

# MAHARASHTRA POLLUTION CONTROL BOARD

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RED/LSI

Consent order No:-Format 1.0/AST/RONM/EIC No. NM-5968-15/O/ Amalgamation /CC-10017  
Date- 23/09/2016

To,  
M/s. Mylan Laboratories Ltd.,  
Plot No. 1-A/2 & 1-A/3, MIDC Talaja,  
Navi Mumbai, Dist Raigad

**Subject:** Consent to 1st operate with amalgamation RED category.

- Ref :**
1. Earlier consent to operate is granted vide No. *Format 1.0/AST/RONM/EIC No. NM-6146-16 /R/CC-8919 Dtd. 11.07.2016*
  2. Consent to establish is granted vide No. *BO/AS(T)/RONM/EIC No. NM-4614-13/R/CC-9314. Dtd. 06.11.2013*
  3. Minutes of CC meeting held on 24.08.2016

Your application: CO1510000272

Dated: 08.10.2015

For Consent to 1<sup>st</sup> operate with amalgamation 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 and other Wastes (M & 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 upto 30.04.2021
2. The total capital investment of the industry is Rs. 61.24 Cr. (Existing CI was Rs. 38.80 Cr + increased CI Rs. 22.44 Cr.) (As per C. A Certificate submitted by industry)
3. The Consent is valid for the manufacturing of -

Sr. No.	Existing Product Name	Maximum Quantity KG/A
1.	Cardio Vascular System	251
2.	Central Nervous System	15
3.	Osteoporosis	20
4.	Oncology	80
5.	Respiratory	50

Sr. No.	New Product Name	Maximum Quantity MT/A
1.	Bosentan	2000
2.	Rasagiline mesylate	5
3.	Vorinostat	20
4.	Clopidogrel hydrogen bromide	20000
5.	Lenalidomide	20
6.	Sunitinib maleate	50
7.	Zofenopril	1200

8.	Formoterol Fumarate dihydrate	20
9.	Salmeterol Xinafoate	30
10.	Rivastigmine	400
11.	osteoporosis	10
12.	Erlotinib Hydrochloride	50
13.	Letrozole	500
14.	Proguanil HCL	2000
15.	Pregablin	5000
16.	Febuxostat IB	480
17.	Capecitabine	9000
18.	Roflumilast	10
19.	Imatinib Mesylate	10
20.	Olopatadine Hydrochloride	10
21.	Atropine	100
22.	Tizanidine HCL	100
23.	Pramipexole HCL	50
24.	Frovatriptan	10
25.	Adefovir Dipivoxil	100
26.	Rotogotin	200
27.	Tolvaptan	15
28.	Diphenoxylate	1800
29.	Fluticasone	1800
30.	Dimethyl Fumarate	4500
31.	Other Validation Products (API)	500
	<b>Total</b>	<b>49990 MT/A</b>

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	46.5	As per Schedule -I	100 % recycle of treated effluent generated from expansion and only 10 CMD shall dispose to CETP
2.	Domestic effluent	10	As per Schedule -I	Soak pit

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-I	1	As per Schedule -II
2.	Boiler-II	1	As per Schedule -II
3.	Pilot Plant	1	As per Schedule -II
4.	MB-01 Intermediate Block	1	As per Schedule -II
5.	Process plant	1	As per Schedule -II
6.	Plant Prosta	1	As per Schedule -II
7.	HVAC-I	1	As per Schedule -II
8.	HVAC-II	1	As per Schedule -II
9.	DG Set 1500 KVA	1	As per Schedule -II

6. Conditions about Non Hazardous Wastes:

Sr. No.	Type Of Waste	Quantity/ UOM	Treatment	Disposal
1.	Metal scrap (MS, Iron, Aluminum GI, SS)	500 MT/A	....	Sale to authorized recyclers
2.	Paper waste and other discarded stationeries	5 MT/A	....	Sale to authorized recyclers
3.	Wood scrap	100 MT/A	....	
4.	Plastic scrap	25 MT/A	....	
5.	Glass scrap	25 MT/A	....	
6.	PVS, PVDC, Aluminium Foils	25 MT/A	....	
7.	Carton Boxes & packing waste	25 MT/A	....	
8.	Insulation waste	25 MT/A	....	CHWTSDF
9.	Garbage	5 MT/A	....	Used as manure

