

MAHARASHTRA POLLUTION CONTROL BOARD

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Kalpataru Point, 3rd & 4th floor, Sion- Matunga
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Sion Circle, Sion (E),
Mumbai - 400 022

Consent order No: - *Formate I.0/* BO/CAC-Cell/ EIC No NK-20984-16/1stCAC 8695
Date- 02/07/2016

To,
M/s. Mylan Laboratories Limited
Plot No. F-4, F-12 & F-2, MIDC Malegaon,
Tal. Sinnar Dist. Nashik- 422 113
Maharashtra.

Subject: Consent to First Operate of 2nd Expansion and Renewal of existing Consent to operate with amalgamation.

- Ref : 1. Earlier Consent granted vide no. BO/CAC-Cell/EIC No NK-18438-15/6th CAC - 12172 Dtd 19/09/2015
2. Earlier Consent granted vide no. BO/CAC-Cell/EIC No NK-1498-13/5th CAC - 5885 Dtd 21.06.2014
3. Your application approved in CAC meeting held on 27.04.2016.

Your application:CO1602000331

Dated: 30.01.2016

For: Consent to First Operate of 2nd Expansion and Renewal of existing Consent to 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 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 01.05.2016 upto 30.04.2021.
2. The capital investment of the industry is Rs. 594.17 Cores. (As per CA certificate submitted by industry). The proposed CI for 3rd expansion is Rs 500 crs.
3. The Consent is valid for the manufacture of -

Sr. No.	Product / By-Product Name	Maximum Quantity
1.	Injection Vials	1,45,60,000 Nos./Month
2.	Injection Ampoules	1,04,00,000 Nos./Month
3	Tablets	86,78,00,000 Nos./Month
4	Capsules	8,32,00,000 Nos./Month

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	432	As per Schedule -I	Total generation of effluent is 539.6 CMD out of which 508 CMD shall be used in cooling Tower & other purposes & remaining 31.6 CMD shall be used on land for gardening
2.	Domestic effluent	107.6	As per Schedule -I	

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.	D.G. Set (1500 KVA X 5 nos)	05 No.	As per Schedule -II
2.	D.G. Set (600 KVA X 2 nos)	02 No.	As per Schedule -II
3.	D.G. Set (140 KVA)	01 No.	As per Schedule -II
4.	Boiler (6 TPH)	01 No.	As per Schedule -II
5.	Boiler (3 TPH)		As per Schedule -II
6.	Boiler (2 TPH)		As per Schedule -II

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

Sr. No.	Type Of Waste	Category	Quantity	UOM	Treatment	Disposal
1	ETP Sludge from W.W. Treatment	34.3	709.1	MT/A	-	CHWTSDF
2	Discarded medicine	28.4	679.2	MT/A	-	CHWTSDF OR Cement factory for Co-Processing
3	Waste Oil	5.1	24400	Lts/A	-	Disposal to MPCB Authorized recycler
4	Discarded Batteries	Sch-II, B-4	200.0	Nos./A	-	Disposal to Authorized recycler
5	Discarded Liners	33.3	30	MT/A	-	Disposal to Authorized recycler
6	Discarded Container	33.3	1000	Nos/Day	-	Disposal to Authorized recycler
7	Spent Organic Solvent	28.5	200	MT/A	-	CHWTSDF
8	Off Specification products	28.3	350	MT/A	-	CHWTSDF OR Cement factory for

						Co-Processing
9	Flue gas residue from Boiler stack	34.1	45	MT/A	-	CHWTSDF
10	Oil Soaked cotton waste	5.2	15	MT/A	-	CHWTSDF
11	Spent ion Exchange resin	23.1	15	MT/A	-	CHWTSDF
12	E-Waste	-	2	MT/A	-	Disposal to Authorized recycler

7. Conditions under Non Hazardous Waste and disposal of non hazardous waste:

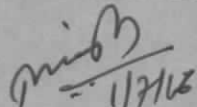
Sr. No.	Type Of Waste	Quantity	UOM	Treatment	Disposal
1.	M.S. Scrap	114	MT/A	--	Sale to Authorized Dealer
2.	Wooden Scrap	218	MT/A	--	Sale to Authorized Dealer
3.	Plastic Scrap	700	MT/A	--	Sale to Authorized Dealer
4	Corrugated Drums	74	MT/A	--	Sale to Authorized Dealer
5	Corrugated Box	382	MT/A	--	Sale to Authorized Dealer
6	PVC/PVDC/Alum Foil	612	MT/A	--	Sale to Authorized Dealer
7	Aluminum Scrap	12	MT/A	--	Sale to Authorized Dealer
8	GI Scrap	42.8	MT/A	--	Sale to Authorized Dealer
9	Garbage(Mix)	7.8	MT/A	--	Used as a manure
10	Polythene Bags	15.5	MT/A	--	Sale to Authorized Dealer
11	HDPE Bottle Scrap	46	MT/A	--	Sale to Authorized Dealer

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.

