

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

Consent order No :- Formate 1.0/ BO/CAC-Cell/ EIC No NK-20666-15/14th CAC/4449
Date- 30/03/2016

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

Subject: Renewal of consent to operate under RED category.

- Ref: 1. Existing Consent granted vide no BO/JD-PAMS/EIC No NK-10874-12/O/CAC-336 dtd 13.03.2012.
2. Consent to operate for briquette fired boiler granted vide no Formate 1.0/ BO/CAC-Cell/ EIC No NK-19427-15/10th CAC/402 dated 08.01.2016 which is valid upto 30.04.2016.
3. Your application approved in CAC meeting held on 02.02.2016.

Your application: CO1512000359
Dated: 17.11.2015

For: Renewal of 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 under Rule 5 of the Hazardous Wastes (M, H & T M) Rules 2008 is considered and the consent is hereby granted subject to the following terms and conditions and as detailed in the schedule I, II, III & IV annexed to this order:

1. The consent is granted for a period from date of 01.01.2016 to 30.04.2020.
2. The actual capital investment of the industry is Rs.283.23 Crs. (As per C.A. Certificate submitted by industry).
3. The Consent is valid for the manufacture of -

Sr. No.	Product / By-Product Name	Maximum Quantity in MTA
1	Atorvastatin calcium	250
2	Bupropion Hydrochloride	16360
3	Clonazepam	1055
4	Dobutamine Hydrochloride	1051
5	Finasteride	211
6	Flurbiprofen Sodium	26
7	Fluvoxamine Maleate	8342
8	Gabapentin	48542
9	Ganirelix acetate	0.02
10	Gemcitabine Hydrochloride	1200
11	Irinotecan Hydrochloride	60
12	Isradipine	10
13	Leuprolide Acetate	0.04
14	Meloxicam	3800
15	Memantine Hydrochloride	247

16	Mesalamine	180000
17	Metoprolol Succinate	4900
18	Metoprolol Tartrate	122321
19	Pantaprazole sodium	4000
20	Phenteramine Hydrochloride	500
21	Pioglitazone Hydrochloride	500
22	Raloxifene Hydrochloride	1000
23	Sodium Valproate	30000
24	Temozolamide	66
25	Terlipressin Acetate	0.08
26	Thymosin Alpha	0.3
27	Tramadol Hydrochloride	81468
28	Venlafaxine Hydrochloride	14900
29	Amifostine Thihydrate	21
30	Anastrozole	2
31	Capecetabin	29
32	Carboplatine	14
33	Cisplatin	42.8
34	Clopidogrel Bisulphate	500
35	Desloratidine	100
36	Desmopressin Acetate	0.4
37	Docetaxel	0.47
38	Donepezil Hydrochloride	300
39	Dothiepin Hydrochloride	2500
40	Epitifibatide	0.37
41	Flurbiprofen	15100
42	Fluvastatin Sodium	60
43	Imatinib Mysilate	131
44	Lercanidipine Hydrochloride	264
45	Letrozole	13
46	Metformine Hydrochloride	741460
47	Mitoxantrone Hydrochloride	0.7
48	Octreotide Acetate	0.36
49	Olanzapine	247
50	Oxaliplatin	6
51	Pentoxifylline (Oxpentifylline)	5000
52	Piroxicam Betacyclodextrin	2507
53	Quetiapine Fumarate	1100
54	Rivastigmine Tartrate	70
55	Tegaserod Maleate	10
56	Tetrabenazine	163
57	Ziprasidone Hydrochloride	100
58	Zoledronic Acid	0.05
59	Acitretin	15
60	Amisulpride	2000
61	Atosiban acetate	0.5
62	Adapalene	15
63	Bicalutamide	315
64	Bortezomib	0.2
65	Bendamustine Hcl	2
66	Calcitonin	0.19
67	Cetrorelix Acetate	0.01