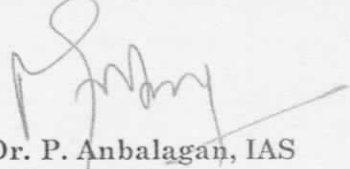
7. Conditions under Hazardous and Other Wastes (M & TM) Rules, 2016 for treatment and disposal of hazardous waste:

Sr. No.	Type Of Waste	Category	Quantity	UOM	Treatment	Disposal
1.	Used / spent oil	5.1	7000	Lit/A	....	Authorized recycler
2.	Residues and wastes	28.1	228	MT/A	....	CHWTSDF/ Sale to authorized recycler
3.	Off specification products	28.2	74	MT/A	....	CHWTSDF/ Sale to authorized recycler
4.	Spent organic solvents	28.6	10000	KL/A	....	Authorized recycler
5.	Discarded containers/ barrels/ liners	33.1	22000	Nos/A	....	Sale after detoxification
6.	Chemical sludge from waste water treatment	35.3	40	MT/A	....	CHWTSDF
7.	Toxic metal containing residue from water purification	35.5	5	MT/A	....	CHWTSDF
8.	Date expired, discarded and off specification drugs	28.5	2	MT/A	....	CHWTSDF/ Sale to authorized recycler
9.	Forced evaporation salts	37.3	240	MT/A	....	CHWTSDF
10	Spent ion exchange resin	35.2	5	MT/A	....	CHWTSDF
11	E-waste	....	25	MT/A	....	Authorized recycler/dismantler/Collection centre

12	Components of electrical waste like Switch Boards, Tube Lights, Mercury lamps etc.	Schedule 4,18	25	MT/A	....	CHWTSDF
13	Flue Gas Residue	Schedule 1, 35.1	2	MT/A	....	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 industry shall also comply with the Industry specific standards notified under Environment Protection Act.
11. The industry shall comply with the all conditions imposed in Environmental Clearance issued vide no. SEAC-2013/CR-249/CR-2 dtd. 01.12.2014.
12. This consent is issued with amalgamation of earlier Consent to Operate granted by the Board vide no. *Format 1.0/AST/RONM/EIC No. NM-6146-16 /R/CC-8919* Dtd. 11.07.2016 and consent to establish is granted vide No. BO/AS (T)/RONM/EIC No. NM- 4614-13/R/CC-9314. Dtd. 06.11.2013
13. This consent is issued pursuant to the decision of the Consent Committee held on 24.08.2016

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	100,100/-	030900	07.10.2015	HDFC Bank

Copy to:

1. Regional Officer -Navi Mumbai and Sub-Regional Officer, Taloja, 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 updating purposes.

### Schedule-I

#### Terms & conditions for compliance of Water Pollution Control:

1) A] As per your application, you have provided Effluent Treatment Plant (ETP) with the design capacity of 50 CMD comprising primary, secondary and tertiary treatment systems RO with forced evaporation system.

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
	<b>I. Compulsory Parameters</b>	<b>Limiting Concentration in mg/l, except for pH</b>
01	pH	5.5 to 8.5
02	Oil & Grease	10.0
03	BOD (3 days 27oC )	100
04	Suspended Solids	100
05	COD	250
06	Chloride (as Cl)	600
07	Sulphate as (SO <sub>4</sub> )	1000
08	Total Dissolved solids	2100
09	% Sodium	60 %
10	Bio assay test in fish shall show 90% survival in 96 hrs	

C] Total generation of treated effluent is 46.5 CMD out of that 36.5 CMD of treated effluent generated from the expansion shall be 100% recycle within the process and only 10 CMD shall be sent to CETP through MIDC pipeline.

2) A] As per your consent application, you have provided soak pit as a treatment for sewage.

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 | 100 | mg/l. |
| (2) | BOD 3 days 27oC.  | Not to exceed | 100 | mg/l. |

C] The treated sewage shall be used on land for gardening/plantation only in the factory premises.