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10. Industry shall comply the guidelines to ensure sustainable environmental management in pursuance of Notification No S.O.3252 (E) of 22/12/2014 under EIA Notification 2006 vide O.M of MoEF dated 09.06.2015

For and on behalf of the
Maharashtra Pollution Control Board



(P.K.Mirashe)

Member Secretary

Received Consent fee of -

Sr. No.	Amount (Rs.)	DD. No.	Date	Drawn On
1.	35,65,120	012393	27.01.2016	HDFC Bank
2	2376580	110219	21.06.2016	HDFC Bank

The balance fees of Rs. 116390/- shall be considered at the time of next renewal of consent.

Copy to:

1. Regional Officer, MPCB, Nashik and Sub-Regional Officer, MPCB, Nashik. They are directed to ensure the compliance of the consent conditions. The BG of Rs 5 lakh and Rs. 2 lakh submitted towards- Not to take effective steps prior obtaining EC, and towards submission of Board resolution respectively shall be returned back as industry has complied the same reported by SRO.
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 Effluent Treatment Plant (ETP) of Capacity 450 CMD.(200 CMD Existing + 250 CMD New installed).

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	6.0 -8.5
02	Oil & Grease	10
03	BOD (3 days 27oC)	100
04	Total Dissolved Solids	2100
05	Bioassay Test	90% survival of fish after 96 hrs in 100 % effluent
06	Total Suspended Solids	100
07	COD	250
08	Chloride	600
09	Sulphate	1000

C) Out of the total treated effluent of 539.6 CMD (I.E + D.E) , 508 CMD shall be used in utility and 31.6 CMD will be used on land for gardening

2) A.] As per your consent application, you have provided the sewage treatment system with the design capacity of 120 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 | 100 | mg/l. |
| (2) | BOD 3 days 27°C. Not to exceed | 100 | mg/l. |

C] Out of the total treated effluent of 539.6 CMD (I.E + D.E) , 508 CMD shall be used in utility and 31.6 CMD will be used 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	400
2.	Domestic purpose	130
3.	Processing whereby water gets polluted & pollutants are easily biodegradable	515
4.	Processing whereby water gets polluted & pollutants are not easily biodegradable and are toxic	0

- 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.

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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 erected following stack (s) and to observe the following fuel pattern-

Sr. No.	Stack To	Attached	APC System	Height in Mtrs.	Type of Fuel	Qty. & UoM	S %	SO ₂ Kg/Day
1	D.G. Set (1500 KVA)- 5 nos.	(1500)	Muffler & silencer with stack	30 (each)	HSD	240 kg/Hr (each)	1	115.0 (each)
2	D.G. Set (600 KVA)- 2 Nos.	(600)	Muffler & silencer with stack	4.5 each (above the roof Level)	HSD	120 kg/Hr (each)	1	57.0 (each)
3	D.G. Set (140 KVA)- 1 nos.		Muffler & silencer with stack	4.5 (above the roof Level)	HSD	35 kg/Hr	1	17.0
4.	Boilers (6 TPH- 1 Nos.)		Common Stack	39.0	FO	360 kg/Hr	3.07	530
5.	Boilers (3 TPH- 2 Nos.)				FO	304 kg/Hr	3.07	447
6.	Boilers (2 TPH- 1 Nos.)							

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.
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 .
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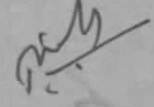
4. The Applicant shall obtain necessary prior permission for providing additional control equipment with necessary specifications and operation thereof or alteration or replacement/alteration well before its life come to an end or erection of new pollution control equipment.
5. The Board reserves its 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).

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Schedule-III
Details of Bank Guarantees

Sr. No.	Consent (C to E/O/R)	Amt of BG Imposed	Submission Period	Purpose of BG	Compliance Period	Validity Date
1	C to R	Rs 5 lakhs	Submitted *	O & M of PCS	30.04.2021	30.08.2021

*The BG of Rs 5 lakh towards O & M of PCS shall be extended for a period upto 30.08.2021.



Maharashtra Pollution Control Board

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) 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 Waste (M,H & TM) Rules, 2008 for the preceding year April to March in Form-IV by 30th June of every year.
- 9) An inspection book shall be opened and made available to the Board's officers during their visit to the applicant.
- 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 applicant shall make an application for renewal of the consent at least 60 days before the date of the expiry of the consent.**
- 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.