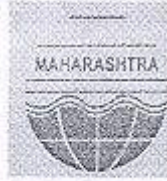


# MAHARASHTRA POLLUTION CONTROL BOARD

Phone : 4010437/4020781  
/4037124/4035273  
Fax : 24044532/4024068 /4023516  
Email : enquiry@mpcb.gov.in  
Visit At : <http://mpcb.gov.in>



Kalpataru Point, 3rd & 4th floor, Sion- Matunga  
Scheme Road No. 8, Opp. Cine Planet Cinema, Near  
Sion Circle, Sion (E),  
Mumbai - 400 022

Red/L.S.I

Date: 16/11/2011

Consent No: BO/JD-PAMS/EIC No.NK-7714-11/E/EE-CA(-09

Consent to Establish under Section 25 of the Water (Prevention & Control of Pollution) Act, 1974 & under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and Authorization / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules 2008

[To be referred as Water Act, Air Act and HW (M&H) Rules respectively].

.....  
CONSENT is hereby granted to

M/s. Sun Pharmaceutical Industries Ltd  
Plot No.A-7 and 8,MIDC Ahmednagar,  
Tal. and Dist. Ahmednagar.

located in the area declared under the provisions of the Water Act, Air act and Authorization under the provisions of HW(M&H) Rules and amendments thereto subject to the provisions of the Act and the Rules and the Orders that may be made further and subject to the following terms and conditions:

1. The Consent to Establish for expansion with product mix is granted for a period up to: Commissioning Of the UNIT Or 5 years whichever is earlier .
2. The Consent is valid for the manufacture of Bulk Drugs & Pharmaceutical products as below-

A] Existing (Original) list of 73 products.

Sr. No.	Product Name	Maximum Quantity	UOM (Kg)
1.	Clonazepam		480
2.	Dobutamine Hydrochloride		480
3.	Dothiepin Hydrochloride		6000
4.	Flurbiprofen		36000
5.	Tramadol Hydrochloride		12000
6.	Mesalamine		22000
7.	Flurbiprofen Sodium		10
8.	Fluvoxamine Maleate		3000
9.	Gabapentin		12000
10.	Meloxicam		1500
11.	Metoprolol Succinate/Tartrate		36000
12.	Pentoxifylline		20350



13.	Piroxicam Betacyclodextrin	3600
14.	Sertraline Hydrochloride	300
15.	Tetrabenazine	300
16.	Acetonitrile	5000
17.	Metformin Hydrochloride	1164000
18.	Olanzapine	300
19.	Bupropion Hydrochloride	1500
20.	Mirtazapine	360
21.	Atorvastatine Calcium	12
22.	Methyl phenidate HCl	25
23.	Repaglinde	50
24.	Pioglitazone Hydrochloride	300
25.	Cisplatin	120
26.	Carboplatin	120
27.	Sodium Valproate	10000
28.	Venlafaxine Hydrochloride	1200
29.	Octreotide Acetate	1
30.	Leuprolide Acetate	1
31.	Desmopressin acetate	1
32.	Amifosmtine Trihydrate	200
33.	Oxaliplatin	10
34.	Citalopram	204
35.	Clopidogrel Bisulphate	1000
36.	Rivastigmine Tartrate	100
37.	Letrozole	100
38.	Isradipine	10
39.	Mitoxantrone Hydrochloride	2
40.	Lercanidipine Hydrochloride	600
41.	Ziprasidone Hydrochloride	1200
42.	Quetiapine Fumarate	1200
43.	Disodium Pamidronate	1200
44.	Capecitabine	100
45.	Eptifibatide	2
46.	Gemcitabine Hydrochloride	100
47.	Imatinib Mesylate	300
48.	Zoledronic acid	10
49.	Innotecan Hydrochloride	5



50.	Thymosin Alpha	0.2
51.	Bivalirudin	5
52.	Ganirelix Acetate	0.1
53.	Fluvastatine Sodium	100
54.	Docetaxel	2
55.	Terlipressin acetate	1
56.	Balsalazide	100
57.	Finasteride	10
58.	Anastrozole	5
59.	Valacyclovir	100
60.	Desloratadine	500
61.	Metoprolol Tartrate with no water	48203.7
62.	Sodium Phenyl butyrate	250
63.	Donepezil Hydrochloride	500
64.	Entacapone	500
65.	Memantine Hydrochloride	100
66.	Nateglinide	300
67.	Pantoprazole sodium	400
68.	Phenteramine Hydrochloride	400
69.	Raloxifene Hydrochloride	300
70.	Ropinirole Hydrochloride	100
71.	Glimipride	200
72.	Tegaserod Maleate	100
73.	Temozolamide	10
	Total	1395540 kg/A 1395.54MT/A