68	Chlorothiazide	
69	Decitabine	60
70	Desvenlafaxine Fumarate	10
71	Divalproex Sodium	320
72	Esomeprazole magnesium	100410
73	Eszopiclone	160
74	Exemestane	10
75	Exenatide	7
76	Glucagon	0.02
77	Ibandronic acid monosodium monohydrate	10
78	Isotretinoin	146
79	Lamotrigine	6
80	Lansoprazole	50
81	Lenalidomide	700
82	Naratriptan Hydrochloride	10
83	Olopatadine	5
84	Paliperidone palmitate	10
85	Pemetrexed disodium heptahydrate	12
86	Pramlintide acetate	1
87	Pregabline	0.05
88	Risedronate sodium hemipentahydrate	1110
89	Tazarotene	50
90	Tenatoprazole	2
91	Teriparatide	10
92	Temsirolimus	0.05
93	Fulvestrant	1.5
94	Febuxostat	0.05
95	Omeprazole	0.5
		0.02

4. Conditions under Water (P&CP), 1974 Act for discharge of effluent:

Sr. no.	Description	Permitted quantity of discharge (CMD)	Standards to be achieved	Disposal
1.	Trade effluent	70	As per Schedule -I	70 % recycled and remaining on land for gardening.
2.	Domestic effluent	8	As per Schedule -I	On land for gardening

5. Conditions under Air (P&CP) Act, 1981 for air emissions:

Sr. no.	Description of stack / source	Number of Stack	Standards to be achieved
1.	Boiler 2 nos	1	As per Schedule -II
2.	Boiler 5 TPH (stand -by)	1	As per Schedule -II
3.	Boiler 8 TPH (stand -by)	1	As per Schedule -II

4.	DG set (320 KVA X 2 nos, 500 KVA X 2 nos, 750 KVA, 1000 KVA	6	As per Schedule -II
5.	Process stacks	11	As per Schedule -II

6. Conditions about Non Hazardous Wastes:

Sr. no.	Type Of Waste	Quantity & UOM	Treatment	Disposal
1	Ash	2 MT/D	NA	Sale to Brick Manufactures
2.	Biological sludge	6 MT/M	NA	Composting

7. Conditions under Hazardous Waste (MH & TM) Rules, 2008 for treatment and disposal of hazardous waste:

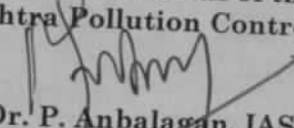
Sr. No.	Type Of Waste	Categor.	Quantit	UOM	Treatment	Disposal
1	Used oil	5.1	30	MT/A	NA	Sale to authorized recycler
2	Distillation residue	20.3	8	MT/A	NA	CHWTSDF
3	Spent carbon/Raney nickel	28.1	75	MT/A	NA	Sale to authorized recycler
4	Spent solvent	28.5	720	MT/M	NA	Sale to authorized recycler/ recovered in own SRP
5	Discarded containers, PE bags, HDPE, Fibre drums	33.3	32.8	MT/A	NA	Sale to authorized recycler
6	Sludge from waste water treatment plant	34.3	85	MT/A	NA	CHWTSDF

8. The Board reserves the right to review, amend, suspend, revoke etc. this consent and the same shall be binding on the industry.
9. This consent should not be construed as exemption from obtaining necessary NOC/permission from any other Government authorities.
10. The applicant shall operate online continuous stack emission monitoring system and online effluent quality monitoring systems at the outlet of effluent treatment plant for measurement of consented parameters.

(Handwritten signature)

11. This consent is granted by overriding consent no *Formate 1.0/BO/CAC-Cell/ EIC No NK-19427-15/10th CAC/402* dated 08.01.2016.

For and on behalf of the
Maharashtra Pollution Control Board


(Dr. P. Anbalagan, IAS)
Member Secretary

Received Consent fee of -

Sr. No.	Amount(Rs.)	DD. No.	Date	Drawn On
1	2832449	025933	21.10.2015	ICICI

The balance fees Rs. 142372 , with the Board will be considered at the time of next renewal of consent.

Copy to:

1. Regional Officer -Nashik and Sub-Regional Officer-Nashik, MPCB: They are directed to ensure the compliance of the consent conditions.
2. Chief Accounts Officer, MPCB, Mumbai.
3. CC/CAC desk- for record & website updation purposes.

Schedule-I

Terms & conditions for compliance of Water Pollution Control:

- 1) A] As per your application, you have provided the Effluent Treatment Plant (ETP) with the design capacity of 70 CMD followed by RO and MEE .
- B] The Applicant shall operate the effluent treatment plant (ETP) to treat the trade effluent so as to achieve the following standards prescribed by the Board or under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.