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	72.5
2.	Domestic purpose	10
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	24
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	NIL
5.	For gardening	8

- 6) 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.

*Md. Jony*  
Maharashtra Pollution Control Board

## Schedule-II

### Terms & conditions for compliance of Air Pollution Control:

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

Sr. No.	Stack Attached To	APC System	Height in Mtrs.	Type of Fuel	Quantity & UoM	S %	SO <sub>2</sub> Kg/Day
1.	Boiler-I	Stack	30	Natural Gas or LDO	600 M <sup>3</sup> /D or 1.24 MT/D	00/ 1.8	00/ 44
2.	Boiler-II	Stack	30				
3.	Pilot Plant	5000 CFM Scrubber Provided	13	....	....	....	....
4.	MB-01 Intermediate Block	5000 CFM Scrubber Provided	16	....	....	....	....
5.	Process plant	1200 CFM Scrubber Provided	13	....	....	....	....
6.	Plant Prosta	700 CFM Scrubber Provided	13	....	....	....	....
7.	HVAC-I	6000 CFM Scrubber Provided	13	....	....	....	....
8.	HVAC-II	1500 CFM Provided	13	....	....	....	....
9.	DG Set 1500 KVA	Acoustic Enclosure Provided	9*	HSD	200 Ltr/Hr	....	....

\* Above the roof

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.
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 <sup>3</sup> .
Acid Mist	Not to exceed	35 ppm
HCL	Not to exceed	35 ppm

4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement 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).

**Schedule-III**  
**Details of Bank Guarantees**

Bank Guarantee History: Fresh and Existing BG's

Sr. No.	Consent (C to E/O/R)	Amt of BG Imposed	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	Existing BG	10 Lakh	15 days	Towards O & M of Pollution Control Systems.	Continuous	31.08.2021



## 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) If the MIDC pipeline is broken/ overflowing chamber, in such cases industry shall not discharge their treated effluent into MIDC drain, it shall be sent to CETP by tanker.
- 3) Industry should monitor effluent quality, stack emissions and ambient air quality monthly.
- 4) 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.
- 5) 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.
- 6) 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.
- 7) 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.
- 8) The industry shall recycle/reprocess/reuse/recover Hazardous Waste as per the provision contain in the Hazardous and Other Wastes (M & TM) Rules, 2016, 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.
- 9) The industry should comply with the Hazardous and Other Wastes (M & TM) Rules, 2016 and submit the Annual Returns as per Rule 5(6) & 22(2) of Hazardous Waste (M,H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30<sup>th</sup> June of every year.
- 10) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 11) The applicant shall obtain Consent to Operate from Maharashtra Pollution Control Board before actual commencement of the Activity.
- 12) 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](http://www.mpcb.gov.in)).
- 13) 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.
- 14) 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.

- 15) Neither storm water nor discharge from other premises shall be allowed to mix with the effluents from the factory.
- 16) 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.
- 17) 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) 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.
  - d) Installation of DG Set must be strictly in compliance with recommendations of DG Set manufacturer.
  - e) 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
  - f) D.G. Set shall be operated only in case of power failure.
  - g) The applicant should not cause any nuisance in the surrounding area due to operation of D.G. Set.
  - h) The applicant shall comply with the notification of MoEF dated 17.05.2002 regarding noise limit for generator sets run with diesel
- 18) The industry should not cause any nuisance in surrounding area.
- 19) 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.
- 20) The applicant shall maintain good housekeeping.
- 21) 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 31<sup>st</sup> March of the year and number of trees planted by September end.
- 22) 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.
- 23) 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.
- 24) 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.
- 25) The industry shall submit quarterly statement in respect of industries obligation towards consent and pollution control compliance's duly supported with documentary evidences (format can be downloaded from MPCB official site).
- 26) The industry shall submit official e-mail address and any change will be duly informed to the MPCB.
- 27) The industry shall achieve the National Ambient Air Quality standards prescribed vide Government of India, Notification dt. 16.11.2009 as amended.

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