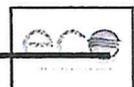


*M/s Sun Pharmaceutical Industries Limited  
Village Sathammai, PO Karunkuzhi, Taluk Maduranthagam,  
Dist. Chengalpattau (Formerly kancheepuram), Tamil Nadu.*

**FORM-I**

9.3	Set a precedent for later developments.	Yes	The industry is an API manufacturing unit which will boost the growth of API industry.
9.4	Have cumulative effects due to proximity to other existing or planned projects with similar effects	No	Not Applicable

(III) Environmental Sensitivity			
S.No.	Areas	Name/ Identity	Aerial distance (within 15 km) Proposed project location boundary
1	Areas protected under international conventions, national or local legislation for their ecological, landscape, cultural or other related value	Vedanthangal lake bird sanctuary	Approx. 3.72 Km (W)
2	Areas which are important or sensitive for ecological reasons - Wetlands, watercourses or other water bodies, coastal zone, biospheres, mountains, forests	Pudupattu lake	Approx. 0.06 Km (WNW)
3	Areas used by protected, important or sensitive species of flora or fauna for breeding, nesting, foraging, resting, over wintering, migration	Valluvapakkam RF	Adjacent to site (E)
4	Inland, coastal, marine or underground waters	No	--
5	State, National boundaries	No	--
6	Routes or facilities used by the public for access to recreation or other tourist, pilgrim areas	NH-32	Approx. 1.13 Km (E)
7	Defense installations	No	--
8	Densely populated or built-up area	Karunguzhi	Approx. 1.44 Km (SE)



Name of Wildlife Sanctuary	Sanctuary Area in Ha	District in which located	Designation of the Officer	Year in which started
<b>Total</b>	606389.657			
<b>BIRDS SANCTUARIES</b>				
Vettangudi birds Sanctuary	38.40	Sivagangai	DFO, Sivagangai	1977
Pulicat Lake Birds Sanctuary	15367	Tiruvallur	WLW, Chennai	1980
Karikili Birds Sanctuary	61.21	Kancheepuram	WLW, Chennai	1989
Kanjirankulam Birds Sanctuary	104.00	Ramanathapuram	WLW, Ramad	1989
Chitrangudi Birds Sanctuary	47.63	Ramanathapuram	WLW, Ramad	1989
Koonthankulam-Kadankulam Birds Sanctuary	129.00	Tirunelveli	DFO, Tirunelveli	1994
Vellode Birds Sanctuary	77.18	Erode	DFO, Erode	1997
Vedanthangal Birds Sanctuary	30.00	Kancheepuram	WLW, Chennai	1998
Udayamarhandpuram Birds Sanctuary	45.28	Tiruvarur	DFO, Tiruvarur	1998
Melaselvanur-Kilaselvanur Birds Sanctuary	593.08	Ramanathapuram	WLW, Ramad	1998
Vaduvloor birds Sanctuary	128.10	Tiruvarur	DFO, Tiruvarur	1999
Karaivetti Birds Sanctuary	453.71	Ariyalur	DFO, Ariyalur	2000
Theerthangal Bird Sanctury	29.29	Ramanathapuram	WLW, Ramad	2010
Sakkarakottai Tank Birds Sanctuary	230.49	Ramanathapuram	WLW, Ramad	2012
Oussudu Lake Birds Sanctuary	331.785	Villupuram	DFO, Villupuram	2015
<b>Total</b>	17666.155			
<b>NATIONAL PARKS</b>				
Guindy National Park	270.57	Chennai	WLW, Chennai	1978
Gulf of Mannar Marine Park (21 Islands) Reserve Land - 623.12 Ha + Sea area - 51978.88 Ha	52602	Ramanathapuram & Tuticorin	WLW, Ramnad	1986



**Map showing Industry location, Vedanthagal Bird Sanctuary and Maduranthagam Lake**

#### 4. NECESSARY CLEARANCES AND CONSENT AND OTHER PERMISSION:

The Sun Pharma an existing pharmaceutical industry was established in the year 1992-93 located at Survey No. 90/2, 90/3, 90/4, 99/1, 99/2, 99/3, 99/4, 99/5, 100/1, 100/2A, 100/2B, 100/3, in Sathammai Village, Karunkuzhi Post, Maduranthagam Taluk, Chengalpattu District, Tamil Nadu. Total land area is 17.27 acres with 31.47% of greenbelt along the periphery and other areas. From the industry, the Vedanthagal Bird Sanctuary is located at 3.72 Km of west. The important water bodies like Maduranthagamlake is located south west of the industry (Maduranthagam Tank: 1.13 km SW Direction; Maduranthagam High Level Channel: 4.93 km SSW Direction)

##### 4.1. Consent under Air and Water Acts:

**Consent issued in 1992:** As per the documents submitted to the Committee, initially, Consent was issued to the M/s Pradeep Exports (A unit of Pradeep drug Company Ltd), Sathammai Village (Maduranthagam Taluk) vide Consent Order No.8850 dated 9-4-1992 under the Water Act, 1974 with validity up to 31-03-1993 and thereafter modification issued on 5-6-1992. The company was later merged with/converted into M/s Sun Pharma Industries Ltd. (Copy of Consent given at ANNEXURE -3).

**Environmental viability study:** A study was conducted in June 2005 by the Anna University, Chennai to assess the environmental viability for the additional products/processes of Sun Pharma (A copy of the report is at ANNEXURE-4)

## GOVERNMENT OF TAMIL NADU

## ABSTRACT



Forests - Declaration of Vedanthangal Lake, Maduranthagan Taluk, Kancheepuram District as Birds Sanctuary - Notification under Section 26 A(i) of the Wildlife (Protection) Act, 1972 - Orders-Issued.

## ENVIRONMENT AND FORESTS (FR.V(1)) DEPARTMENT

G.O.Ms.No.199

Dated: 3.7.1998.

Read :

1. G.O.Ms.No.67, Environment and Forests Department, dated 13.3.96.
2. From the Collector, Kancheepuram District Lr.No.153618/91 FSO, dated 21.5.97.
3. From the Chief Conservator of Forests (Wildlife) and Chief Wildlife No.3137/91 D, dated 5.6.97.

ORDER :

In its orders first read above, the Government have notified its intention to constitute the lake area measuring an extent of 73.06 acres in S.No.220 5 kms. surrounding the lake in Vedanthangal Village, Maduranthagan Taluk, Kancheepuram District, as a Birds Sanctuary under Section 13 (1) of the Wildlife (Protection) Act, 1972. The notification was published in the Tamil Nadu Government Gazette No.13, Part-II Section 2, dated 3.4.1996 in English and in the District Gazette July 1996 of Kancheepuram District, in Tamil Nadu.

2. After observing the due formalities prescribed in Sections 19-25 of the Wildlife (Protection) Act, 1972, the Collector of Kancheepuram District and the Chief Conservator of Forests (Wildlife) and Chief Wildlife Warden in their letters second and third read above respectively have stated that no claims and objection have been received for the constitution of the said area as Birds Sanctuary and that the final notifications may be issued under Section 26 (A)(i) of the Wildlife (Protection) Act, 1972 for declaring the said area as a Birds Sanctuary.

3. The Government, after careful consideration, accept the proposals of the Chief Conservator of Forests (Wildlife) and Chief Wildlife Warden sent in his letter second read above and direct that the lake area in S.No.220 measuring an extent of 73.06 acre and 5 kms. surrounding the said lake in Vedanthangal Village, Maduranthagan Taluk, Kancheepuram District, by reason of the ecological, fauna, flora, geomorphological and zoological associations and importance, be constituted as a Birds Sanctuary for the purpose of protection, propagation and development of wildlife and its environment under Section 26 A(i) of the Wildlife (Protection) Act, 1972.

: 2 :

4. The Notification appended to this Order shall be published both in English and in Tamil in the next issue of Tamil Nadu Government Gazette and in Tamil in the District Gazette of Kancheepuram District.

5. The Tamil Development and Culture Department is requested to send immediately a Tamil translation of the Notification to the works Manager, Government Central Press, Chennai for publication in the Tamil Nadu Government Gazette and in the District Gazette of Kancheepuram District.

6. The works Manager, Government Central Press, Chennai is requested to send twenty copies of each (in English and in Tamil) of the Notifications to the Principal Chief Conservator of Forests, Chennai-15, Chief Conservator of Forests (Wildlife, and Chief Wildlife warden, Chennai-15, Government in Environment and Forests Department and to the Collector of Kancheepuram District, as soon as the Notification is published.

(BY ORDER OF THE GOVERNOR)

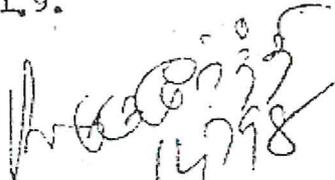
K.S. SRIPATHI  
SECRETARY TO GOVERNMENT

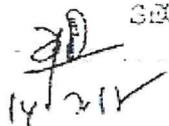
The Works Manager, Government Central Press, Chennai-79.  
The Director of Stationery and Printing, Chennai-2.  
The Principal Chief Conservator of Forests, Chennai-15.  
The Chief Wildlife Warden, Chennai-15.  
The Collector of Kancheepuram District.  
The Tamil Development and Culture Department, Chennai-9.

Copy to:

The Senior PA to the Hon'ble Minister (Forests & Printing), Chennai-9.  
The Secretary to Government of India, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, Lodi Road, New Delhi-3.  
The Law Department, Chennai-9.  
The Revenue Department, Chennai-9.  
The Senior Personal Assistant to the Hon'ble Minister for Revenue, Chennai-9.  
The Senior personal Assistant to the Hon'ble Minister for Public Works, Chennai-9.

FORWARDED/BY ORDER

  
SECTION OFFICER

  
14/3/14

THE SCHEDULE

- (1) Name of the district : Kancheepuram  
 (2) Name of the forest division : Chengalpattu  
 (3) Name of the Taluk : Madurantagam  
 (4) Number and Name of the village : 27, Vedanthangal  
 (5) S.F. Number : 220  
 (6) Name of the sanctuary : Vedanthangal Lake Birds Sanctuary  
 (7) Area of the sanctuary : 73.06 acres or 29.51.6 Hectares  
 and surroundings five kilometres  
 around the lake.

BOUNDARIES

North:- It starts from the trifunction of S.F.No.215, 213 and 220 of Vedanthangal Village.. Thence it runs towards east along the northern boundary of SF Nos.213,234,232,231, 228, 229 and 271.

East :- Thence it runs towards the south along the eastern boundary of S.F.Nos.274, 217 and 226.

South :- Thence it runs north-west along the southern boundary of S.F.Nos.138, 152, 153 and 178 western boundary of S.F.Nos.184 and 218.

West :- Thence it runs towards north along the western boundary of S.F.Nos.215 and 215 until it meets the starting point.

K.S. SRIPATHI  
 SECRETARY TO GOVERNMENT

/ True Copy /

*[Handwritten signature]*  
 11.7.92

ENVIRONMENT AND FORESTS DEPARTMENTAPPENDIXNOTIFICATION

WHEREAS the area specified in the schedule below is not and is not to be comprised within the reserved forest of the territorial matters.

AND WHEREAS the Government of Tamil Nadu considered that the area specified in the schedule below is of adequate ecological and environmental significance for the purpose of protecting birds and their environment.

AND WHEREAS in the Notification issued under sub section (1) of section 18 of the Wildlife (Protection) Act, 1972 (Central Act No. 53 of 1972), the Government of Tamil Nadu declared the intention to constitute the area specified in the schedule to be a Sanctuary and the same has been notified as the Vedanthangal Lake Birds Sanctuary and the same has been published in the Environment and Forests (FR.V) Department Notification No.II(2)/EF/790/96, at page 218 of Part-II Section-2 of the Tamil Nadu Government Gazette, dated the 3rd April, 1996.

AND WHEREAS, the Collector, Kancheepuram District have published a proclamation under Section 21 of the said Act, in and around the village and in the Government Offices of the area comprised therein requiring any person, claiming any right mentioned in Section 19 of the said Act within two months from the date of publication of the proclamation and preferred within the time specified above.

NOW, THEREFORE, in exercise of the powers conferred by sub section (1) of section 26-A of the Wildlife (Protection) Act, 1972 (Central Act 53 of 1972), the Governor of Tamil Nadu hereby declares that the area specified in the schedule below shall be a sanctuary called the 'Vedanthangal Lake Birds Sanctuary' with effect from and from the date of publication of this



निर्गम के लिए नहीं NOT FOR EXPORT

OPEN SERIES MAP

No. D44T14

Scale 1:50,000

D44T9 (57P/9)	D44T13 (57P/13)	D44U1 (65D/1)
Thiruvannamalai TAMIL NADU	Kanchipuram TAMIL NADU	
D44T10 (57P/10)	D44T14 (57P/14)	D44U2 (65D/2)
D44T11 (57P/11)	D44T15 (57P/15)	D44U3 (65D/3)
Vilupuram TAMIL NADU		BAY OF BENGAL

1 Vellore, TAMIL NADU      3 Chennai, TAMIL NADU  
2 Tiruvallur, TAMIL NADU      4 Vilupuram, TAMIL NADU

भारतीय सर्वेक्षण विभाग SURVEY OF INDIA

1st Edition 2011. Price - Rs. 77/-

CONVENTIONAL SYMBOLS

Express highway with toll with bridge with distance road		20
Roads, metalled, according to importance		
Roads, double carriageway, according to importance		
Unmetalled road, Cart-track, Push-back with pass, Feud path		
Streams with track in bed, underflow, Canal		
Dam, masonry or non-flood, with or without Wall		
River, dry with water channel, with island & locks, Tidal river		
Submerged road, Small Swamp, Roads		
Wells, lined, unlined, Tube-well, Spring, Tanks, perennial, dry		
Entertainment road or rail, bank, Breakers ground		
Railways, broad gauge, double, single with station, under earth		
Railways, other gauges, double, single with distance stone		
Mineral line or railway, Kite, Cutting with forest		
Contours with sub-features, Rocky slopes, Cliffs		
Band features (fict. ground subdivisions), (Byamangling)		
Boundaries, political, district, taluk, village, P.T.S.		
Boundaries, religious, Temples, Ancestral		
Temples, Church, Mosque, Jain, Tomb, Graves		
Lighthouses, Lightships, Buoy, lighted, unlighted, Aeronautics		
Mine, Vire on hills, Quarries, Earth		
Fauna, primary, other, Plantation, Conifer, Bamboo, Other trees		
Areas, cultivated, wooded, Surveyed, tree		
Boundary, international		
State, demarcated, undemarcated		
district, sub-division, taluk or block, forest		
Boundary pillars, surveyed, unlocated		
Height, triangulation station, point, approximate		A 200, 200, 200
Bench-mark, geodetic, tertiary, canal		BM 63 3, 63 3, 63 3
Post office, Telegraph office, Overhead tank		
Head house or inspection bungalow, Guard house, Police station		
Camping ground, Forest, reserved, unreserved		
Special areas, administrative, health, or other		KORU, NAGA
Hospital, Dispensary, Veterinary, Hospital, Dispensary		
Aerodrome, Helipad, Tented site		
Power line, with pylons surveyed, with poles unsurveyed		

REFERENCES

NH 45 National Highway No. 45      PHD Public Works Department

NOTES

Height and contour have not been shown.  
Tanks shown by in the area usually contain water from October to February.  
Wells and tube wells are numerous throughout the sheet, some of them have been omitted.  
Papers from the same series, some of them covering tube wells have been omitted.  
Families with occupations are shown thus.