B. List of products which proposed to decrease in production quantity.

Sr.No.	Name of product	Existing production qty. (Kg)	Proposed production qty. (Kg)
1	Amifostine Trihydrate	200	21
2	Anastrozole	5	2
3	Atorvastatin calcium	5	0.82
4	Capecitabine	100	29
5	Carboplatin	120	14
6	Cisplatin	120	42.8
7	Clopidogrel Bisulphate	1000	500
8	Desloratidine	500	100
9	Desmopressin Acetate	1	0.4



10	Docetaxel	2	0.47
11	Donepezil Hydrochloride	500	300
12	Dothiepin Hydrochloride	6000	2500
13	Eptifibatide	2	0.37
14	Flurbiprofen	36000	15100
15	Fluvastatin Sodium	100	60
16	Imatinib Mysilate	300	131
17	Lercanidipine Hydrochloride	600	264
18	Letrozole	100	13
19	Metformin Hydrochloride	1164000	741460
20	Mitoxantrone Hydrochloride	2	0.7
21	Octreotide Acetate	1	0.36
22	Olanzapine	300	247
23	Oxaliplatin	10	6
24	Pentoxifylline ( Oxpentifylline)	20350	5000
25	Piroxicam Belacyclodextrin	3600	2507
26	Quetiapine Fumarate	1200	1100
27	Rivastigmine Tartrate	100	70
28	Tegaserod Maleate	100	10
29	Tetrabenazine	300	163
30	Ziprasidone Hydrochloride	1200	100
31	Zoledronic Acid	10	0.05
	Total	1198.92 MT/A	769.74 MT/A

C. List of products in which production quantity is proposed to increase.

Sr.No.	Name of product	Existing production qty.	Proposed Qty. Prod. Kg/ A
1	Atorvastatin calcium	12	250
2	Bupropion Hydrochloride	1500	16360
3	Clonazepam	480	1055
4	Dobutamine Hydrochloride	480	1051
5	Finasteride	10	211
6	Flurbiprofen Sodium	10	26
7	Fluvoxamine Maleate	3000	8342
8	Gabapentin	12000	48542
9	Ganirelix acetate	0.1	0.02
10	Gemcitabine Hydrochloride	100	1200
11	Irinotecan Hydrochloride	5	60
12	Isradipine	10	10
13	Leuprolide Acetate	1	0.04
14	Meloxicam	1500	3800
15	Memantine Hydrochloride	100	247



16	Mesalamine ( Mesalazine)	22000	180000
17	Metoprolol Succinate	3600	4900
18	Metoprolol Tartrate	120000	122321
19	Pantaprazole sodium	400	4000
20	Phenteramine Hydrochloride	400	500
21	Pioglitazone Hydrochloride	300	500
22	Raloxifene Hydrochloride	300	1000
23	Sodium Valproate	10000	30000
24	Temozolamide	10	66
25	Terlipressin Acetate	1	0.08
26	Thymosin Alpha -1	0.2	0.3
27	Tramadol Hydrochloride	12000	81468
28	Venlafaxine Hydrochloride	1200	14900
	<b>Total</b>	<b>189.21 MT/A</b>	<b>520.36 MT/A</b>

D. List of proposed 37 Nos of Products-

Sr.No.	Name of product	Existing production qty.	Proposed Qty. Prod. Kg/Year
1	Acitretin	0	15.00
2	Amisulpride	0	2000
3	Atosiban acetate	0	0.5
4	Adapalene	0	15
5	Bicalutamide	0	315
6	Bortezomib	0	0.2
7	Bendamustine Hcl	0	2
8	Calcitonin	0	0.19
9	Cetrorelix Acetate	0	0.01
10	Chlorothiazide	0	60
11	Decitabine	0	10
12	Desvenlafaxine Fumarate	0	320
13	Divalproex Sodium	0	100410
14	Esomeprazole magnesium	0	160
15	Eszopiclone	0	10
16	Exemestane	0	7
17	Exenatide	0	0.02
18	Glucagon	0	10
19	Ibandeonic acid monosodium	0	146
20	Isotretinoin	0	6
21	Lamotrigine	0	50
22	Lansoprazole	0	700
23	Lenalidomide	0	10
24	Naratriptan Hydrochloride	0	5
25	Olopatadine	0	10
26	Paliperidone palmitate	0	12
27	Pemetrexed disodium	0	1
28	Pramlintide acetate	0	0.05
29	Pregabline	0	1110



30	Risedronate sodium	0	50
31	Tazarotene	0	2
32	Tenatoprazole	0	10
33	Teriparatide	0	0.05
34	Temsirolimus	0	1.5
35	Febuxostat	0	0.05
36	Fulvestint	0	0.5
37	Omeprazole	0	0.02
	Total	0	105.44 MT/A

Total production for all above(List of B+C+D) products shall not exceed 1395.54 MT/A.

