

MAHARASHTRA POLLUTION CONTROL BOARD

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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: 13/03/2012

Consent No: BO/JD-PAMS/EIC No.NK-10874-12/O/CAC- 33 6

Consent to Operate under Section 26 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 & Trans-boundary 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 Operate is granted for a period up to:31/12/2015.
2. The Consent is valid for the manufacture of Bulk Drugs & Pharmaceuticals as below -

Sr. No.	Product Name	Maximum Quantity Kg/Year
1	Amifostine Thihydrate	21
2	Anastrozole	2
3	Atorvastatin calcium	0.82
4	Capecitabine	29
5	Carboplatin	14
6	Cisplatin	42.8
7	Clopidogrel Bisulphate	500
8	Desloratidine	100
9	Desmopressin Acetate	0.4
10	Docetaxel	0.47
11	Donepezil Hydrochloride	300
12	Dothiepin Hydrochloride	2500
13	Eptifibatide	0.37
14	Flurbiprofen	15100
15	Fluvastatin Sodium	60
16	Imatinib Mysilate	131
17	Lercanidipine Hydrochloride	264
18	Letrozole	13
19	Metformin Hydrochloride	741460
20	Mitoxantrone Hydrochloride	0.7

21	Octreotide Acetate	0.36
22	Olanzapine	247
23	Oxaliplatin	6
24	Pentoxifylline (Oxpentifylline)	5000
25	Piroxicam Betacyclodextrin	2507
26	Quetiapine Fumarate	1100
27	Rivastigmine Tartrate	70
28	Tegaserod Maleate	10
29	Tetrabenazine	163
30	Ziprasidone Hydrochloride	100
31	Zoledronic Acid	0.05
32	Atorvastatin calcium	250
33	Bupropion Hydrochloride	16360
34	Clonazepam	1055
35	Dobutamine Hydrochloride	1051
36	Finasteride	211
37	Flurbiprofen Sodium	26
38	Fluvoxamine Maleate	8342
39	Gabapentin	48542
40	Ganirelix acetate	0.02
41	Gemcitabine Hydrochloride	1200
42	Irinotecan Hydrochloride	60
43	Isradipine	10
44	Leuprolide Acetate	0.04
45	Meloxicam	3800
46	Memantine Hydrochloride	247
47	Mesalamine (Mesalazine)	180000
48	Metoprolol Succinate	4900
49	Metoprolol Tartrate	122321
50	Pantaprazole sodium	4000
51	Phenteramine Hydrochloride	500
52	Pioglitazone Hydrochloride	500
53	Raloxifene Hydrochloride	1000
54	Sodium Valproate	30000
55	Temozolamide	66
56	Terlipressin Acetate	0.08
57	Thymosin Alpha -1	0.3
58	Tramadol Hydrochloride	81468
59	Venlafaxine Hydrochloride	14900
60	Acitretin	15.00
61	Amisulpride	2000
62	Atosiban acetate	0.5
63	Adapalene	15
64	Bicalutamide	315
65	Bortezomib	0.2
66	Bendamustine Hcl	2
67	Calcitonin	0.19
68	Cetrorelix Acetate	0.01
69	Chlorothiazide	60
70	Decitabine	10
71	Desvenlafaxine Fumarate	320
72	Divalproex Sodium	100410

73	Esomeprazole magnesium	160
74	Eszopiclone	10
75	Exemestane	7
76	Exenatide	0.02
77	Glucagon	10
78	Ibandronic acid monosodium monohydrate	146
79	Isotretinoin	6
80	Lamotrigine	50
81	Lansoprazole	700
82	Lenalidomide	10
83	Naratriptan Hydrochloride	5
84	Olopatadine	10
85	Paliperidone palmitate	12
86	Pemetrexed disodium heptahydrate	1
87	Pramlintide acetate	0.05
88	Pregabline	1110
89	Risedronate sodium hemipentahydrate	50
90	Tazarotene	2
91	Tenatoprazole	10
92	Teriparatide	0.05
93	Temsirolimus	1.5
94	Febuxostat	0.05
95	Fulvestint	0.5
96	Omeprazole	0.02

(Total production capacity for above all 96 products shall not exceed 1395.54 MT/Year.)