COMPILED INDEX

A Surveyed during 1955-80. Updated for major details during 2004-05.

Projection - UTM Datum - WGS 84

Magnetic Variation from True North about 2° West in 2005. (Values change regularly)

Scale 1:50,000

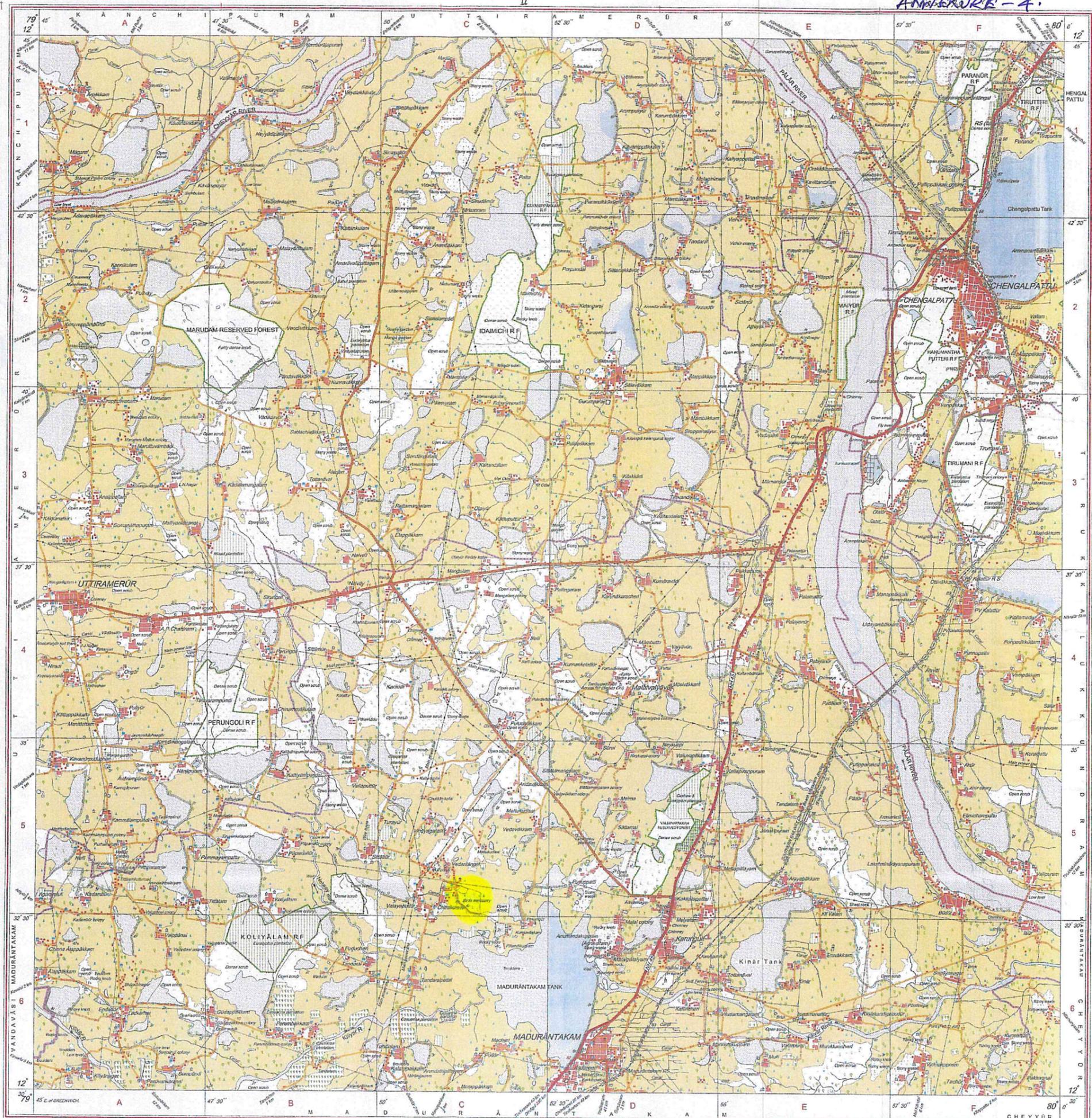


For further details about this map, please contact

Director,  
Tamil Nadu, Puducherry & Andaman Nicobar Islands Geo-Spatial Data Centre  
Survey of India, Guindy  
Chennai.

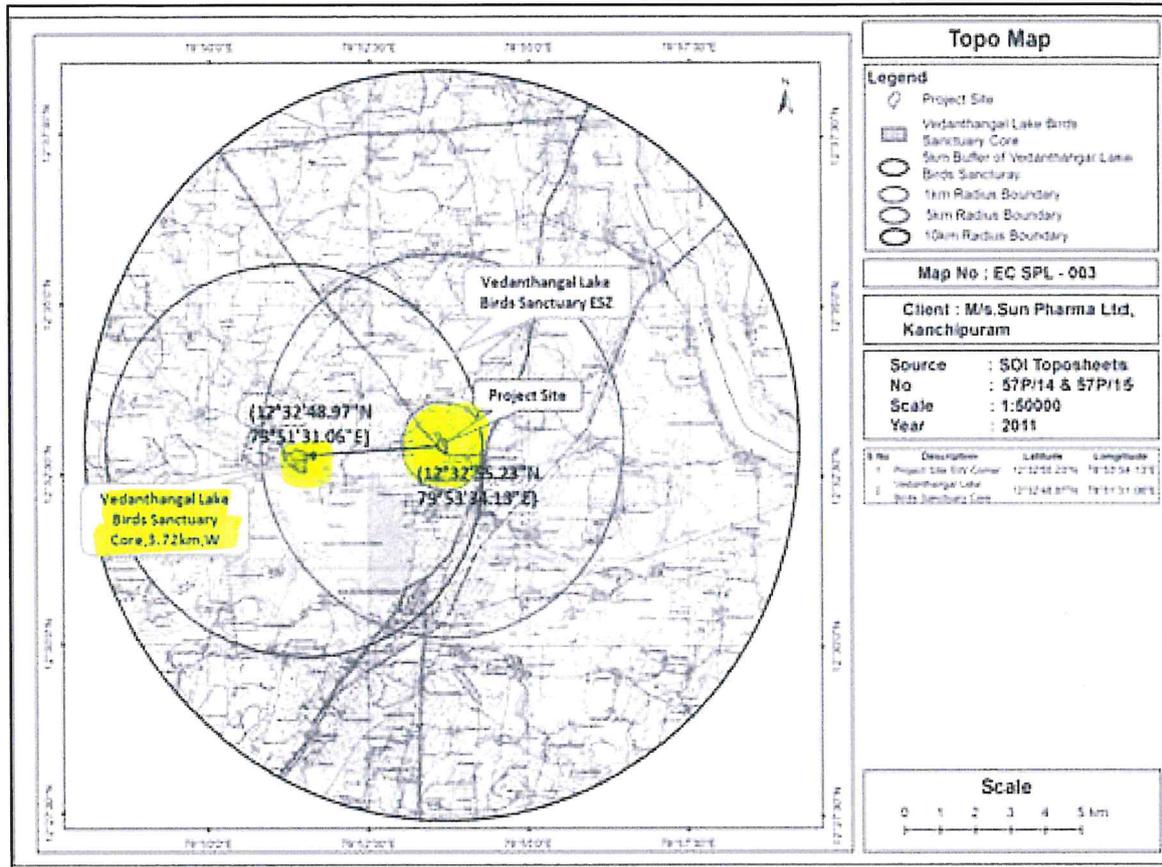
WEBSITE - www.surveyofindia.gov.in

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National Mapping Agency.



M/s Sun Pharmaceutical Industries Limited  
Village Sathammai, PO Karunkuzhi, Taluk Maduranthagam,  
Dist. Chengalpattau (Formerly kancheepuram), Tamil Nadu.

**PRE FEASIBILITY REPORT**



**Figure 6 Topo Map of the Study area**

(iv) Existing land use pattern (agriculture, non- agriculture, forest, water bodies (including area under CRZ)), shortest distances from the periphery of the project to periphery of the forests, national Park, wild life sanctuary, eco sensitive areas, water bodies (distance from the HFL of the river), CRZ. In case of notified industrial area, a copy of the Gazette notification should be given:

Land Use /Land Cover statistics of 10 Km radius of the Study Area is given in **Table 11** and land Use pattern of Study area is given in **Figure 7(a)** and LULC map of the Study area is given in **Figure 7(b)**

**Table 11- Land Use/Land Cover statistics of 10 Km radius of the Study Area**

S.No	Description	%	Sq.Km	Acre	Hec.
1	Cropland	56.58	185.13	45746.55	18513
2	Reservoirs/ Lakes/ Ponds	16.01	52.37	12940.89	5237

**Eco Laboratories & Consultants Pvt. Ltd.**

(QCI-NABET Approved EIA Consultant) EL/EIA/F-5.3/9 Dated 15.07.2019, Rev.01



the EIA Notification, 2006. In the instant case, CTE for the change in product mix was obtained during 2005 and the unit is required to obtain EC under the EIA Notification, 2006 only if it meets the criteria specified in the said Notification, as mentioned in para 11 above. Subsequently, the Ministry vide circular dated 14.12.2006 inter-alia mentioned that in case of change in product mix, changes in the quantities or numbers of products may be allowed without prior EC by the concerned SPCB provided such changes in the quantities of products are in the same category and are within the previously granted total limits.

True copy of above mentioned circulars has been annexed as **ANNEXURE A/8**.

24. It is further submitted that the Project Proponent submitted the Proposal No. IA/TN/IND3/248368/2021 on dated 30.12.2021 for Expansion of APIs Bulk Drug manufacturing unit with production capacity from 25.5 TPM to 134.082 TPM within the Existing Plant which is covered under Category 'B-2'-API of item 5 (f) 'Synthetic, Organic Chemicals Industry' of the schedule to the EIA Notification, 2006 (amendment on 27.03.2020, 15.10.2020 & 16.07.2021).

25. The Project Proponent submitted that the project attracts general conditions as the unit is located at 3.72 km (West) from the boundary of Vedanthangal Bird Sanctuary. Due to the applicability of General Conditions the project was considered in in 27<sup>th</sup> EAC Meeting held on March 7-8, 2022.

True copy of 27<sup>th</sup> EAC Meeting minutes of meeting has been annexed as **ANNEXURE A/9**.

26. That it is submitted that for the projects located inside the wildlife sanctuaries notified under the Wildlife (Protection) Act, 1972 or located in the notified Eco-Sensitive Zone (hereinafter referred to as ESZ) around the wildlife sanctuary or within 10 km of wildlife sanctuary (if ESZ is not notified), require clearance from the Standing Committee of National Board for Wildlife (hereinafter referred to as SCNBWL). The Eco-Sensitive Zone around the Vedanthangal lake Bird Sanctuary is yet to be notified.



Dr. R. Sridhar,  
Scientist 'D'  
Government of India  
Min. of Environment Forest and Climate Change  
Integrated Regional Office  
1st Floor, Additional Office Block for GPOA,  
Shastri Bhawan, Haddows Road  
Nungambakkam, Chennai - 600 006.

27. The Answering Respondent vide Office Memorandum 22-43/2018-IA.III dated 8<sup>th</sup> August, 2019 issued procedure for consideration of developmental projects located within 10 Km of National Park/Wildlife Sanctuary seeking environmental clearance under the provision of Environment Impact Notification, 2006 (hereinafter referred to as EIA Notification, 2006) wherein at SI No 4(iii) it has been mentioned that:

*"(...) Proposals involving developmental activity/project located within 10 km of National Park/Wildlife Sanctuary wherein final ESZ notification is not notified (or) ESZ notification is in draft stage, prior clearance from Standing Committee of the National Board for Wildlife (SCNBWL) is mandatory. In such cases, the project proponent shall submit the application simultaneously for grant of Terms of Reference/environmental clearance as well as wildlife clearance."*

28. That the Project Proponent in its proposal submitted to the Answering Respondent for grant of EC mentioned that project site is located at a distance of 3.72 KM from the Vedanthangal lake Bird Sanctuary. Further, before the grant of EC the Project Proponent has submitted a proposal No. FP/TN/IND/5079/2020 dated 30.05.2020 to state government for obtaining clearance from SCNBWL. Accordingly, the proposal was considered in the Ministry for grant of EC and specific condition was stipulated in EC dated 31st March, 2022 that:

*"(...) (ii) This Environmental Clearance is subject to obtaining the NBWL clearance from the Standing Committee on Wildlife as the Unit is located at 3.72 km (West) from the Vedanthangal Bird Sanctuary."*

A copy of the above mentioned EC dated 31.03.2022 is annexed as ANNEXURE A/10.

29. That it is humbly submitted, after grant of EC, the Integrated Regional Office of the Answering Respondent has inspected the unit on 24.05.2022 and confirmed that the expansion work has not yet started.



**Dr. R. Sridhar,**  
Scientist 'D'  
Government of India  
Min. of Environment Forest and Climate Change  
Integrated Regional Office  
1st Floor, Additional Office Block for GPOA,  
Shastri Bhawan, Haddows Road  
Nungambakkam, Chennai - 600 006.

29

**TimeLine Details**

ANNEXURE - 8

**Proposal received date at each stage of flow.****A. General Details**

(i). Proposal No. : FP/TN/IND/5079/2020

(ii). Name of Project for which Forest Land is required : PROPOSED CHANGE IN PRODUCT MIX AND ENHANCEMENT OF PRODUCTION CAPACITY WITHIN THE EXISTING FACILITY

(iii). Short narrative of the proposal and Project/scheme for which the forest land is required : M/s. Sun Pharmaceuticals Industries Limited an existing Pharmaceutical industry was established in the year 1992-93 located at Sy.No. 90/2, 90/3, 90/4, 99/1, 99/2, 99/3, 99/4, 99/5, 100/1, 100/2A, 100/2B, 100/3, in Sathammai Village, Karunkuzhi PO, Maduranthagam T.K, KancheepuramDist, Tamil Nadu. No

(iv). State : Tamil Nadu

(v). Category of the Project : Industry

(vi). Shape of forest land proposed to be diverted : Linear

(vii). Area of forest land proposed for diversion(in ha.): NIL

**B. Time Line**

Submitted by User Agency	Query for Shortcoming(if any) by Wildlife Warden	Resubmission of Proposal by User Agency	Query by Wildlife Warden for submitting Hard Copies	Uploading(by U.A.) of copies of receipt received from Wildlife Warden	Wildlife Warden	Chief Wildlife Warden	State Government/SBWL	Final Disposal
30/05/2020	15/06/2020	26/12/2020			Wildlife Warden, Chennai			

**C. Essential Details Sought History**

Communication between MoEFCC(WL),New Delhi & State Government	Communication between State Government & Chief Wildlife Warden	Communication between Chief Wildlife Warden & Wildlife Warden	Communication between Wildlife Warden & User Agency

NOTE:- Proposal is pending at : **Wildlife Warden.**

not available, the IAA can examine the project on the basis of available data.