3. **CONDITIONS UNDER WATER ACT:**

- (i) The daily quantity of trade effluent from the factory shall be **NIL**.
- (ii) The daily quantity of sewage effluent from the factory shall be **NIL**.
- (iii) **Trade Effluent : For Existing-Treatment :** The applicant shall provide comprehensive treatment system consisting of primary / secondary and/or tertiary treatment as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of the treated effluent to the following standards :

1)	pH	Between	5.5 to 9.0
2)	Suspended Solids	Not to exceed	100 mg/l.
3)	BOD 3 days 27 Deg. C.	Not to exceed	100 mg/l.
4)	COD	Not to exceed	250 mg/l.
5)	Oil & Grease	Not to exceed	10 mg/l.
6)	Total Dissolved Solids	Not to exceed	2100 mg/l.
7)	Chlorides	Not to exceed	600 mg/l.
8)	Sulphates	Not to exceed	1000 mg/l.
9)	Phrenolic compound	Not to exceed	1 mg/l.
10)	Iron	Not to exceed	3 mg/l.
11)	Zinc	Not to exceed	3 mg/l.
12)	Total Ammonical Nitrogen	Not to exceed	50 mg/l.
13)	Sulphides as S	Not to exceed	2 mg/l.
14)	Chromium (Hexavalent)	Not to exceed	0.1 mg/l.

- (i) **Trade Effluent Disposal :** The treated effluent of 70 M<sup>3</sup>/day from existing operations shall be **reused/recycled minimum up to 70 %** in the process including cooling/flushing and remaining shall be disposed on land for gardening only.
- (iii) **Sewage Effluent Treatment:** The applicant shall provide comprehensive treatment system as is warranted with reference to influent quality and operate and maintain the same continuously so as to achieve the quality of treated effluent to the following standards.
- |     |                   |               |           |
|-----|-------------------|---------------|-----------|
| (1) | Suspended Solids  | Not to exceed | 100 mg/l. |
| (2) | BOD 3 days 27° C. | Not to exceed | 100 mg/l. |
- (vi). **Sewage Effluent Disposal :** The treated domestic effluent shall be soaked in a soak pit, which shall be got cleaned periodically. Overflow, if any, shall be used on land for gardening / plantation only.

(vii). **Non-Hazardous Solid Wastes :**

Type of Waste	Qty	Treatment	Disposal
NIL	---	-	-



- (viii) Other Conditions: - The industry shall monitor effluent quality regularly.  
 4. The applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 (to be referred as Cess Act) and Rules there under:

The daily water consumption for the following categories is as under (existing)-

(i) Domestic	...	13.0	CMD
(ii) Industrial Processing	...	70.0	CMD
(iii) Industrial cooling/ Floor washing...	...	360.0	CMD
(iv) Agriculture/Gardening	...	140.0	CMD

The applicant shall regularly submit to the Board the returns of water consumption in the prescribed form and pay the Cess as specified under Section 3 of the said Act.

5. **CONDITIONS UNDER AIR ACT:**

- (i) The applicant shall install a comprehensive control system consisting of control equipments as is warranted with reference to generation of emission and operate and maintain the same continuously so as to achieve the level of pollutants to the following standards;

A) **Control Equipment:**

- 1) Scrubber of adequate capacity shall be provided to process reactor to control the emissions & shall be operate properly & continuously. 2. Scrubber/ Bagfilter shall be provided to Briquette/Coal fired boiler.  
 2) There shall not be any fugitive emission.

B) **Standards for Emissions of Air Pollutants :**

(i)	SPM/TPM	Not to exceed	-	mg/Nm <sup>3</sup>
(ii)	SO <sub>2</sub> (process)	Not to exceed	-	Kg/Day.

D) **The applicant shall observe the following fuel pattern:-**

(i)	<u>Sr.No.</u>	<u>Type of Fuel</u>	<u>Quantity</u>
	---	---	---

- (ii) The applicant shall erect the chimney(s) of the following specifications:-

Sr.No.	Chimney attached to	Height in Mtrs.
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- (iii) The applicant shall provide ports in the chimney/(s) and facilities such as ladder, platform etc. for monitoring the air emissions and the same shall be open for inspection to/and for use of the Board's Staff. The chimney(s) vents attached to various sources of emission shall be designated by numbers such as S-1, S-2, etc. and these shall be painted/displayed to facilitate identification.

