad@gmail.com **Telephone No.:**91-44-2433 5068 **Fax No.:**91-44-2432 1830

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 case where there is no legal framework for the issuing of a licence.
4) 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.
5) 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.

LIST OF ALREADY PERMITTED ITEMS IN FORM 25 BEARING NO. 777/93 DATED: 27.02.2002 VALID UPTO 26.02.2022 OF M/S SUN PHARMACEUTICAL INDUSTRIES LTD, SATHAMMAI VILLAGE, KARUNKUZHI POST, MADHURANTHAGAM TALUK, KANCHEEPURAM DISTRICT, TAMIL NADU - 603 303, INDIA., ARE INCLUDED UNDER WHO GMP CERTIFICATE WHICH IS VALID UPTO 31.12.2021.

K.DIS. 17264/D1/4/2018 DATED: 01.04.2019

Name of the Product

01. AMISULPRIDE B.P

02. AMISULPRIDE I.P

03. AMISULPRIDE Ph. Eur.

04. CLOPIDOGREL BISULFATE I.P

05. CLOPIDOGREL BISULFATE B.P

06. CLOPIDOGREL BISULFATE U.S.P

07. DIVALPROEX SODIUM U.S.P.

08. DIVALPROEX SODIUM I.P

9. MAGNESIUM VALPROATE

10. MEPHENTERMINE SULPHATE USP

11. MEPHENTERMINE SULPHATE. I.P.

12. METOPROLOL TARTRATE I.P.

13. METOPROLOL TARTRATE B.P.

14. METOPROLOL TARTRATE U.S.P.

15. METOPROLOL TARTRATE Ph. Eur.

16. OXETACAINE B.P.

17. RANOLAZINE

18. SODIUM VALPROATE I.P

19. SODIUM VALPROATE B.P.

20. SODIUM VALPROATE Ph. E

DIRECTOR OF DRUGS CONTROL

Director of Drugs Control
Chennai-600 006

LIST OF ALREADY PERMITTED ITEMS IN FORM 25 BEARING NO. 777/93 DATED: 27.02.2002 VALID UPTO 26.02.2022 OF M/S SUN PHARMACEUTICAL INDUSTRIES LTD, SATHAMMAI VILLAGE, KARUNKUZHI POST, MADHURANTHAGAM TALUK, KANCHEEPURAM DISTRICT, TAMIL NADU - 603 303, INDIA., ARE INCLUDED UNDER WHO GMP CERTIFICATE WHICH IS VALID UPTO 31.12.2021.

K.DIS. 17264/D1/4/2018 DATED: 01.04.2019

Name of the Product

21. TRAMADOL HYDROCHLORIDE B.P.
22. TRAMADOL HYDROCHLORIDE Ph. Eur.
23. TRAMADOL HYDROCHLORIDE U.S.P
24. VALPROIC ACID U.S.P.
25. VALPROIC ACID B.P.
26. VALPROIC ACID Ph. Eur.
27. VALPROIC ACID I.P

DIRECTOR OF DRUGS CONTROL

Director of Drugs Control
Chennai-600 006

LIST OF ALREADY PERMITTED ITEMS IN FORM 28 BEARING NO. 605/95 DATED: 27.02.2002 VALID UPTO 26.02.2022 OF M/S SUN PHARMACEUTICAL INDUSTRIES LTD, SATHAMMAI VILLAGE, KARUNKUZHI POST, MADHURANTHAGAM TALUK, KANCHEEPURAM DISTRICT, TAMIL NADU - 603 303, INDIA., ARE INCLUDED UNDER WHO GMP CERTIFICATE WHICH IS VALID UPTO 31.12.2021.

K.DIS. 17264/D1/4/2018 DATED: 01.04.2019

Name of the Product

METADOXINE I.P

DIRECTOR OF DRUGS CONTROL

Director of Drugs Control
Chennai-600 006