## 7. Application Form

(i) In order to remove any hardship to the project proponent in providing any information, the project proponent may, where some information is not available or would cause inordinate delay, mention this in their application form. The IAA may consider the project proposal based on the information available.

(ii) Quality and quantity of ground water

If 15 years data on the quantity and quality variation of ground water is not available with the concerned Department or Authorities, the project proponent may mention this accordingly in the application form prescribed in Schedule-II to the notification. Further, in case of projects, where ground water is not to be used, and effluents are not to be discharged on the land, the requirement of ground water variation data for the previous 15 years will be dispensed with.

(iii) A project proponent may write the words "Not Applicable" while filling the application form as mentioned in Schedule-II to the notification in respect of items which are not relevant for the purposes of the proposed project.

## 8. Exemption for projects already initiated

For projects listed in Schedule-I to the notification in respect of which the required land has been acquired and all relevant clearances of the State Government including NOC from the respective State Pollution Control Boards have been obtained before 27th January, 1994, a project proponent will not be required to seek environmental clearance from the IAA. However those units who have not as yet commenced production will inform the IAA.

Registered Post with  
Acknowledgement Due  
(This document contains 3 pages)



## TAMIL NADU POLLUTION CONTROL BOARD, MADRAS

**CONSENT ORDER No. 6219**

**DATED: 7.4.92**

Proceedings No: **TI/CBT-MGR (S)/F-2057/A/**

**DATED: 7.4.92**

Consent for Existing/New operation of the plant under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981 as amended.

Sub: TAMIL NADU POLLUTION CONTROL BOARD - CONSENT -  
MESSRS

**Pradeep Exports,**  
R.S.No.90/3, 90/4, 99/1, 99/3, 99/4, 99/5,  
100/1, 100/2 A, 100/2B, 100/3,  
**Sathanai,**  
**Maduranthagam Taluk,**  
**Chengalpattu-MGR District.**

for the existing/new operation of the plant under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981 as amended.

Ref: 1. Your Application No. **20462** dt.9.1.92

2. I.R.No. DEE/CA(S)/F-112-10/W&A/ dt.24.1.92

Board Resolution No. **117 - 225**

**Dated: 6.3.92**

CONSENT is hereby granted under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981 (Central Act 14 of 1981) as amended (hereinafter referred to as "The Act") and the rules and orders made thereunder to

**The Managing Director,**  
**M/s. Pradeep Exports,**  
R.S.No.90/3, 90/4, 99/1, 99/3, 99/4, 99/5,  
100/1, 100/2A, 100/2B, 100/3,  
**Sathanai,**  
**Maduranthagam Taluk,**  
**Chengalpattu-MGR District.**

(hereinafter referred to as "The Applicant") authorising him/her/them to operate his/her/their industrial plant in the Air Pollution Control Area as notified by the Government and to ~~continue to make existing discharge of emissions~~/make new discharge of emissions from the stacks/chimneys.

This is subject to the provisions of the Act and the rules and orders made thereunder and further subject to the terms and conditions incorporated in the Special and General Conditions annexed.

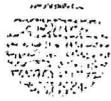
This CONSENT is valid for a period ending with the 31st day of March 1993.

Thirty First, March, Nineteen Ninety three.

for   
Chairman  
Tamil Nadu Pollution Control Board  
Madras



V.C.P.  
By Registered Post with  
Acknowledgement Due  
(This document contains 12 pages)



TAMIL NADU POLLUTION CONTROL BOARD, MADRAS

CONSENT ORDER NO: 8859

DATED: 7.4.92

Proceedings No: TL/GPE-MR(S)/E-2057/W

DATED: 7.4.92

Consent for Existing/New or Altered-outlet/dischage of sewage and/or-trade effluent under Section 25/26 of the Water (Prevention and Control of Pollution) Act, 1974 as amended.

Sub: TAMIL NADU POLLUTION CONTROL BOARD - CONSENT -  
MESSRS.

Pradeep Exports  
R.S.No.90/3, 90/4, 99/1, 99/3, 99/4, 99/5, 100/1,  
100/2A, 100/2B, 100/3  
Sathanal  
Maduraothayam Taluk  
Chengalpattu MR District.

for its discharge of sewage and/or trade effluent under Section 25/26 of the Water (Prevention and Control of Pollution) Act, 1974 (Central Act, 6 of 1974) as amended.

- Ref: 1. Your Application No. 20502 dated 9.1.92
- 2. I. R. NO. DCE/CA(S)/E-112-10/MSA/dated 24.1.92.

CGP/Board Resolution No. 117.....225

Dated: 6.3.92

CONSENT is hereby granted under Section 25/26 of the Water (Prevention and Control of Pollution) Act, 1974 (Central Act, 6 of 1974) as amended (hereinafter referred to as "The Act") and the rules and orders made thereunder to

The Managing Director  
M/s. Pradeep Exports  
R.S.No.90/3, 90/4, 99/1, 99/3, 99/4, 100/1, 100/2A, 99/5,  
100/2B, 100/3  
Sathanal  
Maduraothayam Taluk  
Chengalpattu MR District.

(hereinafter referred to as "The applicant") authorizing further (here) to continue/commence into make new discharge or re-new/alter outlet for discharge of sewage and/or trade effluent

This is subject to the provisions of the Act and the rules and orders made thereunder and further subject to the terms and conditions incorporated in the Special and General Conditions annexed.

This CONSENT is valid for a period ending with the 31st day of March 1993.  
(Thirty First March Nineteen Ninety and Ninety).

Managing Director  
Tamil Nadu Pollution Control Board  
Madras

To

7  
 The Building Director  
 M/s. Pradeep Exports  
 (A unit of M/s. Pradeep Drug Co. Ltd.)  
 26B, Lloyds Road  
 Madras - 600 014.

Copy to: The District Environmental Engineer, Tamil Nadu Pollution Control Board,

Tambaram

for information and necessary action

Copy to: The Senior Environmental Engineer, Tamil Nadu Pollution Control Board,  
 Madras Region.

Copy to: The Commissioner/Executive Officer  
 Maduranthagam Panchayat Union  
 Maduranthagam  
 Chengalpattu MR District.

Encl.

SPECIAL CONDITIONS1. Details of the Products Manufactured

Sl.No. (1)	Description (2)	Quantity/Month (3)
1.	Paracetamol	3.0 T.
2.	Aspirin	30.0 T.
3.	Mebendazole	3.0 T.

This consent is valid for the manufacture of products and rate of production mentioned above. Any change in the quantity or quality of the products has to be brought to the notice of the Board and fresh consent has to be obtained.

2. Discharge of effluent is permitted from the following outlets. The quantity of effluent discharged shall not exceed the figures mentioned below:

Outlet Number. (1)	Description of Outlet (2)	Maximum daily Discharge (in litres/day) (3)	Point of Disposal (4)
1.	Domestic	6000	On Industry's land.
2.	Trade effluent	48500	Inland surface water.
3.			
4.			
5.			
6.			
7.			

RECEIVED  
5 JUN 1992  
SECRET



TAMILNADU POLLUTION CONTROL BOARD

Proceedings No. T3/CPT-MGR(5)/F-2057/NEA/G.M.: 2.6.92.

D. V. K. N.  
1.6.92

Sub: TNPC Bd - Industries - M/s. Pradeep Exports -  
Sathammai, Maduranthakam Taluk - Chengalpattu  
M.G.R. District - Amendment Issued - Regarding.

- Ref: 1. T.O. Proc. No. T1/CPT-M.G.R. (5)/F-2057/A/  
dated 7.4.92.  
2. T.O. Proc. No. T1/CPT-M.G.R./F-2057/A/  
dated 7.4.92.

\*\*\*\*\*

Under Section 25 of the Water (Prevention and Control of Pollution) Act, 1974 and under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981, consent has been issued to the unit to manufacture the following products,

- |                |   |          |
|----------------|---|----------|
| 1. Furosemide  | - | 3.0 T/M  |
| 2. Analgin     | - | 30.0 T/M |
| 3. Mebenezolol | - | 3.0 T/M  |

Under section 27 of the Water (Prevention and Control of Pollution) Act, 1974 and under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981, the manufacturing products may be altered to read as follows:

- |                |   |          |
|----------------|---|----------|
| 1. Furosemide  | - | 3.0 T/M  |
| 2. Analgin     | - | 30.0 T/M |
| 3. Mebenezolol | - | 5.0 T/M  |

All other conditions stipulated in the consent order remain unaltered.

*D. V. K. N.*  
1.6.92  
FOR CHAIRMAN.

To  
The Managing Director,  
M/s. Pradeep Exports,  
(A unit of Pradeep Drug Company Limited,  
268 Lloyds Road, Madras 600 014.

Copy to  
The District Environmental Engineer,  
TNPC Board, Tambaram.

Copy to  
The Senior Environmental Engineer,  
TNPC Board, Madras.

The Commissioner, Maduranthakam Panchayat Union,  
Maduranthakam, Chengalpattu M.G.R. District - 603 772. Tel: 75744, 75745  
Tel: 044 - 7574 7501-18. Telephone: 044 - 757420

**EXPLANATORY NOTE REGARDING THE IMPACT  
ASSESSMENT NOTIFICATION  
DATED 27TH JANUARY, 1994**

**1. Expansion and modernisation of existing projects**

A project proponent is required to seek environmental clearance for a proposed expansion/modernisation activity if the resultant pollution load is to exceed the existing levels. The words "pollution Load" will in this context cover emissions, liquid effluents and solid or semi-solid wastes generated. A project proponent may approach the concerned State Pollution Control Board (SPCB) for certifying whether the proposed modernisation/expansion activity as listed in Schedule-I to the notification is likely to exceed the existing pollution load or not. If it is certified that no increase is likely to occur in the existing pollution load due to the proposed expansion or modernisation, the project proponent will not be required to seek environmental clearance, but a copy of such certificate issued by the SPCB will have to be submitted to the Impact Assessment Agency (IAA) for information. The IAA will however, reserve the right to review such cases in the public interest if material facts justifying the need for such review come to light.

**2. Availability of Summary Feasibility Report, EIA/EMP Report etc. to concerned parties or groups**

The project proponent will have to submit an executive summary incorporating in brief the essence of project details and findings of environmental impact assessment study which could be made available to concerned parties or environmental groups on request.

**3. Clarification about concerned parties or environmental groups**

The concerned parties or environmental groups will be the bonafide residents located at or around the project site or

7. As mentioned above, M/s Pradeep Exports had obtained consent for manufacturing of three products viz. Furosemide, Analgin and Mebenzole from Tamil Nadu Pollution Control Board on 03.06.1992 i.e. prior to the EIA Notification, 1994. As the respondent unit started its operations prior 1994, the unit would have to apply for EC under EIA Notification, 1994 if there was any expansion or modernization of any activity if pollution load is to exceed the existing one.
8. Subsequently, as claimed by the applicant, the plant had been acquired by M/s Sun Pharmaceutical Industries Ltd in the year 1999. It is submitted that although the plant had been acquired by the M/s Sun Pharmaceutical Industries Ltd from M/s Pradeep Exports but there was no provision for transfer of EC in EIA Notification, 1994.
9. Environment and Forest Department of Govt. of Tamil Nadu vide G.O.Ms. No. 67 dated 13.03.1996, notified its intention to constitute the lake area measuring an extent of 73.06 acers in S.No. 220, 5 km surrounding the Vedanthangal Village as Bird Sanctuary.
10. Subsequently, on 3.07.1998 G.O. Ms No. 199 was issued by the Government of Tamil Nadu under Section 26 (A) of the Wildlife Protection Act, 1972 notifying the lake and surrounding 5 km as Vedanthangal lake Bird Sanctuary.  
A copy of the G.O. Ms No. 199 issued by the Government of Tamil Nadu dated 3.07.1998 is annexed as ANNEXURE A/3.
11. However, it is submitted that subsequently the Answering Respondent notified EIA Notification, 2006 on 14.09.2006 under the provisions of the Environment (Protection) Act, 1986 in supersession of the notification number S.O. 60 (E) dated 27th January, 1994. The notification mandated the following:

*"(...) required construction of new projects or activities or the expansion or modernization of existing projects or activities listed in the Schedule to this notification entailing capacity addition with change in process and or technology shall be undertaken in any part of India only after the*

*C. Palpandi*

Dr. C. Palpandi,  
Scientist "D"  
Government of India  
Min. of Environment Forest and Climate Change  
Integrated Regional Office  
1st Floor, Additional Office Block for GPOA,  
Shastri Bhawan, Haidowas Road  
Nungambakkam, Chennai - 600 006.

"(...)3. Further, it is also seen from the report that there was manufacturing of certain new product have been included after 1994 and whether they had obtained necessary Environmental Clearance (EC) even as per the Notification 1994 is not clear from the report submitted.

5. The Ministry of Environment, Forests and Climate Change is also directed to clarify this aspect especially, when M/s Sun Pharma Industries Limited (Sun Pharma) is situated within Vedanthangal Lake/ Bird Sanctuary itself."

5. That it is humbly submitted that as per available information the Tamil Nadu Pollution Control Board (hereinafter referred to as TNPCB) initially granted consent vide order no. 8850 dated 07.04.1992 with a validity upto 31.03.1993 and thereafter modification was issued on 03.06.1992, vide which consent was granted under Section 25 of the Water (Prevention and Control of Pollution) Act, 1974 and under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981 to M/s Pradeep Exports for manufacturing of three products viz. Furosemide (3.0 Tons/Month), Analgin (30.0 Tons/Month) and Mebenezole (3.0 Ton/month) with a total production capacity of 38 T/M.A copy of the Consent order granted to M/s Pradeep Exports dated 07.04.1992 & 03.06.1992 is annexed as ANNEXURE A/1.
6. That it is submitted that the answering respondent issued Environment Impact Notification, 1994, vide S.O. 60 (E) dated 27.01.1994 (hereinafter referred to as EIA, Notification 1994) mandating the requirement of Environment Clearance (hereinafter referred to as EC) for undertaking any expansion or modernization of any activity if pollution load is to exceed the existing one, or new project listed in Schedule-I to this notification in any part of India. That it is further submitted that the requirement of prior EC for Bulk drugs and Pharmaceuticals was inserted in the Schedule-I at entry 8 in EIA Notification, 1994.

True copy of the above mentioned notification has been annexed as ANNEXUREA/2.

*C. Palpandi*  
Dr. C. Palpandi,  
Scientist "D"  
Government of India  
Min. of Environment Forest and Climate Change  
Integrated Regional Office  
1st floor, Additional Office Block for GPOA,  
Shastri Bhawan, Haddows Road  
Nungambakam, Chennai - 600 006.

