



DEPARTMENT OF FOOD SAFETY AND DRUGS CONTROL ADMINISTRATION
GOVERNMENT OF TAMILNADU

359, Anna Salai, Chennai - 600 006, Tamil Nadu.

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: K Dis No: 18739/D1/2/2016, Dated: 06.03.2017

On the basis of the inspection carried out on **05.01.2017 to 06.01.2017** 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,
Madhurantagam Taluk,
Kancheepuram Dist – 603 303
- 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

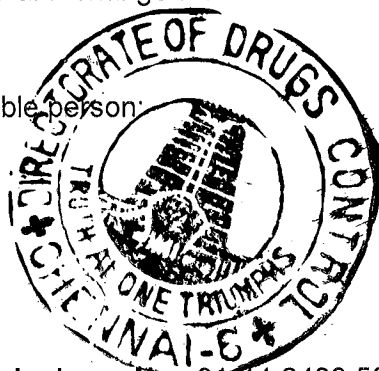
3 Table 1:

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 **31.12.2018** 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:
Place: Chennai
Date: 06.03.2017



S. Abdul Khader, B.Pharm.,

S. Abdul Khader
Director of Drugs Control,
Tamil Nadu
359, Anna Salai, Chennai-600 006.
Fax No.:91-44-2432 1830

Email: tndcad@gmail.com

Telephone No.: 91-44-2433 5068

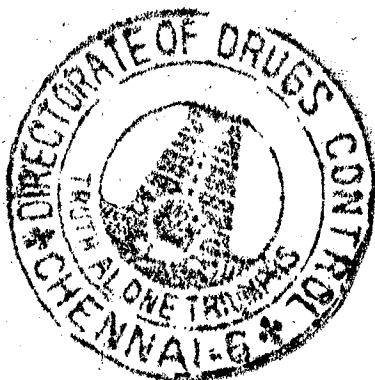
Explanatory notes

- 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 ITEMS PERMITTED TO BE MANUFACTURED UNDER DRUG LICENCE IN
FORM 25 BEARING LICENCE NUMBER 777 DATED 27/02/2002 GRANTED TO M/S SUN
PHARMACEUTICAL INDUSTRIES LTD, SATHAMMAI VILLAGE, KARUNKUZHI POST,
MADHURANTHAGAM TALUK, KANCHEEPURAM DISTRICT TAMIL NADU -603 303,
INDIA., UNDER WHO GMP NORMS. *and valid upto 31.12.2018*

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
09. DIVALPROEX SODIUM
10. MAGNESIUM VALPROATE
11. MEPHENTERMINE SULPHATE USP
12. MEPHENTERMINE SULPHATE. I.P.
13. METOPROLOL TARTRATE I.P.
14. METOPROLOL TARTRATE B.P.
15. METOPROLOL TARTRATE U.S.P.
16. METOPROLOL TARTRATE Ph. Eur.
17. OXETACAIN B.P.
18. RANOLAZINE
19. SODIUM VALPROATE I.P
20. SODIUM VALPROATE B.P.
21. SODIUM VALPROATE Ph. Eur.

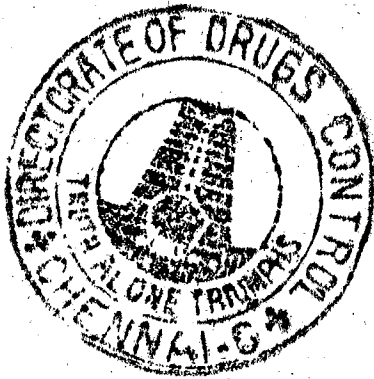
K. DIS No. *18739* D1/2/2016 dt: *...../...../2017*



S. Abdul Khader
S. ABDUL KHADER, B.Pharm.,
Director of Drugs Control
359, Anna Salai, Chennai-600 006.

LIST OF ITEMS PERMITTED TO BE MANUFACTURED UNDER DRUG LICENCE IN
FORM 25 BEARING LICENCE NUMBER 777 DATED 27/02/2002 GRANTED TO M/S SUN
PHARMACEUTICAL INDUSTRIES LTD, SATHAMMAI VILLAGE, KARUNKUZHI POST,
MADHURANTHAGAM TALUK, KANCHEEPURAM DISTRICT TAMIL NADU -603 303,
INDIA., UNDER WHO GMP NORMS. and Valid upto 31.12.2018

22. TRAMADOL HYDROCHLORIDE B.P. K. DIS No. 18739. D1/2/2016 dt:...../...../2017
23. TRAMADOL HYDROCHLORIDE Ph. Eur.
24. TRAMADOL HYDROCHLORIDE U.S.P
25. VALPROIC ACID U.S.P.
26. VALPROIC ACID B.P.
27. VALPROIC ACID Ph. Eur.
28. VALPROIC ACID I.P



S. Abdul Khader
7/2/17
S. ABDUL KHADER, B.Pharm.,
Director of Drugs Control
359, Anna Salai, Chennai-600 006.

LIST OF ITEMS PERMITTED TO BE MANUFACTURED UNDER DRUG LICENCE IN
FORM 28 BEARING LICENCE NUMBER 605 DATED 27/02/2002 GRANTED TO M/S SUN
PHARMACEUTICAL INDUSTRIES LTD, SATHAMMAI VILLAGE, KARUNKUZHI POST,
MADHURANTHAGAM TALUK, KANCHEEPURAM DISTRICT TAMIL NADU -603 303,
INDIA., UNDER WHO GMP NORMS *and valid upto 31.12.2018*

K. DIS No. *18739* D1/2/2016 dt:...../...../2017

1. METADOXINE.

S. Abdul Khader
T/12/17

S. ABDUL KHADER, B.Pharm.,
Director of Drugs Control
359, Anna Salai, Chennai-600 006.