Sr No.	Parameters	Standards prescribed by Board (If any)
		Limiting Concentration in mg/l, except for pH
01	pH	5.5 to 9.0
02	Oil & Grease	10
03	BOD (3 days 27°C)	30
04	Total Dissolved Solids	2100
05	Phenolics (C6H5OH)	1.0
06	Suspended Solids	100
07	COD	250
08	Chloride	600
09	Sulphate	1000
10	Iron	3
11	Total Ammonical Nitrogen	50

- C) The treated effluent shall be 70 % recycled in process including cooling/flushing and remaining on land for gardening.

- 2) A.] As per your consent application, you have provided the sewage treatment system with the design capacity of 8 CMD.

- B] The Applicant shall operate the sewage treatment system to treat the sewage so as to achieve the following standards/ prescribed under EP Act, 1986 and Rules made there under from time to time, whichever is stringent.

(1)	Suspended Solids.	Not to exceed	50	mg/l.
(2)	BOD 3 days 27°C.	Not to exceed	30	mg/l.
(3)	COD	Not to exceed	100	mg/l.

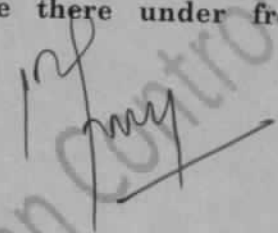
- C] The treated sewage shall be disposed on land for gardening.

- 3) The Board reserves its rights to review plans, specifications or other data relating to plant setup for the treatment of waterworks for the purification thereof & the system for the disposal of sewage or trade effluent or in connection with the grant of any consent conditions. The Applicant shall obtain prior consent of the Board to take steps to establish the unit or establish any treatment and disposal system or /and extension or addition thereto.
- 4) The industry shall ensure replacement of pollution control system or its parts after expiry of its expected life as defined by manufacturer so as to ensure the compliance of standards and safety of the operation thereof.

- 5) The Applicant shall comply with the provisions of the Water (Prevention & Control of Pollution) Cess Act, 1977 and as amended, by installing water meters, filing water cess returns in Form-I and other provisions as contained in the said act.

Sr. no.	Purpose for water consumed	Water consumption quantity (CMD)
1.	Industrial Cooling, spraying in mine pits or boiler feed	360
2.	Domestic purpose	13
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	70
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0
5.	Agriculture/Gardening	140

The Applicant shall provide Specific Water Pollution control system as per the conditions of EP Act, 1986 and rule made there under from time to time/ Environmental Clearance / CREP guidelines.



Schedule-II

Terms & conditions for compliance of Air Pollution Control:

1. As per your application, you have installed the Air pollution control (APC) system and also erected following stack and to observe the following fuel pattern-

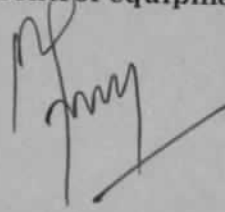
Sr. No.	Stack Attached To	APC System	Height in Mtrs.	Type of Fuel	Quantity & UoM	S %	SO ₂ Kg/Day
1	Boiler (15TPH)	Cyclone separator / high efficiency deduster followed by Bag filter	30	Briquette	30 T/D	0.06	36
2	Boiler (12 TPH) (stand - by)						
3	Boiler 5 TPH (stand -by)	Stack	36	FO	8 TPD	4.5	720
4	Boiler 8 TPH (stand -by)	Stack	46	FO			
5	DG sets (320 KVA X 2 nos,	Stack	8.5 each	Diesel	80 Kg/Hr each	1	38.4 each
6	DG sets (500 KVA X 2 nos)	Stack	8.5 each	Diesel	120 Kg/Hr each	1	57.4 each
7	DG set 750 KVA	Stack	11	Diesel	150 Kg/Hr	1	72
8	DG set 1000 KVA	Stack	30	Diesel	22 Kg/Hr	1	11
9	Process stack (12 nos)	Scrubbers	14,14,7.5 ,14,11,26 ,27,27,27 ,27,27	NA	NA	NA	NA