5. That it is respectfully submitted that the matter OA No. 88 of 2020 titled Meenava Thanthai K. R. Selvaraj Vs Union of India & Ors. is under adjudication before this Hon'ble Tribunal with respect to the same project nonetheless with a different prayer.
6. That it is humbly submitted that as per available information the Tamil Nadu Pollution Control Board (hereinafter referred to as TNPCB) initially granted consent vide order no. 8850 dated 07.04.1992 with a validity upto 31.03.1993 and thereafter modification was issued on 03.06.1992, vide which consent was granted under Section 25 of the Water (Prevention and Control of Pollution) Act, 1974 and under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981 to M/s Pradeep Exports for manufacturing of three products viz. Furosemide (3.0 Tons/Month), Analgin (30.0 Tons/Month) and Mebenzole (3.0 Ton/month) with a total production capacity of 38 T/M.  
A copy of the Consent order granted to M/s Pradeep Exports dated 07.04.1992 & 03.06.1992 is annexed as ANNEXURE A/1.
7. That it is submitted that the answering respondent issued Environment Impact Notification, 1994, vide S.O. 60 (E) dated 27.01.1994 (hereinafter referred to as EIA, Notification 1994) mandating the requirement of Environment Clearance (hereinafter referred to as EC) for undertaking any expansion or modernization of any activity if pollution load is to exceed the existing one, or new project listed in Schedule-I to this notification in any part of India. That it is further submitted that the requirement of prior EC for Bulk drugs and Pharmaceuticals was inserted in the Schedule-I at entry 8 in EIA Notification, 1994.  
True copy of the above mentioned notification has been annexed as ANNEXUREA/2.
8. As mentioned above, M/s Pradeep Exports had obtained consent for manufacturing of three products viz. Furosemide, Analgin and Mebenzole from Tamil Nadu Pollution Control Board on 03.06.1992 i.e. prior to the EIA Notification, 1994. As the respondent unit started its operations prior 1994, the unit would have to apply for EC under EIA Notification, 1994 if there

  
Dr. R. Sridhar,  
Scientist 'D'  
Government of India  
Min. of Environment Forest and Climate Change  
Integrated Regional Office  
1st Floor, Additional Office Block for GPOA,  
Shastri Bhawan, Haddows Road  
Nungambakkam, Chennai - 600 006.

*Report on*

**PREPARATION OF ENVIRONMENTAL VIABILITY FOR SUN  
PHARAMACEUTICAL INDUSTRIES LIMITED, SATHAMAI VILLAGE,  
MADHURANTHAKKAM TALUK**

*submitted to*

**Sun Pharmaceutical Industries Limited  
(SPIL)**

*Prepared by*



**Centre for Environmental Studies  
Anna University, Chennai – 600 025**

**June, 2005**

## Chapter I

### Introduction

#### 1.0 General

Sun Pharmaceuticals Industries Limited (SPIL) is an established public limited company, managing its operation in the field of bulk drugs and intermediates manufacturing in the region of Maharashtra and Gujarat. The present manufacturing facility was originally established during the year of 1990 and is located at Sathammai Village under Maduranthakam Taluk in Kancheepuram District.

The SPIL is proposing to manufacture ten new pharmaceutical products at the facility in Sathammai village, Maduranthakam Taluk. The SPIL has already obtained license for three products that are

1. Frusemide
2. Analgin
3. Mebendazole

In the present scenario, the SPIL has approached Centre for Environmental Studies (CES) to evaluate ten new products that are listed below:

1. Metadoxine
2. Metoprolol Tartrate
3. Analgin Magnesium
4. Tramadol HCl
5. Carbamazepine
6. Flurbiprofen
7. Danazol
8. Clomipramine
9. Sodium Valproate
10. Oxetacaine



The scope of the study was to evaluate the processes of the ten new products and prepare an Environmental Viability Report based on the waste generated by the ten proposed process.

The scope of the present study on preparation of an Environmental Viability Report for SPIL is to evaluate stoichiometrically the reaction equations of all the processes and to check the validity of the processes. Further, based on the input given by the SPIL a detailed mass balance study was conducted for each processes and the total waste generated have been determined.

### 1.1 Objectives

The overall aim of the present study is to prepare an Environmental viability report based on waste generated by the ten new processes. Accordingly the following objectives have been formulated and furnished below

1. To determine stoichiometrically, the validity of the reaction equations for all the processes.
2. To conduct a mass balance study to determine the waste generated by the processes.
3. To prepare the Environmental viability report based on the information derived from the above objectives.



## Chapter II Process Evaluation

### 2.0 Introduction

The Sun Pharmaceutical Unit has obtained permission and environmental clearance to manufacture the following Pharmaceutical products with the rate of production per month

- 1. Frusemide - 3.0 T/M
- 2. Analgin - 30.0 T/M
- 3. Mebendazole - 5.0 T/M

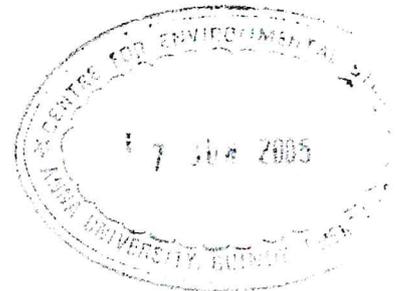
[Vide Lr. Procs. No. T3/CPT-MGR (S)/F -2057W&A dated 2.6.92  
Tamil Nadu Pollution Control Board (copy of this is annexed at the end of this report)].

The SPIL has know proposed to abandoned the existing manufacturing processes and commence production of ten new products as detailed in chapter I. It is now essential that in the event of new processing and consequently the loading of the waste into the environment has to be understood so as to ascertain the environmental quality. Hence, it is mandatory to determine the amount of waste generated by individual processes.

The following sections discuss the methodology adopted to determine the waste generated by the processes.

### 2.1 Methodology

The reaction equations for all the processes have been obtained (though it is confidential and not to be shared with any agencies). The equations have been checked stoichiometrically and number of moles of all the reactants in the reaction equations have been ascertained. The critical reactant has been identified and the number of moles of the yield has been checked for the validity of the reactions equations.



### 2.1.1 Mass Balance

Based on the data supplied by the SPIL for all the ten products, mass balance on reactants, solvents, products and waste generated have been analyzed. The summary of the waste generated by individual processes have been furnished.

### 2.2. Evaluation of Proposed Processes

The detailed process flow chat for all the processes have been collected and the stage wise input of all the processes have been worked out and listed in the Flow Chart. Similarly, the stage wise output from the process flow chart has been determined and furnished in the flow chart.

- The Summary of all the input into the control volume and output from the control volume have been summarized at the end of the process evaluation. The following sections discuss the process evaluation of the ten products.



The waste to be generated in the ten proposed processes are summarized below in the Table 2.2

Table 2.2. Summary of Waste generation

S. No.	Product	Cumulative Waste			Total
		Solid Kg.	Liquid (Weak + Strong)	Solvent Loss Lt.	
1.	Metadoxine	40.72	140(W) + 0 (S)	100	40.72 kg + 240 L
2.	Metaprolol Tartrate	Nil	1870 (W) + 1260 (S)	20	3150 L
3.	Analgin Magnesium	Nil	470 (W) + 172 (S)	4	646 L
4.	Tramadol HCL	Nil	0 (W) + 4100 (S)	87	4187 L
5.	Carbamezepine	3.0	1100 (W) + 2368.4 (S)	100	3 kg + 3568.4 L
6.	Flurbiprofen	50	2250 (W) + 5700 (S)	25	50 kg + 7975 L
7.	Danazol	2.0	158 (W) + 870 (S)	20	2 kg + 1048 L
8.	Clomipramine	65.0	6900 (W) + 107 (S)	90	65 kg + 7097 L
9.	Sodium Valporate	24.4	3175 (W) + 725 (S)	21	24.4 kg + 3921 L
10.	Oxetacine	5.0	5060 (W) + 1237 (S)	40	5 kg + 6297 L
	<b>Total Waste</b>	190	21123 (W) + 16539.4 (S)	507	190 kg + 38169.4 L

Waste oil – Apart from the process waste pump operation (maintenance section) generates waste oil to the extent of 0.125 ton per month.



## Chapter III

### Summary and Conclusion

#### 3.0 Introduction

The detailed calculation based on stoichiometry of the new processes (10 no's) and the relevant information is furnished by the SPIL. The waste generated per batch size of production has been arrived at and summed up in chapter II. The total waste generated by the processes for their varying target. The product wise waste generation has been worked out and the details of which is furnished in table 3.1.

#### 3.1 Waste Comparison

The Table 3.1 reveals the total effluent in the form of liquid, solid and other losses for all the proposed processes per month.

The total Solid waste generated = 1315 Kg

The total Liquid waste generated = 10,36,380 Lt

The total Solvent Loss generated= 4646 Lt

The Wastewater generation during the present and future scenario is provided in table 3.2.

The above figures have been compared with the permitted discharge of effluent by the TNPCB is shown in table 3.3 below. To ensure the minimization of solvent loss to atmosphere, proper scrubber system should be in operation.

**Table 3.3**

Comparison of permitted waste Vs Generated by process reactions

Permitted Waste by TNPCB	Proposed Waste to be generated (per day)
Trade effluent – 48,500 L/day Sewage - 6,000 L/day	Liquid Waste = 34546 Lt Solvent Loss = 155 Lt Sewage = 6000 Lt (no change)
Total 54,500 L/day	Total 40689 Lt

**Note:** 44 Kg of Solid Waste generated per day to be managed as per TNPCB norms



### 3.2 Conclusion:

It is observed from the above Table 3.2 that the waste generated by the proposed processes are less than the permitted amount of waste generation by TNPCB vide Annexure I enclosed.

TNPCB has given consent for the three approved products namely Frusemide, Analgin, Mebendazole for discharge of trade effluent of 48,500 L/day and Sewage of 6000 L/day.

The liquid waste likely to be generated in view of the new proposed activity is worked out to be 34500 L/day which is less than is less than the earlier permitted effluent discharge load. This trade effluent and sewage are to be managed as per discharge standards of TNPCB.

The solid waste likely to be generated because from the process of the new proposed activity is worked to be 22.09 T/year. This is also in the limit of TNPCB earlier approved quantity of 46.8 T/year. The waste oil to be managed per year is 1.5 ton. This is also within the permitted limit of 1.5 ton. These solid waste and waste oil are to be managed as per hazardous waste rule.

The waste generation is expected to be reduced during the production of the proposed new products in the place of the existing products.



F. No. J-11013/41/2006-IA-II (I)  
Government of India  
Ministry of Environment and Forest  
IA Division

Paryavaran Bhawan, CGO Complex  
Lodi Road, New Delhi-110 003  
Dated the December 14, 2006

**CIRCULAR**

Subject: **EIA Notification dated 14<sup>th</sup> September, 2006 - Clarification regarding EIA Clearance for Change in Product-Mix.**

Pursuant to the new Environment Impact Assessment Notification of 14<sup>th</sup> September 2006 (EIA 2006) replacing the EIA Notification of 27<sup>th</sup> January 1994 and its various amendments (EIA 1994) and in terms of the provisions of Para 12 of EIA 2006, the Ministry had earlier issued Interim Operational Guidelines on 13<sup>th</sup> October 2006. Further to these Guidelines, the following clarification is issued for Environment Clearance for the category of products involving change in Product- Mix.

- (i) **In cases of change in Product -Mix, changes in the quantities or numbers of products may be allowed without prior Environmental Clearance by the concerned State Pollution Control Board provided such changes in the quantities of products are in the same category and are within the previously granted overall total limits.**
  - (ii) Projects involving modernization of the existing unit with increase in the total production capacity beyond the threshold limit specified in the Schedule to the Notification, through change in process or technology or change in the product mix or debottle-necking or a combination of these, involving increase in pollution load will obtain prior Environment Clearance from the concerned regulatory authority under the EIA Notification, 2006.
2. This issues with the approval of the Competent Authority.

(Sanchita Jindal)  
Additional Director

**To:**

1. All State Environment Departments
2. All State Pollution Control Boards
3. All Officers of IA Division, MoEF
4. UT Administrations

**Copy to:** (i) PPS to Secretary (E&F), (ii) PPS to AS (CC) and (iii) PPS to JS (CC-II)

TAMIL NADU POLLUTION CONTROL BOARD

By Registered Post with Acknowledgement Due (This document contains 2 Pages)

TAMIL NADU POLLUTION CONTROL BOARD

CONSENT ORDER NO. : 3094

Proceeding No. : 110/TRPCDU/T2037/27/A

DATE : 30.11.2005

DATE : 30.11.2005

Consent for Establishment under Section 21 of the AIR (Prevention and Control of Pollution) Act-1986 as amended in 1987.

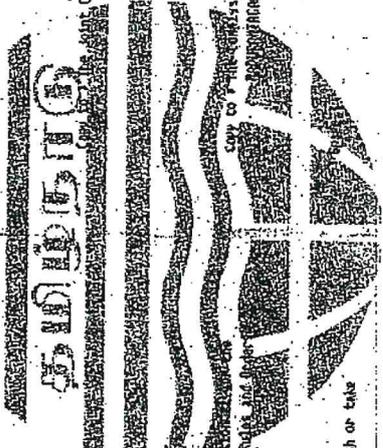
Sub : TREC Board - Consent for establishment RESELES SUN PHARMACEUTICAL INDUSTRIES LIMITED, S.NO.90/3 ETC., SATHANAHAI VILLAGE, MADURANTHAR TALUK, KANCHEEPURAM DISTRICT.

Copy to : The District Environmental Engineer, Tamil Nadu Pollution Control Board, KANCHEEPURAM DISTRICT.

For information and necessary action.

- Ref : 1. YOUR APPLICATION NO.678 DATED 22.6.2005
- 2. AIR NO.662/TRPCDU/KP/28-29/2005 DATED 25.7.2005
- 3. SUBCOMMITTEE RESOLUTION NO.2-50 DATED 16.11.2005

For the establishment or take steps to establish the industry under Section 21 of the AIR (Prevention and Control of Pollution) Act, 1986 as amended in 1987.



Chief Environmental Engineer, TRCO,

BOARD RESOLUTION NO :

DATE :

Consent to establish or take steps to establish is hereby granted under Section 21 of the AIR (Prevention and Control of Pollution) Act, 1986 as amended in 1987 and the Rules and orders there under to

THE NONGER-OPERATION,

S/6, SUN PHARMACEUTICAL INDUSTRIES LIMITED,

(hereinafter referred to as 'the Applicant') authorising him/herself to establish or take steps to establish the industry in the site mentioned below

S-NO.90/3 ETC., SATHANAHAI VILLAGE,

MADURANTHAR TALUK,

KANCHEEPURAM DISTRICT.

This consent to establish is valid for TWO years, or till the industry ceases to operate under Section 21 of the AIR (Prevention and Control of Pollution) Act, 1986 as amended in 1987 whichever is earlier.

*Chairman*

FOR MEMBER SECRETARY  
TAMIL NADU POLLUTION CONTROL BOARD  
SECRETARY

2/12

ANNEXURE - 15

49

# TAMIL NADU POLLUTION CONTROL BOARD

3-

## SECTION - CONDITIONS

### 1. Details of the products manufactured

Sl.No.	DESCRIPTION	QUANTITY/RATE
(1)	(2)	(3)

ANNEXURE-I ENCLOSED

This consent is to establish its valid for the manufacture of products and the rate of emission of pollutants as mentioned above. Any change in the quantity or quality of the products has to be brought to the notice of the Board.



### 2. The height of following chimney/stacks shall not be less than the figures mentioned below for the discharge of effluent.