3. CONDITIONS UNDER WATER ACT:

- (i) The daily quantity of trade effluent from the factory shall not exceed 70 M³.
- (ii) The daily quantity of sewage effluent from the factory shall not exceed 8.0 M³.
- (iii) **Trade Effluent :**

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)	Phenolic compound	Not to exceed	1 mg/l.
10)	Iron	Not to exceed	3 mg/l.
11)	Total Ammonical Nitrogen	Not to exceed	50 mg/l.
12)	Sulphides as S	Not to exceed	2 mg/l.

- (i) **Trade Effluent Disposal** : The treated effluent of 70 M³/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
Biological Sludge	6 MT/M		Composting

- (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-

(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	150.0 mg/Nm ³
(ii)	SO ₂ (process)	Not to exceed	720.0 Kg/Day.
(iii)	HCL/Acid Mist	Not to exceed	35.0 mg/Nm ³
(iv)	So ₂ /NOX	Not to exceed	50.0 mg/Nm ³
(V)	Bromine	Not to exceed	3.0 ppm.
(vi)	NH ₃	Not to exceed	50.0 ppm

c. **Conditions for D.G. Set**

- a. Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
- b. Industry should provide acoustic enclosure for control of noise. The acoustic enclosure/ acoustic treatment of the room should be designed for minimum 25 dB (A) insertion loss or for meeting the ambient noise standards,

whichever is on higher side. A suitable exhaust muffler with insertion loss of 25 dB (A) shall also be provided. The measurement of insertion loss will be done at different points at 0.5 meters from acoustic enclosure/room and then average.

- c. The industry shall take adequate measures for control of noise levels from its own sources within the premises in respect of noise to less than 75 dB(A) during day time and 70 dB(A) during the night time. Day time is reckoned between 6 a.m. to 10 p.m and night time is reckoned between 10 p.m to 6 a.m.
- d. Industry should make efforts to bring down noise level due to DG set, outside industrial premises, within ambient noise requirements by proper siting and control measures.
- e. Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
- f. A proper routine and preventive maintenance procedure for DG set should be set and followed in consultation with the DG manufacturer which would help to prevent noise levels of DG set from deteriorating with use
- g. D.G. Set shall be operated only in case of power failure
- h. The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set

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

(i)	<u>Sr.No.</u>	<u>Type of Fuel</u>	<u>Quantity</u>
	1	Briquette (Agro based)	30 TPD
		OR	
	2.	FO	8.0 TPD

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

Sr.No.	Chimney attached to	Height in Mtrs.
1	Coal/ Briquette fired Boiler	30
2	Boiler- ii	22
3	Boiler – iii & iv (stand by)	30
4	D.G Set (320 KVA- 2 Nos)	2.5 above the roof
5	D.G Set (500 KVA & 750 KVA)	4.5 above the roof

- (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:-

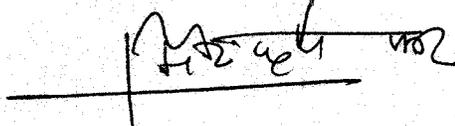
Sr. No.	Item No. of Process Generating H.W. as per Schedule-I	Type of Waste	Quantity	Disposal
1	5.1	Used oil	3.0 MT/A	Sale to autho. Recycler
2	20.3	Distillation residue	8.0 MT/A	CHWTSDF
3	28.1	Spent carbon/Raneynickel	75 MT/A	Sale to autho recycler
4	28.5	Spent solvent	720 MT/M	Sale to autho recycler/recovered in own.srp.
5	33.3	Discarded containers, PE bags, hdpe, Fiber drums	32.8 MT/A	Sale to autho. Recycler
6	34.3	Sludge forom w.w.t.	85.0 MT/A	CHWTSDF

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 30th day of September every year, the Environmental Statement Report for the financial year ending 31st 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 if 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 with an overriding effect on earlier consent granted by the Board vide consent No. BO/JD-PAMS/EIC No. NK-7714-11/R/CC-155, dtd. 03.10.2011.
12. This consent is issued pursuant to the decision of Consent Appraisal Committee meeting of the Board held on dtd. 02/ 03 / 2012.
13. 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. 3,00,000/-	017913	30/01/2012	ICICI Bank.

4] Cess Branch, MPCB.

5] Master file.