2. The Applicant shall provide Specific Air Pollution control equipments as per the conditions of EP Act, 1986 and rule made there under from time to time / Environmental Clearance / CREP guidelines.
3. The applicant shall operate and maintain above mentioned air pollution control system, so as to achieve the level of pollutants to the following standards:

Particulate matter	Not to exceed	150 mg/Nm ³ .
HCl/Acid mist	Not to exceed	35 mg/Nm ³ .
NOx	Not to exceed	50 mg/Nm ³ .
SO2 process	Not to exceed	50 mg/Nm ³ .
Bromine	Not to exceed	3 ppm
NH3	Not to exceed	50 ppm

4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation

- thereof or alteration or replacement/alteration well before its life come to an end or erection of new pollution control equipment.
5. The Board reserves its rights to vary all or any of the condition in the consent, if due to any technological improvement or otherwise such variation (including the change of any control equipment, other in whole or in part is necessary).

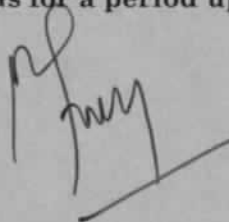


Maharashtra Pollution Control Board

Schedule-III
Details of Bank Guarantees

Sr. No.	Consent (C to E/O/R)	Amt of BG Imposed	Submissi on Period	Purpose of BG	Compliance Period	Validity Date
1	C to R	Rs 5 lakhs	Submitted *	O & M of PCS	30.04.2020	30.08.2020
2	C to R	100 % of the cost of the online monitoring systems (emissions and effluents which ever applicable)	Submitted *	The applicant shall install online continuous stack emission monitoring system and online effluent quality monitoring systems at the outlet of effluent treatment plant for measurement of consented parameters & to connect and upload the online emissions and effluent monitoring data at MPCB and CPCB server in time bound manner	30.04.2020	30.08.2020

*Industry shall extend the both the BGs for a period upto 30.04.2020.



Schedule-IV

General Conditions:

- 1) 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.
- 2) Industry should monitor effluent quality, stack emissions and ambient air quality monthly.
- 3) 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.
- 4) 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.
- 5) The applicant shall provide an alternate electric power source sufficient to operate all pollution control facilities installed 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.
- 6) 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.
- 7) The industry shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the HW(MH&TM) Rules 2008, which can be recycled/processed/reused/recovered and only waste which has to be incinerated shall go to incineration and waste which can be used for land filling and cannot be recycled/reprocessed etc should go for that purpose, in order to reduce load on incineration and landfill site/environment.
- 8) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 9) The applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.
- 10) Industry shall strictly comply with the Water (P&CP) Act, 1974, Air (P&CP) Act, 1981 and Environmental Protection Act, 1986 and industry specific standard under EP Rules 1986 which are available on MPCB website(www.mpcb.gov.in).
- 11) The industry should comply with the Hazardous Waste (M, H & TM) Rules, 2008 and submit the Annual Returns as per Rule 5(6) & 22(2) of Hazardous Wastes (M,H &TM) Rules, 2008 for the preceding year April to March in Form-IV by 30th June of every year.
- 12) The industry shall constitute an Environmental cell with qualified staff/personnel/agency to see the day to day compliance of consent condition towards Environment Protection.
- 13) 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 downstream of the terminal manholes. No effluent shall find its way other than in designed and provided collection system.
- 14) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.

- 15) 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.
- 16) Conditions for D.G. Set
- Noise from the D.G. Set should be controlled by providing an acoustic enclosure or by treating the room acoustically.
 - 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.
 - 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.
 - Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
 - 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
 - D.G. Set shall be operated only in case of power failure.
 - The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
 - The applicant shall comply with the notification of MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel
- 17) The industry should not cause any nuisance in surrounding area.
- 18) 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.
- 19) The applicant shall maintain good housekeeping.
- 20) The applicant shall bring minimum 33% of the available open land under green coverage/ plantation. The applicant shall submit a yearly statement by 30th September every year on available open plot area, number of trees surviving as on 31st March of the year and number of trees planted by September end.
- 21) 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 of solid waste.
- 22) 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. The industry will not carry out any activity, for which this consent has not been granted/without prior consent of the Board.
- 23) The industry shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the factory premises.
- 24) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 25) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dtd. 16.11.2009 as amended.

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