Sl.No.	Description of chimney / Stack	Height (Above ground)

ANNEXURE-II ENCLOSED

4-

### 3. The Unit shall install the following air-pollution control equipments / systems for the control of emissions generated from the various sources of the plant.

#### a. For suspended particulate emission

Sl.No.	SOURCE	DETAILS OF CONTROL OF EQUIPMENT

#### b. For gaseous emission

Sl.No.	SOURCE	DETAILS OF CONTROL OF EQUIPMENT

ANNEXURE-III ENCLOSED

# TAMIL NADU POLLUTION CONTROL BOARD

3. For fugitive emissions :

BL.NO. SOURCE

Sl. No. Location of the Sensor No. of Sensor Parameters

7. The unit shall provide sensors connected with the alarm system for the following locations in the plant:



4. The unit shall procure of sufficient air quality in respect of the parameters SPH, PM, SO<sub>2</sub>, NO<sub>x</sub>.
5. The unit shall procure monitoring for the SPH, SO<sub>2</sub>, NO<sub>x</sub> parameters and keep ready.
6. The unit shall provide on line / automatic continuous stack monitoring unit for the stacks mentioned below :

Sl. No. SOURCE

Sl. No. SOURCE STACK

ANNEXURE-24 ENCLOSED

provide port holes and sampling facilities for the following stacks as per the Central Pollution Control Board guidelines.

# TAMIL NADU POLLUTION CONTROL BOARD

7. The unit shall provide sufficient acoustic measures for the following equipments:

Sl. No.	SOURCE	TYPE OF MEASURES
01.	DIESEL GENERATOR SET	ACQUISITE ACOUSTIC MEASURES

## GENERAL CONDITIONS

1. The above consent to establish cannot be continued or renewed or extended.
2. The applicant shall make a request for grant of consent to operate within sixty days before the commencement of trial production.
3. The unit shall carry out ambient air quality survey atleast for seasons for the collection of baseline data, on the existing ambient air quality level within the plant / outside the plant.
4. The applicant shall provide a meteorological station to collect the data on wind velocity, direction, temperature, rainfall etc.
5. The applicant shall prepare and submit a detailed risk assessment report alongwith on site and off-site Emergency preparedness plan for within the premises of the plant as required under the Rules 13 and 14 of the Manufacture, Storage and Import of Hazardous Chemicals Act, 1988 as amended.

## BIBIPICO



10. The unit shall install separate energy meter for the operation of the following Pollution Control equipments:

Sl. No.	SOURCE	AIR POLLUTION CONTROL MEASURE

- The unit shall install an capacity generator exclusively for the operation of Air Pollution Control measures in case of power failure.
- The unit shall also establish laboratory for analysis of gases / particulates/acid rain.
- The unit shall ensure that the conditions has to be brought to the notice of the Board and get approved by the Board before obtaining consent to operate when the unit is to be started.
- The unit has to comply with the provisions of Public Liability Insurance Act, 1971 to provide immediate relief in the event of any hazard to human beings / other living creatures/plants and properties while handling and storage of hazardous substances.
- Consent to operate will not be issued unless the unit complied with the conditions of consent to establish, otherwise the order of consent to establish already issued will be revoked with immediate effect.

(Continued in Measure-1)

*[Signature]*  
 Chairman  
 FOR MEMBER-SECRETARY  
 TAMIL NADU POLLUTION CONTROL BOARD  
 CHENNAI  
 2/12

*[Signature]*  
 Chairman  
 FOR MEMBER-SECRETARY  
 TAMIL NADU POLLUTION CONTROL BOARD  
 CHENNAI  
 2/12

**CONSENT TO ESTABLISHMENT UNDER AIR (P&CP) Act, 1981,  
AS AMENDED CONSENT ORDER NO.3094, Dated 30-11-2005**

**ANNEXURE-I**

Details of Products manufactured:-

Sl.No.	Description	Quantity/month
1.	Analgin Magnesium	6 T/Month
2.	Sodium Valporate	8 T/Month
3.	Oxectacine	1 T/Month
4.	Clomipramine	1 T/Month
5.	Flurbiprofen	1 T/Month
6.	Carbamazepine	4 T/Month
7.	Mepoprolol tartrate	3 T/Month
8.	Tramadol Hcl	1 T/Month
9.	Metadoxine	0.4 T/Month
10.	Danazole	0.1 T/Month

**ANNEXURE-II**

2. The height of chimneys/stacks:

Chimney /Stack Number	Description of Chimney	Point of discharge in Metres (Above ground level)
01	Attached to Process reactor in plant-II	12 M
02	Attached to Process reactor (part) in plant-III	12 M
03	Attached to Process reactor (part) in plant-III	12 M
04	Attached to Ester plant	10 M
05	Attached to Fluidised bed drier in Material finishing section	5 M
06	Attached to Peptide Pilot plant chimney	4.25 M
07	Attached to Boiler 2 Nos. - 3T/Hr. each	13 M
08	Attached to Thermic fluid heater - 1.No.	8 M
09-11,	Attached to Diesel Generator set capacity 165 KVA - 2 Nos., 380 KVA - 1 No., 500 KVA - 1 No.	7 M each

ANNEXURE-III

## 3B. For Gaseous Emission:

Sl.No.	Source	Details of Control Equipment
01	Process reactors in Plant II	Alkali Wet scrubber, stack
02	Process reactors (part) in plant III	Alkali Wet scrubber, stack
03	Process reactor (part) in plant III	Scrubber, stack
04	Ester plant	Alkali scrubber, stack
05	Fluidised bed drier	Stack
06	Peptide pilot plant	Stack
07	Boilers	Stack
08	Thermic fluid heater	Stack
09	Diesel Generator sets	Stack

ANNEXURE-IV

## 8. Stacks as per the CPCB guidelines:

Sl.No.	Source	Stack
01	Process reactors in Plant II	No.1
02	Process reactors (part) in plant III	No.2
03	Process reactor (part) in plant III	No.3
04	Ester plant	No.4
05	Fluidised bed drier	No.5
06	Peptide pilot plant	No.6
07	Boilers	No.7
08	Thermic fluid heater	No.8
09 to 11	Diesel Generator sets	No.9 to No.11

ANNEXURE-VSPECIAL CONDITIONS

11. The unit shall operate and maintain the Air Pollution Control measures and ensure that the emission from the unit shall satisfy the Ambient Air Quality/emission standards prescribed by the Board.

12. The unit shall develop green belt around the periphery of the unit to attenuate air and noise pollution.

Note:- Item No.3A, 3C, 6, 7 & 10 of Special conditions are not applicable

*[Signature]*  
for CHAIRMAN  
TNPC BOARD-CHENNAI  
A.S.  
2/12

# TAMIL NADU POLLUTION CONTROL BOARD

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TAMIL NADU POLLUTION CONTROL BOARD

CONSENT ORDER NO. : 3130

Proceedings No. : 110/TNP/CO/2267/KPK/04

Consent For Establishment under Section 25 of the WATER (Prevention and Control of Pollution) Act, 1974, as amended in 1988.

Subj : TNP/CO - Consent For establishment  
MESSRS SUN PHARMACEUTICAL INDUSTRIES LIMITED,  
S.NO.90/3 ETC., SATHARAI VILLAGE,  
MADURANTHAR TALUK,  
KANCHEEPURAM DISTRICT.

THE MANAGER-OPERATION,  
M/S.SUN PHARMACEUTICAL INDUSTRIES LIMITED,  
SATHARAI VILLAGE, KANCHEEPURAM DISTRICT,  
MADURANTHAR TALUK,  
KANCHEEPURAM DISTRICT.

DATED : 30/11/2005

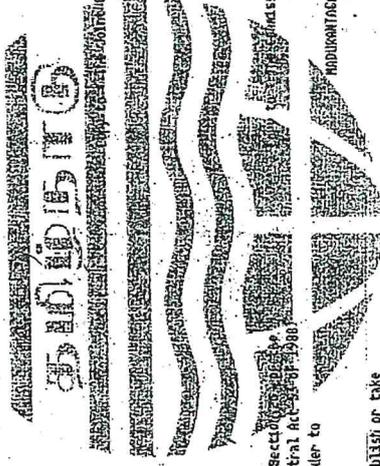
DATED : 30/11/2005

Copy to : The District Environmental Engineers, Tamil Nadu Pollution Control Board  
KANCHEEPURAM DISTRICT.

For information and necessary action.

For the establishment or take steps to establish the industry under Section 25 of the WATER (Prevention and Control of Pollution) Act, 1974 as amended in 1988 (Central Act 53 of 1988).

- Ref :
- 1.YOUR APPLICATION NO.2292 DATED 22.6.2005
  - 2.JR NO.DEE/TNP/CO/2267/KPK/04 DATED 25.7.2005
  - 3.SUBCOMMITTEE RESOLUTION NO.2-30 DATED 19.11.2005



Board Resolution No :

DATED :

Consent to establish or take steps to establish is hereby granted under Section 25 of the WATER (Prevention and Control of Pollution) Act, 1974 as amended in 1988 (Central Act 53 of 1988) (hereinafter referred to as 'The Act') and the Rules and Orders made there under to THE MANAGER-OPERATION,

M/S.SUN PHARMACEUTICAL INDUSTRIES LIMITED,

(hereinafter referred to as 'The Applicant') authorising him/her/then to establish or take steps to establish the industry in the site mentioned below:

S.NO.90/3 ETC., SATHARAI VILLAGE,  
MADURANTHAR TALUK,  
KANCHEEPURAM DISTRICT.

Commissioner / Executive Officer,

MADURANTHAR PANCHAYAT UNION, KANCHEEPURAM DISTRICT.

Share :

This Consent to establish is valid for two years, or till the industry obtains consent to operate under Section 25 of the Water (Prevention and Control of Pollution) Act, 1974 as amended in 1988 whichever is earlier.

*M. S. Prasad*  
Chairman

FOR MANAGER-SECRETARY  
TAMIL NADU POLLUTION CONTROL BOARD  
CHENNAI

*A. S. Prasad*

55

# TAMIL NADU POLLUTION CONTROL BOARD

SPECIAL CONDITIONS

1. Details of the products manufactured

Sl. No.	DESCRIPTION	QUANTITY/MONTH
(1)	(2)	(3)

ANNEXURE-I ENCLOSED

This consent is valid for the manufacturing of products and the rate of effluent mentioned above. Any change in rate of and the quantity or quality of the effluent brought to the notice of the Board.

2. The unit shall install Effluent Treatment Plant as proposed to ensure that the effluent to be discharged shall satisfy the standards prescribed by the Board for disposal of effluent into inland surface waters/public sewers/marine coastal areas/on land for irrigation.

3. The unit shall install sewage treatment systems for the treatment of waste water coming out of the sanitary facility and waste water generated from canteen in the Annexure-I.

4. The unit shall construct effluent drains/catch drains/storm water drains, separately and provide different colour, sign boards along with alignment of various drains as illustrated in the site plan, furnished by the industry.

5. Each vessel/reactor should have its own catch pit for the collection of spills and catch pump in the process section must be mounted on its own catch pit with the suction line of the pump connected to pit to empty it periodically/regularly/continuously.

6. It has to be ensured by the unit that the floors with the sprayed metal, slotted angle steel slabs, steel grates shall be built to the maximum possible to avoid floor washings.

7. If the plant layout demands that the vessels should be installed in upper floor, it shall provide suitable system to minimize spill/leakage and also to collect and drain the spillages into effluent drain leading to the effluent treatment plant by providing suitable gradient to the properly litged bottom floor.

8. The unit shall construct tank or lapson of adequate capacity with corrugated aluminium material for the storage of hazardous/solid wastes.

9. The unit shall ensure that the corrosion prone areas and construction material liable to atmospheric and process induced corrosion shall be given special attention for immediate replacement with least preventive maintenance.

10. The unit has to provide facilities separately outside the main production plant for carrying out detoxification operations if any.

11. In order to collect spills from a particular vessel before the spilled materials get a chance of contamination with spills from another vessel, the two vessels must be installed at such a distance to ensure that inter-contamination cannot take place.

12. The unit shall ensure that the pipe joints should be avoided wherever possible.

13. The unit shall establish laboratory with adequate analytical equipments for analysing the effluent/leakage as well as samples of water collected from the wells nearby if any.

14. The unit shall construct compound wall around the boundary of the unit to a height of metres from ground level.

15. The unit shall appoint an Environmental Engineer with experience of minimum three years in maintenance of waste water treatment plants, before commissioning, along with supporting staff, chemist, technician and operators.

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# TAMIL NADU POLLUTION CONTROL BOARD

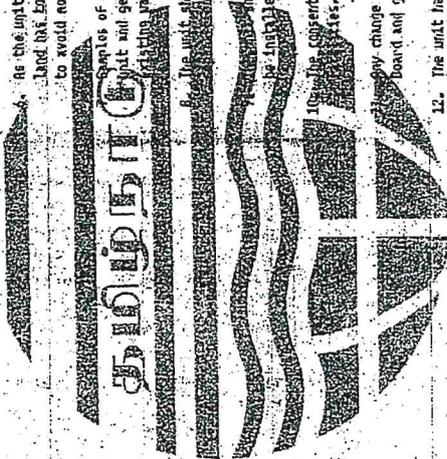
-6-

## GENERAL CONDITIONS

1. The above consent to establish cannot be construed as consent to operate.
2. The industry shall make a request for grant of consent to operate at least sixty days before the commencement of trial production.
3. The applicant shall maintain good house keeping both within the factory and in the premises. All pipes, valves, sewers and drains shall be leak proof. Floor washings shall be admitted in to the effluent collection system only and shall not be allowed to find their way to storm water drains or open areas.
4. The unit has to provide sudge and silt traps and skimmers along the effluent drains for periodical desludging and desludging operation.
5. All places of storage of solid/liquid material are to be dyked with bunding facilities and the bunding within the dyked and bunding area shall be lined with impervious materials depending upon the nature of the solid/liquid to be stored.
6. As the unit proposes to utilise the treated trade effluent on inland for irrigation, the land has to be made fit for irrigation in consultation with the agricultural scientist to avoid more percolation of water from the wells or any other nearby water sources have to be taken by the unit and get them analysed by the Board Laboratory to develop base line data to assess the existing water quality.
7. The unit shall provide separate power connection for the Effluent Treatment Plant and install a flow meter for the Effluent Treatment Plant as well as for aerators if any.
8. The unit shall provide an alternate power source sufficient to operate all the facilities to be installed in Effluent Treatment Plant by the applicant.
9. The consent does not authorize or approve the construction of any physical structures or sites, or the undertaking of any work in any natural water course.
10. Any change in the details furnished in the conditions has to be brought to the notice of the Board and got approved by the Board, before obtaining consent to operate under the said Act.
11. The unit has to comply with the provisions of Public Liability Insurance Act, 1991 to provide immediate relief in the event of any hazard to human beings, other living creatures/plants and properties while handling and storage of hazardous substances.
12. Consent to operate will not be issued unless the unit complied with the conditions of consent to establish, otherwise, the order of consent to establish already issued will be revoked with immediate effect.