- (iv) The industry shall take adequate measures for control of noise levels from its own sources within the premises so as to maintain ambient air quality standard in respect of noise to less than 75 dB(A) during day time and 70 dB(A) during night time. Day time is reckoned in between 6 a.m. and 10 p.m. and night time is reckoned between 10 p.m. and 6 a.m.

(v) **Other Conditions:**

- 1) The industry should not cause any nuisance in surrounding area.  
 2) The industry should monitor stack emissions and ambient air quality regularly.

6. **CONDITIONS UNDER HW (M, H & T) RULES, 2008:**

- (i) The applicant shall handle hazardous waste as specified below:-

Sr. No.	Item No. of Process Generating H.W. as per Schedule-I	Type of Waste	Quantity	Disposal
--	---	---	NIL	--



7. Whenever due to any accident or other unforeseen act or even, such emissions occur or is apprehended to occur in excess of standards laid down, such information shall be forthwith Reported to Board, concerned Police Station, office of Directorate of Health Services, Department of Explosives, Inspectorate of Factories and Local Body. In case of failure of pollution control equipments, the production process connected to it shall be stopped.


**8. General Conditions-**

- I. The applicant shall maintain good house keeping and take adequate measures for Control of pollution from all sources so as not to cause nuisance to surrounding area/inhabitants.
- II. The applicant shall bring minimum 33% of the available open land under green coverage/ plantation.
- III. Solid Waste – The non-hazardous solid waste arising in the factory premises, sweepings, etc. be disposed of scientifically so as not to cause any nuisance / pollution. The applicant shall take necessary permissions from civic authorities for disposal to dumping ground.
- IV. The applicant shall provide for an alternate electric power source sufficient to operate all pollution control facilities installed by the applicant to maintain compliance with the terms and conditions of the consent. In the absence, the applicant shall stop, reduce or otherwise, control production to abide by terms and conditions of this consent regarding pollution levels.
- V. The applicant shall not change or alter the quantity, quality, the rate of discharge, temperature or the mode of the effluent/emissions or hazardous wastes or control equipments provided for without previous written permission of the Board.
- VI. The applicant shall provide facility for collection of environmental samples and samples of trade and sewage effluents, air emissions and hazardous waste to the Board staff at the terminal or designated points and shall pay to the Board for the services rendered in this behalf.
- VII. The applicant shall make an application for renewal of the consent at least 60 days before the date of expiry to the consent
- VIII. The firm shall submit to this office, the 30<sup>th</sup> day of September every year, the Environmental Statement Report for the financial year ending 31<sup>st</sup> March in the prescribed Form-V as per the provisions of rule 14 of the Environment (Protection) (Second Amendment) Rules, 1992.
- IX. An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- X. The applicant shall install a separate meter showing the consumption of energy for operation of domestic and industrial effluent treatment plants and air pollution control system. A register showing consumption of chemicals used for treatment shall be maintained.
- XI. Separate drainage system shall be provided for collection of trade and sewage effluents. Terminal manholes shall be provided at the end of the collection system with arrangement for measuring the flow. No effluent shall be admitted in the



pipes/sewers down stream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system.

- XII. Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
09. The consent should not be construed as any exemption from obtaining necessary NOC from other Govt. agencies as may deemed fit necessary.
10. This consent is issued in accordance with the pollution load assessment certificate issued by Padmashri Dr. Vitthalrao Vikhe Patil College Of Engineering, Ahmednagar vide letter No. COEA/Civil 09/Testing/2011/4331, dtd.19/09/2011.
11. This consent is issued pursuant to the decision of Consent Appriasal Committee meeting of the Board held on dtd. 09/ 11 / 2011.
12. Capital investment is Rs.160/- Crs.existing + Rs 33/- Crs. Expansion, Total CI is Rs. 193.0/- Crs

  
(Milind Mhaiskar. IAS)  
Member Secretary

To,  
M/s. Sun Pharmaceutical Industries Ltd;  
Plot No. A- 7/A- 8, MIDC, Ahmednagar,  
Dist. Ahmednagar.

Copy to:

- 1) Regional Officer, MPCB, Nashik } They are directed to ensure  
2) Sub-Regional Officer, MPCB, Ahmednagar } compliance of consent conditions  
3) Chief Accounts Officer, MPCB, Mumbai

Received Consent fee of -

<u>Amount</u>	<u>D.D.No.</u>	<u>Date</u>	<u>Drawn on</u>
Rs. 50,000/-	013453	04/12/2010	ICICI
Rs. 25,000/-	017061	30/09/2011	ICICI.

4] Cess Branch, MPCB.

5] Master file.