16. Following location specific conditions must be satisfied:

17. The following process specific conditions must be satisfied:



(Continued in Annexure-I)

*Manoj Das*  
Chairman  
FOR MEMBER SECRETARY  
TAMIL NADU POLLUTION CONTROL BOARD  
CHENNAI  
12/2/12

*Manoj Das*  
Chairman  
FOR MEMBER SECRETARY  
TAMIL NADU POLLUTION CONTROL BOARD  
CHENNAI  
12/2/12

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CONSENT FOR ESTABLISHMENT UNDER WATER (P&CP) Act, 1974,  
AS AMENDED CONSENT ORDER NO.3150, Dated 30.11.2005.

ANNEXURE-I

Details of Products manufactured:-

Sl.No.	Description	Quantity/month
1.	Analgin Magnesium	6 T/Month
2.	Sodium Valporate	8 T/Month
3.	Oxectacine	1 T/Month
4.	Clomipramine	1 T/Month
5.	Flurbiprofen	1 T/Month
6.	Carbamazepine	4 T/Month
7.	Mepoprolol tartrate	3 T/Month
8.	Tranadol Hcl	1 T/Month
9.	Meladoxine	0.4 T/Month
10.	Danazole	0.1 T/Month

ANNEXURE-II

SPECIAL CONDITIONS

18.The unit shall treat the sewage in the septic tank and the overflow shall be treated along with the trade effluent.

19.The unit shall treat the lean trade effluent along with the overflow from the septic tank in the ETP provided. The treated trade effluent is further treated through Reverse Osmosis Plant. The permeate shall be reused.

20.The Reverse Osmosis Plant rejects along with High TDS effluent shall be disposed through three stage mechanical evaporator system. The condensate shall be reused and the concentrate from the MEE shall be disposed through elevated solar evaporation pan thereby the unit has to ensure zero discharge.

21.The unit shall provide thin film drier or any other mechanical drier instead of disposing the concentrate from mechanical evaporator through elevated solar evaporation pan.

22.The unit shall handle the hazardous waste complying with the conditions stipulated in the authorization issued by the Board under the Hazardous Waste (Management & Handling) Rules, 1989 as amended.

Note:- Item No.16 & 17 of Special conditions and Item No.6 of General conditions are not applicable.

*[Signature]*  
for CHAIRMAN  
TNPC BOARD-CHENNAI-32.

*[Signature]*  
2/12

# TAMIL NADU POLLUTION CONTROL BOARD

By Registered Post with  
acknowledgement Due  
(This document contains 0 Pages)

- 2 -

To

TAMIL NADU POLLUTION CONTROL BOARD

THE MANAGER-OPERATION,

M/S. SUN PHARMACEUTICAL INDUSTRIES LIMITED,  
SATHANAI VILLAGE, KARURUKULI HQT.,  
MADRASHTAGAN TALUK,  
KANCHEEPURAM DISTRICT.

Dated 19/06/2006

CONSENT ORDER NO. : 16641

Dated 19/06/2006

PROCEEDINGS NO. : TNO/MPCB/2007/HPM/A/2006

Consent for Existing / New operation of the plant under Section 21 of the Air (Prevention and Control of Pollution) Act, 1986 as amended.

Sub : TAMIL NADU POLLUTION CONTROL BOARD - CONSENT -  
RESSEPS SUN PHARMACEUTICAL INDUSTRIES LIMITED,  
S.NO.30/3 ETC.,  
SATHANAI VILLAGE,  
MADRASHTAGAN TALUK,  
KANCHEEPURAM DIST.

for the existing/new operation of the plant under Section 21  
of the Air (Prevention and Control of Pollution) Act,1986  
as amended.

Copy to : The District Environmental Engineer, Tamil Nadu Pollution Control Board  
KANCHEEPURAM  
for information and necessary action

- Ref : 1.YOUR APPLICATION NO.638 DT.22.6.2005  
2.APOC.NO.T10/MPCB/F2057/HPM/A DT.30.11.2005  
3.TP NO.3EE7/HPCB/HPM/A/1-137/244/2006 DT.3-8-2006

Board Resolution No : / / dated / /

CONSENT is hereby granted under Section 21 of the Air (Prevention and Control of Pollution) Act, 1981 (Central Act 14 of 1981) as amended (hereinafter referred to as 'The Act') and the rules and orders made thereunder to

THE MANAGER-OPERATION,  
M/S. SUN PHARMACEUTICAL INDUSTRIES LIMITED,  
S.NO.30/3 ETC.,  
SATHANAI VILLAGE,  
MADRASHTAGAN TALUK,  
KANCHEEPURAM DIST.

(hereinafter referred to as 'The Applicant') authorising him/her/then to operate/maintain/their industrial plant in the Air (Pollution Control) area as notified by the Government and to continue to make existing discharge of emission/make new discharge of emissions from the stacks/chimneys.

This is subject to the provisions of the Act and the rules and orders made thereunder and further subject to the terms and conditions incorporated in the Special and General Conditions annexed.

This CONSENT is valid for a period ending with the 31st day of March 2007 (Thirty first day of March Two Thousand Seven )

For MEMBER SECRETARY, Chairman  
TAMIL NADU POLLUTION CONTROL BOARD  
CHENNAI

21/6/2006

Copy to : The Joint Chief Environmental Engineer, Tamil Nadu Pollution Control Board

Copy to : The Commissioner/Executive Officer/District Collector  
MADRASHTAGAN PAICHAYAT UNION, KANCHEEPURAM DISTRICT.

Spare :

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# TAMIL NADU POLLUTION CONTROL BOARD

- 3 -

**SPECIAL CONDITIONS**

1. Details of the products manufactured

SL. NO.	DESCRIPTION	QUANTITY/MONTH
(1)	(2)	(3)

**ANNEXURE-I**

This consent is valid for the manufacture of products and the rate of production mentioned above. Any change in the quantity or quality of the products has to be brought to the notice of the Board and fresh Consent has to be obtained.

2. Emission is permitted through the following chimneys/stacks and shall not exceed the figures indicated :

Chimney / Stack Number	Description of Chimney / Stack	Maximum discharge in mg/hour	Point of discharge (height) in mts.
(1)	(2)	(3)	(4)

**ANNEXURE-II**

- 4 -

3(a) The emissions shall not contain constituents in excess of the tolerance limits as laid down hereunder.

Serial Number	Part-Unit	Unit	Tolerance Limits			
(1)	(2)	(3)	(i)	(ii)	(iv)	(vi)
			CHIMNEY / STACK NUMBER			

1. SO<sub>2</sub> THE UNIT SHALL ADHERE TO THE EMISSION

2. CO STANDARDS PRESCRIBED BY THE BOARD FROM

3. NO<sub>x</sub> TIME TO TIME.

4. SPH  
5. CL<sub>2</sub>

3(b) The ambient air in the industrial plant area shall not contain constituents in excess of the tolerance limits prescribed below :

Serial Number	Pollutant	Time Weighted average	Unit	Tolerance Limits
(1)	(2)	(3)	(4)	(5)
1.	Sulphur Dioxide (SO <sub>2</sub> )	Annual average 24 Hours	microgram / m <sup>3</sup>	60 80
2.	Oxides of Nitrogen as NO <sub>x</sub>	Annual average 24 Hours	microgram / m <sup>3</sup>	60 80
3.	Suspended particulate matter (SPM)	Annual average 24 Hours	microgram / m <sup>3</sup>	140 200
4.	Respirable particulate matter size less than 10 micron (RPM)	Annual average 24 Hours	microgram / m <sup>3</sup>	60 100
5.	Lead (Pb)	Annual average 24 Hours	microgram / m <sup>3</sup>	0.75 1.00
6.	Carbon monoxide (CO)	8 Hours 1 Hour	microgram / m <sup>3</sup>	2000 4000

3(c). The ambient noise level in the industrial plant area shall not exceed the limits prescribed below.

Limits in dB(A)	Day Time (6 A.M. to 10 P.M.)	Night Time (10 P.M. to 6 A.M.)
	55	45

# TAMIL NADU POLLUTION CONTROL BOARD

- 5 -

4. All units of the air pollution control equipment required to achieve the quality of the emissions to the tolerance limits prescribed above shall be completed within months from the date of this order or before or along with the commissioning of production.
5. The applicant shall provide port holes for sampling the emission & access-platform for carrying out stack sampling and provide electrical outlet points and other arrangements for Chimneys / stacks and other sources of emissions so as to collect samples of emission by the Board or the applicant at any time in accordance with the provisions of the Act or Rules made therein.
6. The applicant shall at his own cost get the samples of emission collected and analysed by the TMC Board Laboratory every month for the parameters indicated in conditions No.3(a) and shall furnish in triplicate the report thereof to the Board by the 10th of succeeding month.
7. This Consent is given by the Board in consideration of the particulars given in the application. Any change or alteration or deviation made in actual practice from the particulars furnished in the application will also be ground for review/variation/revocation of the Consent Order under Section 21 of the Act to make such deviation as deemed fit for the purpose of the Act.
8. The applicant shall not change or alter either the quality or quantity or rate of emission or install, replace or alter the air pollution control equipment or change the raw material or manufacturing process resulting in any change in quality and/or quantity of emissions, without previous written permission of the Board.
9. The applicant shall provide and maintain at his own cost one/two/three ambient air quality monitoring stations for monitoring suspended particulate matter, Sulphur dioxide, Oxides of Nitrogen, Hydro-Carbon, Carbon-monoxide and monitor the same all in a day, once in a week/fortnight/month. The data collected shall be maintained in a register and a monthly extract furnished to the Board.
10. The applicant shall provide and maintain at his own cost a meteorological station to collect the data on wind velocity, direction, temperature, humidity, rainfall, etc. and the daily readings shall be recorded and the extract sent to the Board once in a month.
11. The applicant shall forward the following information to the Member Secretary, Tamil Nadu Pollution Control Board, Madras regularly before 10th of every month.
  - (a) Progress on the installation of Air Pollution Control equipments.
  - (b) Progress on the procurement and installation of equipments for monitoring ambient air quality, stacks, chimneys and meteorological data.
  - (c) Monthly extract of daily discharge of emission through each chimney/stack.
  - (d) Report of analysis of stack monitoring, ambient air quality monitoring, meteorological data as required under Conditions.....
  - (e) Progress on planting of trees and plants as referred to under General Conditions No.6.
12. Any upset conditions if any of the plant/plants of the factory which is likely to result in increased emissions and/or result in violation of the standards mentioned above shall be reported to the Head Quarters and District Environmental Engineer's Office/Regional Joint Chief Environmental Engineer's Office of the Board telegraphically.

- 6 -

13. The applicant shall furnish to the Visiting Officer of the Board any information regarding the stack monitoring system / or operation of the plant or any other particulars as may be pertinent in preventing and controlling of pollution of Act.
14. The applicant shall submit process flow sheet and particulars of proposed control equipments, monitoring equipments and time schedule for completing the installation of the same so as to reach the Board within 30 days from the date of receipt of this order.
15. The conditions imposed as above shall continue in force until revoked under Section 21 of the Act.

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(Continued in Annexure)

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# TAMIL NADU POLLUTION CONTROL BOARD

- 7 -

## GENERAL CONDITIONS

1. The applicant shall make an application for grant of fresh consent atleast 60 days before the date of expiry of this Consent Order.
2. The necessary fee, as prescribed for obtaining consent, shall be paid for by the applicant along with the application for consent.
3. The industry shall immediately submit the revised application for Consent to this Board in the event of any change in the quantity / quality of raw material, manufacturing process, rate of emissions, air pollution control equipment etc.
4. The applicant shall either :
  - (a) Not later than 30 days from the date of issue of this Consent Order, certify in writing to the Member Secretary that the applicant has installed or provided for an alternate electric power source sufficient to operate all facilities installed by the applicant to maintain compliance with the terms and conditions of the consent.
  - (b) Not later than 30 days from the date of this Consent certify in writing to the Member Secretary that upon the reduction, loss or failure of one or more of the primary sources of electric power to any facilities installed by the applicant to maintain compliance with the terms and conditions of this Consent, the applicant shall halt, reduce or otherwise control productions and/or all emissions in order to maintain compliance with the terms and conditions of this Consent.
5. No control equipments or chimney shall be altered or replaced or as the case may be erected or re-erected except with the previous approval of the Board.
6. The liquid effluent arising out of the operation of the air pollution control equipment shall also be treated in a manner and to the satisfaction of standards prescribed by the Board in accordance with the provisions of Water (Prevention and Control) Act, 1974 as amended.
7. The solid waste, such as sweepings, wastage, package, empty containers, residues, sludge including that from air pollution control equipments collected within the premises of the industrial plant shall be disposed off scientifically to the satisfaction of the Board, so as not to cause fugitive emission, dust problems, or water pollutions problem through leaching etc of any kind.
8. The applicant shall plant a minimum of three varieties of trees (Eucalyptus, Subabul and any other suitable variety) at the density of not less than 1,000 trees per acre of land. The plantation is stipulated over and above the bulk plantation of trees in that area and maintain them.
9. The applicant shall provide all facilities for collection of sample to the Board staff.
10. The stack monitoring system employed by the applicant shall be open for inspection of this Board at any time.
11. There shall not be any fugitive or episodic discharge from the premises.

- 6 -

12. In case of such episodic discharge/emissions the industry shall take immediate action to bring down the emission within the limits prescribed by the Board in special conditions No.3(a).
13. The applicant shall at all times maintain in good working order and operate as efficiently as possible all pollution control facilities to achieve the terms and conditions of the Consent.
14. The issue of this Consent does not cover any property right in either real or personal property or any exclusive privileges nor does it authorise any injury to private property or any invasion of personal rights, or any infringement of Central, State Laws or regulations.
15. The applicant shall keep the premises of the industrial plant and air pollution equipments clean and make all hoppers, pipes, valves stacks / chimneys leak proof. The air pollution control equipments, location inspection chambers, sampling port holes shall be made easily accessible at all time.
16. The applicant shall display this Consent granted to him in a prominent place for perusal of the inspecting officers of this Board.
17. An inspection book shall be opened and made available to the Board's Officers during their visit to the factory.
18. If due to any technological improvements or otherwise this Board is of opinion that all or any of the conditions referred to above requires variation (including the change of any control equipment either in whole or in part) this Board shall, after giving the applicant an opportunity of being heard, vary all or any of such condition and thereupon the applicant shall be bound to comply with the conditions so varied.
19. The applicant, his/her/their legal heirs/representatives or assignees shall have no claim whatsoever to the continuation or renewal of this Consent after the expiry of the period of this consent.
20. The Board reserves the right to review, impose additional conditions or conditions, revoke change or alter the terms and conditions of this consent.

*Nov 23/2006*  
For MEMBER-SECRETARY Chairman  
TAMIL NADU POLLUTION CONTROL BOARD  
CHENNAI-32

*Ans*  
*29/12/06*

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TAMIL NADU POLLUTION CONTROL BOARD  
76 Mount Road, Guindy, Chennai 600 032

CONSENT TO OPERATION UNDER AIR (P&CP) Act, 1974,  
AS AMENDED CONSENT ORDER NO.16641, Dated 19-6-2006

ANNEXURE-I

SPECIAL CONDITIONS

Details of Products Manufactured

Sl.No.	Description	Quantity / Month
1	Analgin Magesium	6 T / Month
2	Sodium Valporate	8 T / Month
3	Oxectacine	1 T / Month
4	Clomipramine	1 T / Month
5	Flurbiprofen	1 T / Month
6	Carbamazepine	4 T / Month
7	Mepoprolol tartrate	3 T / Month
8	Tramadol HCL	1 T / Month
9	Metadoxine	0.4 T / Month
10	Danazol	0.1 T / Month

ANNEXURE-II

2. Emission is permitted through the following chimney / stacks and shall not exceed the figures indicated:-

Chimney / Stack Number	Description Chimney / Stack	Maximum discharge in M <sup>3</sup> /hour	Point of discharge (Height) in metres
01	Attached to Process Reactors in Plant – II	-	12 M
02	Attached to Process Reactors (part) in Plant – III	-	12 M
03	Attached to Process Reactors (part) in Plant – III	-	12 M
04	Attached to Ester Plant	-	10 M
05	Attached to Fluidized bed driver in material finishing section	-	5 M
06	Attached to Peptide Pilot plant	-	4.25 M
07	Attached to Boiler 2 Nos. – 3 T/hr. each	-	13 M
08	Attached to Thermic fluid heater – 1 No.	-	8 M
09 to 11	D.G. Set 165 KVA – 2 Nos. 350 KVA – 1 No. 500 KVA – 1 No.	-	7 M each

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ANNEXURE-III

16. The unit shall operate and maintain the Air Pollution Control measures and ensure that the emission from the unit shall satisfy the Ambient Air Quality / emission standards prescribed by the Board.
17. The unit shall continue to develop greenbelt around the periphery of the unit to attenuate air and noise pollution.

*Nov-23*  
*29/11/23*  
for CHAIRMAN  
TNPC BOARD, CHENNAI.

*2/10*  
*29/11*

# TAMIL NADU POLLUTION CONTROL BOARD

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Acknowledgement Due  
(This document contains -- Pages)

TAMIL NADU POLLUTION CONTROL BOARD

CONSENT ORDER NO. : 20607

dated 19/06/2006

Proceedings No. : T10/TNCPB/F2057/KPM/M/2006

dated 19/06/2006

Consent for ~~discharge~~ Altered ~~outlet~~ discharge of sewage and/or trade effluent under Section 25/26 of the WATER (Prevention and Control of Pollution) Act, 1974 as amended.

500 : TAMIL NADU POLLUTION CONTROL BOARD - CONSENT  
MESSRS SUN PHARMACEUTICAL INDUSTRIES LIMITED,  
S.NO. 30/3 ETC.,  
SATHANAI VILLAGE,  
MADURANTAGAN TALUK,  
KANCHEEPURAM DIST.

for the discharge of sewage and/or trade effluent under  
Section 25/26 of the WATER (Prevention and Control of  
Pollution) Act, 1974 (Central Act, 6 of 1974) as amended.

- Ref : 1. YOUR APPLICATION NO.2282 DT.22.6.2005
- 2.PDOC.NO.T10/TNCPB/F2057/KPM/M DT.30.11.2005
- 3.JP.NO.DEL/TNCPB/KPM/AL-137/MAR/2006 DT.3-6-2006

Board Resolution No :

DATED : / /

CONSENT is hereby granted under Section 25/26 of the WATER (Prevention and Control of Pollution Act, 1974 (Central Act 6 of 1974) as amended (hereinafter referred to as 'The Act') and the rules and orders made thereunder to

THE MANAGER-OPERATION,  
M/S. SUN PHARMACEUTICAL INDUSTRIES LIMITED,  
S.NO. 30/3 ETC.,  
SATHANAI VILLAGE,  
MADURANTAGAN TALUK,  
KANCHEEPURAM DIST.

(hereinafter referred to as 'The Applicant') authorising ~~the/their~~ outlet to continue ~~to~~ ~~bring into use~~ ~~the/discharge~~ ~~or use~~ ~~the~~ altered outlet ~~for~~ discharge of sewage and/or trade effluent.

This is subject to the provisions of the Act and the rules and orders made thereunder and further subject to the terms and conditions incorporated in the Special and General Conditions annexed.

This CONSENT is valid for a period ending with the 31st day of March 2007  
(thirty first day of March Two Thousand Seven )

*SRM*  
For ~~MEMBER-SECRETARY~~ Chairman  
TAMIL NADU POLLUTION CONTROL BOARD  
CHENNAI  
*AW*  
*29/6/2006*

To

THE MANAGER-OPERATION,  
M/S.SUN PHARMACEUTICAL INDUSTRIES LIMITED,  
SATHANAI VILLAGE, KARUNKUZHI POST,  
MADURANTAGAN TALUK,  
KANCHEEPURAM DISTRICT.

Copy to : The District Environmental Engineer, Tamil Nadu Pollution Control Board  
KANCHEEPURAM

for information and necessary action

Copy to : The Joint Chief Environmental Engineer, Tamil Nadu Pollution Control Board

Copy to : The Commissioner/Executive Officer/District Collector  
MADURANTAGAN PANCHAYAT UNION, KANCHEEPURAM DISTRICT.

Spare :

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# TAMIL NADU POLLUTION CONTROL BOARD

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## SPECIAL CONDITIONS

1. Details of the products manufactured		
Sl. No.	DESCRIPTION	QUANTITY/MONTH
(1)	(2)	(3)

## ANNEXURE-I

This consent is valid for the manufacture of products and the rate of production mentioned above. Any change in the quantity or quality of the products has to be brought to the notice of the Board and fresh consent has to be obtained.

2. Discharge of effluent is permitted from the following outlets. The quantity of effluent discharged shall not exceed the figures mentioned below :

Outlet Number	Description of Outlet	Maximum daily discharge (in lit./day)	Point of Disposal (Height) in mts.
(1)	(2)	(3)	(4)
	1. SEWAGE	6000	PERMEATE TO BE RECYCLED IN THE PROCESS AND THE CONCENTRATE THROUGH MECHANICAL EVAPORATOR, TRAY DRYER SYSTEM.
	2. TRADE EFFLUENT	25,100	
	A) LOW TDS STREAM	5,400	
	B) HIGH TDS STREAM		

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3. The effluent discharge shall not contain constituents in excess of the tolerance limits as laid down hereunder.

Serial Number	Characteristics	Unit	Tolerance Limits
(1)	(2)	(3)	(4)
	1. pH.	Number	5.5 - 9.0
	2. Temperature	C	40 DEG. C AT THE POINT OF DISCHARGE
	3. Particles size of total Suspended solids.	mm/micron	SHALL PASS 850 MICRON IS SIEVE
	4. Total suspended solids	mg/l	100
	5. Total dissolved solids (Inorganics)	mg/l	2100
	6. Chloride as (Cl)	mg/l	1000
	7. Sulphide as (S)	mg/l	2
	8. Sulphate as (SO4)	mg/l	1000
	9. Fluoride as (F/4)	mg/l	2
	10. Ammonical Nitrogen as(N)	mg/l	50
	11. Sodium	X	-

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# TAMIL NADU POLLUTION CONTROL BOARD

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Serial Number	Characteristics	Unit	Tolerance Limits			
(1)	(2)	(3)	(1)	(2)	(3)	(4)
			Outlet No.			
12.	Copper as (Cu)	mg/l	3			
13.	Zinc as (Zn)	mg/l	1			
14.	Phenolic Compounds as (CS H5 OH)	mg/l	1			
15.	Oil and grease	mg/l	10			
16.	Boron as (B)	mg/l	2			
17.	BOD 5 days @ 20 C	mg/l	30			
18.	COD	mg/l	250			
19.	Total Residual Chlorine	mg/l	1			
20.	Arsenic as (As)	mg/l	0.2			
21.	Cadmium as (Cd)	mg/l	2			
22.	Total Chromium as (Cr)	mg/l	2			
23.	Chromium as (hexavalent Cr+6)	mg/l	0.1			

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Serial Number	Characteristics	Unit	Tolerance Limits			
(1)	(2)	(3)	(1)	(2)	(3)	(4)
			Outlet No.			
24.	Lead as (Pb)	mg/l	0.1			
25.	Selenium as (Se)	mg/l	0.05			
26.	Mercury as (Hg)	mg/l	0.01			
27.	Pesticides		ABSENT			
28.	Alpha emitters	micro Curie/ml	TEN TO THE POWER OF -7			
29.	Beta emitters	micro Curie/ml	TEN TO THE POWER OF -6			
30.	Frees, Raemontia as (MHS)	mg/l	5			
31.	Dissolved Phosphates as (P)	mg/l	5			
32.	Total Kjeldahl Nitrogen as (N)	mg/l	100			
33.	Cyanide as (CN)	mg/l	0.2			
34.	Nickel as (Ni)	mg/l	3			
35.	Residual Sodium Carbonate	mg/l	-			

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# TAMIL NADU POLLUTION CONTROL BOARD

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- 4. All units of the sewage/trade effluent treatment plant to achieve the quality of the effluent according to the tolerance limits prescribed above shall be completed within months from the date of this order or before  
 NOT APPLICABLE or along with the commissioning of production
- 5. Meters must be affixed at the entrance of the water supply connection so that such meters are easily accessible for inspection and maintenance and for other purposes of the Act, provided that the place where it is affixed shall in no case be at a point before which water has been tapped by the consumer for utilisation for any purposes whatsoever.
- 6. Separate meters with necessary pipe - line for assessing the quantity of water used for the purposes mentioned below :
  - a. Industrial cooling, spraying in mine pits or boiler feed.
  - b. Domestic purpose.
  - c. Process.
  - d.
  - e.
- 7. The applicant shall take immediate action to install mechanical composting sampling equipment and continuous flow measuring/recording devices on the effluent drains of trade as well as sewage effluent within three months from the date of this Consent Order. A record of daily effluent discharge shall be maintained.
- 8. This Consent is given by the Board in consideration of the particulars given in the application. Any change or alteration or deviation made in actual practice, from the particulars furnished in the application will also be ground for review/variation / revocation of the Consent Order under section 27 of the Act and to make such variation as deemed fit for the purpose of the Act.
- 9. The applicant shall not change or alter either the quality or quantity or the rate of the discharge or temperature or the route of discharge without the previous written permission of the Board.
- 10. The applicant shall comply with and carryout directives/orders issued by the Board in this Consent order and at all subsequent times without any negligence on his/her/their part. The applicant shall be liable for such legal action as per provisions of the Law/ Act in case of non - compliance of any order/directives issued at any time and or violation of the terms and conditions of this Consent Order.
- 11. The following information shall be forwarded to the Member - Secretary regularly on or before 10th of every month :
  - a. Progress on the installation of effluent treatment plant :
  - b. Progress on the installation of Mechanical compost sampling equipment and continuous flow recording/measuring devices.
  - c. Monthly Statement of daily discharge of sewage as well as trade effluent.

- 12. Any upset condition in any of the plant/plants of the factory which is likely to result in increased effluent discharge and or result in violation of the standards mentioned above shall be reported to the Head Quarters and District Environmental Engineer's office/ Regional Joint Chief Environmental Engineer's Office of the Board telegraphically.
- 13. The applicant shall furnish to the visiting officer of the Board any information regarding the construction, installation or operation of the plant or of effluent treatment plant and any other particulars as may be pertinent to preventing and controlling pollution of water.
- 14. Notwithstanding anything contained in this conditional letter of Consent, the Board hereby reserves to it the right and power under section 21(2) of the Water (Prevention and Control of Pollution) Act, 1974 (as amended) to review any and /or all the condition imposed herein above and to make such variations as deemed fit for the purpose of the Act by the Board.
- 15. The conditions imposed as above shall continue in force until revoked under section 21(2) of the Act.
- 16. The industry has to ensure that minimum three varieties of trees (Eucalyptus, Subabul) and any other suitable variety) are planted at the density of not less than 1,000 trees per acre of land. The trees may be planted along the boundaries of the industry of industrial precincts. This plantation is stipulated over and above the bulk plantation of trees in that area and maintain them.

( Continued in Annexure-I)

# TAMIL NADU POLLUTION CONTROL BOARD

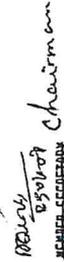
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## GENERAL CONDITIONS

1. The applicant shall make an application for grant of fresh consent atleast 60 days before the date of expiry of this Consent Order.
2. The industry would immediately submit revised application for Consent to this Board in the event of any change in the quantity and quality of raw material/end products/manufacturing process or quantity/quality of the effluent, etc.
3. The applicant shall display suitable caution board at the place where the effluent is entering any water body or any other place to be indicated by the Board, indicating therein that the area into which the effluents are being discharged is not fit for the domestic use/bathing.
4. The applicant shall either :
  - a. Not later than 30 days from the date of issue of this Consent Order, certify in writing to the Member-Secretary that the applicant has installed or provided for an alternate electric power source sufficient to operate all facilities installed by the applicant to maintain compliance with the terms and conditions of the Consent.
  - b. Not later than 30 days from the date of this Consent, certify in writing to the Member-Secretary that upon the reduction, loss or failure of any one or more of the primary sources of electric power to any facilities installed by the applicant to maintain compliance with the terms and conditions of this Consent, the applicant shall halt, reduce or otherwise control production and/or all discharges in order to maintain compliance with the terms and conditions of this Consent.
5. The applicant shall not allow the discharge from other premises to mix with the discharge from his/her/their premises.
6. Storm water shall not be allowed to mix with the sewage and/or trade effluent on the upstream of the terminal sasholes where the flow measuring devices will be installed.
7. All solid wastes arising in the premises shall be properly classified and disposed off to the satisfaction of the Board by :
  - (i) Land fill, in case of inert material, care being taken to ensure that the material does not give rise to leachate which may percolate into ground water or carried away with storm run-off.
  - (ii) Controlled incineration, wherever possible in case of combustible organic material.
  - (iii) Composting, in case of biodegradable material.
8. Any toxic material shall be detoxified otherwise be sealed in steel drums and buried in protected areas after obtaining approval of this Board in writing. The detoxification or sealing and burying shall be carried out in the presence of Board's authorised persons only.
9. The applicant shall maintain good house-keeping both within the factory and in the premises. All pipes, valves, sewers and drains shall be leak proof. Floor washings shall be admitted into the effluent collection system only and shall not be allowed to find their way in storm drains or open areas.
10. The applicant shall provide all facilities to the Board staff for collection of samples.
11. The applicant shall at all times maintain in good working order and operate efficiently all treatment or control facilities or systems installed or used by him to satisfy the terms and conditions of the Consent.
12. The issuance of this Consent does not convey any property right in either real personal property or any exclusive privileges, nor does it authorize any injury to private property or any invasion of personal rights nor any infringement of Central, State laws or regulation.
13. This Consent does not authorise or approve the construction of any physical structures or facilities or the undertaking of any work in any natural water course.
14. Non-compliance with effluent limitations.
  - (a) If for any reason the applicant does not comply with or will be unable to comply with any effluent limitations specified in this Consent, the applicant, shall immediately notify the Consent issuing authority by telephone and provide the Consent issuing authority with the following information in writing within 5 days of such notifications:
    - i) Cause for non-compliance.
    - ii) A description of the non-complied discharge including its impact upon the receiving waters.
    - iii) Anticipated time of continuance of non-compliance if expected to continue or if such condition has been corrected the duration of period of non-compliance.
    - iv) Steps taken by the applicant to reduce and eliminate the non-complying discharge and
    - v) Steps taken by the applicant to prevent recurrence of condition of non-compliance.
  - (b) The applicant shall take all reasonable steps to minimize any adverse impact to natural waters resulting from non-compliance with any effluent limitation specified in this Consent including such accelerated or additional monitoring as necessary to determine the nature and impact of the non-complying discharge.
  - (c) Nothing in this Consent shall be construed to relieve the applicant from civil or criminal penalties for non-compliance whether or not such non-compliance is due to factors beyond his/her/their control, such as break-down, electric failure, accident or natural disaster.
15. The diversion or by-pass of any discharge from facilities utilised by the applicant to maintain compliance with the terms and conditions of this consent is prohibited except :
  - i) Where unavoidable to prevent loss of life or severe property damage or
  - ii) Where excessive storm damage or run off would damage any facilities necessary for compliance with terms and conditions of this Consent. The applicant shall immediately notify the Board in writing of each diversion or by-pass in accordance with procedure specified as under item No.14.
16. The applicant shall at his own cost get the effluent samples collected both before and after treatment and get them analysed at an approved Laboratory of the Board every month for the parameters indicated in Special Condition No.3 and shall submit in duplicate the report there of to the Board.
17. The addition of various treatment chemicals should be done only with mechanical dosers and proper equipment for regulation of correct dosages determined daily and for proper uniform feeding. Curd practices such as dumping of chemicals in drains or sumps or trickling of acids or alkalies arbitrarily and utilising poles for stirring etc., should not be resorted to.

# TAMIL NADU POLLUTION CONTROL BOARD

18. Care should be taken to keep the anaerobic lagoons, if any, biologically active and not to utilise as mere stagnation ponds. The anaerobic lagoons should be fed with the required nutrients for effective digestion. Lagoons should be constructed with sides and bottom made impervious.
19. The utilisation of treated effluent on factory's own lands, if any, should be complete and there should be no possibility of the effluent gaining access into any drainage channel or other water courses either directly or indirectly or by overflow.
20. The effluent disposal on land, if any, should be done without creating any nuisance to the surroundings or inundation of the lands at any time.
21. If at any time the disposal of treated effluent on land becomes incomplete or unsatisfactory or create any problem or becomes a matter of dispute, the industry must adopt alternate satisfactory treatment and disposal measures.
22. The sludge from treatment units shall be dried in shade drying beds and the drained liquid shall be taken to equalisation tank.
23. In the disposal of treated effluent on land for irrigation, the industry shall keep in view of the need for :
  - (i) Rotation of crops.
  - (ii) Change of point of application of effluent on land.
  - (iii) A portion of land kept fallow.
 The adoption of these would avoid soil becoming sick or stale. The industry may ensure this in consultation with the Agricultural Department.
24. It is the sole responsibility of the industry to ensure that there are no complaints at any time from the ryots in the surrounding areas as a result of discharge of sewage or trade effluent.
25. The effluent treatment units and disposal measures, shall become operative at the time of commencement of production.
26. The fact of commissioning of the industry shall be intimated to this office within one week of commissioning.
27. The unit has to ensure that the agency to whom the disposal of solid waste/sludge arising from the process/treatment is entrusted, shall obtain the permission of Tamil Nadu Pollution Control Board under Section 24 of the Water (Prevention and Control of Pollution) Act, 1974 before the disposal.
28. The unit has to put up Effluent Treatment Plant within the specified period indicated in Special Condition No.4 by engaging any one of the consultants approved by the Board and operate and maintain the Effluent Treatment Plant continuously and efficiently so that treated effluent satisfies the standards by the Board.
29. The applicant shall display this Consent granted to him in a prominent place for perusal of the inspecting officers of this Board.

  
 For MEMBER SECRETARY  
 TAMIL NADU POLLUTION CONTROL BOARD  
 CHENNAI  
 ACO  
 29/6/2016



TAMIL NADU POLLUTION CONTROL BOARD  
76 Mount Road, Guindy, Chennai 600 032

CONSENT TO OPERATION UNDER WATER (P&CP) Act, 1974.  
AS AMENDED CONSENT ORDER NO.20607, Dated 19-6-2006

ANNEXURE-I

SPECIAL CONDITIONS

Details of Products Manufactured

Sl.No.	Description	Quantity / Month
1	Analgin Magesium	6 T / Month
2	Sodium Valporate	8 T / Month
3	Oxectacine	1 T / Month
4	Clomipramine	1 T / Month
5	Flurbiprofen	1 T / Month
6	Carbamazepine	4 T / Month
7	Mepoprolol tartrate	3 T / Month
8	Tramadol HCL	1 T / Month
9	Metadoxine	0.4 T / Month
10	Danazole	0.1 T / Month

ANNEXURE-II

17. The unit shall treat the sewage in the septic tank and the overflow shall be treated along with the trade effluent.
18. The unit shall operate and maintain the ETP to treat the lean trade effluent along with the overflow from the septic tank and the treated trade effluent shall be further treated through Reverse Osmosis plant. The permeate shall be reused.
19. The unit shall dispose the R.O. Plant rejects along with high TDS effluent through 3 stage mechanical evaporator system provided. The condensate shall be reused and shall dispose the concentrate from MEEs through tray drier shall ensure zero discharge of effluent.
20. The unit shall handle the hazardous waste complying with the conditions stipulated in the authorization issued by the Board under the Hazardous Waste (M&H) Rules 1989 as amended.

*[Signature]*  
for CHAIRMAN  
TNPC BOARD, CHENNAI.

*[Signature]*  
29/6/2006

sought. If the industry is located outside the notified industrial area, then it is qualified as Category 'A' project and such projects are appraised by the Sectoral EACs and approved by the Answering Respondent. However, if the industry is located within a notified industrial area, it is qualified as category 'B' project to be appraised by the SEACs and approved by the SEIAAs in the respective States/UTs.

18. That it is submitted the projects requiring an Environmental Impact Assessment report shall be termed as Category 'B1' and remaining projects shall be termed as Category 'B2' and the same will not require an Environment Impact Assessment report. For categorization of projects into B1 or B2 except item 8(b), the Answering Respondent shall issue appropriate guidelines from time to time.

19. That, as per the extant provisions, the manufacturing of bulk drug and active pharmaceutical ingredients (hereinafter referred to as API) requires a prior EC under category A of item 5(f) 'Synthetic organic chemicals industry' of EIA Notification, 2006 if it is located outside the notified industrial area/ estate or General Conditions are applicable for the project. All such units attracting the said provisions are allowed to commence their activities only after obtaining prior EC.

20. It is further, submitted that the Answering Respondent deemed it necessary to expedite the prior EC to the projects or activities in respect of bulk drugs and intermediates as a part of comprehensive and robust system to handle the Novel Corona Virus (COVID-19) outbreak, drug availability or production to reduce the impact of the Novel Corona Virus (COVID-19) are to be ensured. Therefore, the Answering Respondent issued S.O. 1223(E) dated 27/03/2020.

True copy of notification dated 27/03/2020 has been annexed as ANNEXURE as A/6.

21. Furthermore, it was submitted that vide the above-mentioned notification, issued by the Answering Respondent, all projects in respect of API are to be

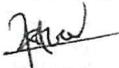
  
Dr. R. Sridhar,  
Scientist 'D'  
Government of India  
Min. of Environment Forest and Climate Change  
Integrated Regional Office  
1st Floor, Additional Office Block for GPOA,  
Shastri Bhawan, Haddows Road  
Nungambakkam, Chennai - 600 006.

appraised as Category "B2" upto 30/09/2020 at Centre or State level depending upon the applicability of general conditions, as stated at para 7 above. Subsequently, the above mentioned period was extended by six months from 30th September, 2020 to 30th March, 2021 vide notification no. S.O. 3636(E) dated 15th October, 2020. In view of the outbreak of the second wave of COVID-19 pandemic, the Central Government received requests for further extension of the time period beyond 30th March, 2021 as there is a continued requirement to expedite drug manufacturing. Therefore, the timeline was extended to 31<sup>st</sup> December 2021 vide notification S.O. 2859 (E) dated 16.07.2021 for all the proposals that were received from 16th July, 2021 to 31<sup>st</sup> December, 2021.

True copy of the above mentioned notification has been annexed as ANNEXURE A/7.

22. It is submitted that the M/s Pradeep Exports obtained CTE for manufacturing of three products viz. Furosemide (3.0 Tons/Month), Analgin (30.0 Tons/Month) and Mebenezole (3.0 Ton/month) with a total production capacity was 38 T/M prior to EIA 1994 and thereafter obtained CTE in 2005 with respect to M/s Sun Pharmaceutical Industries to manufacture 10 products viz Analgin Magesium (6 T/M), Sodium Valporaic (8 T/M), Oxeclacine (1 T/M), Clomipramine (1 T/M), Flurbiprofen (1 T/M), Carbamazepine (4 T/M), Mepoprolol tartrate (3 T/M), Tramadol Hcl (1 T/M), Metadoxine (0.4 T/M) and Danazole (0.1T/M). The total production capacity was 25.5 T/M. Although there was change in product mix but the total capacity of the plant is reduced from 38.0 T/M to 25.5 T/M. Further, there was no requirement of EC for change in product mix as per provision of EIA 1994 and the requirement for the same was mandated by EIA Notification 2006 as mentioned in para 11 above.

23. It is humbly submitted that for the Category of the project which did not require EC under EIA, 1994 and now required the same under EIA, 2006, the Ministry vide Circular dated 21.11.2006 issued guidelines wherein *inter-alia* it was mentioned that projects for which NOCs (CTE) issued before 14<sup>th</sup> September 2006, will not require to take Environmental Clearance under

  
Dr. R. Sridhar,  
Scientist 'D'  
Government of India  
Min. of Environment Forest and Climate Change  
Integrated Regional Office  
1st Floor, Additional Office Block for GPOA,  
Shastri Bhawan, Haddows Road  
Nungambakkam, Chennai - 600 006.

F.No. 22-43/2018-IA.III  
Government of India  
Ministry of Environment, Forest and Climate Change  
(IA Division)

Indira Paryavaran Bhawan  
Jor Bagh Road, Aliganj,  
New Delhi – 110003

Dated: 8<sup>th</sup> August, 2019

**OFFICE MEMORANDUM**

**Subject: Procedure for consideration of developmental projects located within 10 km of National Park/Wildlife Sanctuary seeking environmental clearance under the provisions of the Environmental Impact Assessment (EIA) Notification, 2006 - regarding.**

The Hon'ble Supreme Court vide its Order dated 4.12.2006 in Writ Petition No. 460 of 2004 – Goa Foundation Vs. Union of India, has inter-alia directed that Ministry of Environment and Forests "(MoEF) would also refer to the Standing Committee of the National Board for Wildlife, under section 5(b) & 5(c) (ii) of the Wildlife Protection Act, 1972, the cases where environmental clearances has already been granted where activities are within 10km. zone" of the boundaries of the Sanctuaries and National Parks."

2. In this regard, the erstwhile MoEF vide Circular No. L-11011/7/2004-IAII (I)(Part) dated 27.02.2007 and Office Memorandum No. J-11013/41/2006-IA.II(I) dated 02.12.2009 delineated a procedure for consideration of developmental projects located within 10 km of National Park/Wildlife Sanctuary for grant of environmental clearance under EIA Notification, 2006. As per the stipulated procedure, prior clearance from Standing Committee of the National Board for Wildlife (SCNBWL) would be required for the developmental projects located within 10km of the National Park/Wildlife Sanctuary.

3. Over a period of time, Ministry has notified number of Eco-Sensitive Zones (ESZs) around Protected Areas (PAs). Many of developmental activities are prohibited/regulated in these ESZs *inter-alia* including mining operations to be carried out in accordance with the order of the Hon'ble Supreme Court dated 4.08.2006 in the matter of T.N. Godavarman Thirumulpad Vs. UOI in

W.P.(C) No. 202 of 1995 and dated 21.4.2014 in the matter of Goa Foundation Vs. UOI in W.P.(C) No. 435 of 2012 as per the notifications issued for their constitution.

4. In light of the aforesaid Orders passed by the Hon'ble Supreme Court, the issues related to the prior clearance from SCNBWL for the notified ESZs and the remaining areas have been examined in detail. In this regard, it has been decided by the Competent Authority in the Ministry to adopt a following procedure for consideration of developmental projects located within 10 km of National Park/Wildlife Sanctuary seeking environmental clearance under the provisions of the EIA Notification, 2006, in supersession of the earlier O.M.s dated 27.2.2007 and 2.12.2009:

- i. Proposals involving developmental activity/project located within the notified Eco-Sensitive Zones (ESZ) shall be regulated and governed by the concerned ESZ notification. However, for the developmental project/activity located within the notified ESZ and covered under the schedule of the EIA Notification 2006, prior clearance from Standing Committee of the National Board for Wildlife (SCNBWL) is mandatory. In such cases, the project proponent shall submit the application simultaneously for grant of Terms of Reference as well as wildlife clearance.
- ii. Proposals involving developmental activity/project located outside the stipulated boundary limit of notified ESZ and located within 10 km of National Park/Wildlife Sanctuary, prior clearance from Standing Committee of the National Board for Wildlife (SCNBWL) may not be applicable. However, such proposals from environmental angle including impact of developmental activity/project on the wildlife habitat, if any, would be examined by the sector specific Expert Appraisal Committee and appropriate conservation measures in the form of recommendations shall be made. These recommendations shall be explicitly mentioned in the environmental clearance letter and shall be ensured by the member secretary concerned.
- iii. Proposals involving developmental activity/project located within 10 km of National Park/Wildlife Sanctuary wherein final ESZ notification is not notified (or) ESZ notification is in draft stage, prior clearance from Standing Committee of the National Board for Wildlife (SCNBWL) is mandatory. In such cases, the project proponent shall submit the application simultaneously for grant of Terms of Reference/environmental clearance as well as wildlife clearance.

- iv. Proposals involving mining of minerals within the ESZ (or) one kilometer from the boundaries of National Parks and Sanctuaries whichever is higher is prohibited in accordance with the order of the Hon'ble Supreme Court dated 4.08.2006 in the matter of T.N. Godavarman Thirumulpad Vs. UOI in W.P.(C) No. 202 of 1995 and dated 21.4.2014 in the matter of Goa Foundation Vs. UOI in W.P.(C) No. 435 of 2012.
5. This issues with the approval of the Competent Authority.

*Sharath Kumar Pallerla*  
8/8/19

**(Sharath Kumar Pallerla)**  
**Director**

To

1. Chairman, Central Pollution Control Board (CPCB).
2. Chairman of all the Expert Appraisal Committees
3. Chairperson/Member Secretaries of all the SEIAAs/SEACs
4. All the Officers of I.A. Division
5. Chairpersons/Member Secretaries of all SPCBs/UTPCCs

**Copy for information to:**

1. PS to Hon'ble Minister for Environment, Forest and Climate Change
2. PS to Hon'ble MoS (EF&CC)
3. PPS to Secretary(EF&CC)
4. PPS to SS(AKJ)
5. PPS to AS (RSP)
6. PPS to JS (GM)/ JS(RS)/JS(AKN)
7. Website, MoEF&CC
8. Guard file.