



RED Category

Renewal Consent to be applied before 120 days of validity Period

WEST BENGAL POLLUTION CONTROL BOARD

'Paribesh Bhawan',
Bldg. No. - 10A, Block-LA, Sector-III,
Salt Lake City, Kolkata-700 098



Consent Letter No. C083563

1870 /ka ce s/13/0668

Date 27.11.18

Consent to Operate

Application no. C00000000207782

under

Section 25 & 26 of the Water (Prevention and Control of Pollution) Act, 1974 and
Section 21 of the Air (Prevention and Control of Pollution) Act, 1981.

The West Bengal Pollution Control Board (hereinafter referred to as State Board) under the provisions of Section 25 & 26 of the Water (Prevention and Control of Pollution) Act, 1974, as amended and Section 21 of the Air (Prevention and Control of Pollution) Act, 1981, as amended, and Rules and Orders made thereunder, hereby grants its consent to:

Presenius Kabi Oncology Limited,

WEST BENGAL

(Address of Regd. office/Head/Office/City Office)

(hereinafter referred to as Applicant) for its unit located at D-35, Industrial Area, Vill, P.O. & P.S: Kalyani, Dist. Nadia, Pin- 741235.

(Detailed address of the manufacturing unit)

for a period from 01/01/2019 to 31/12/2023

to operate the industrial unit and to discharge liquid effluent and to emit gaseous effluent from the premises/land of the industrial unit, in accordance with the conditions as mentioned in the Annexure to this consent letter provided on any day at any instance the quantity and quality of liquid discharge and gaseous emission shall not exceed the permissible limit as specified in the Table I & II of this consent letter and in the Environmental (Protection) Act, 1986.

Breach of the conditions and / or failure to comply with the directions as set out in the Annexure shall render the applicant liable for prosecution under the provisions of the Water (Prevention and Control of Pollution) Act, 1974 and Air (Prevention and Control of Pollution) Act, 1981.

The State Board reserve the right to revoke, withdraw or make any reasonable variation / change / alter the conditions of this consent letter giving one month's notice to the applicant.

For and on behalf of the State Board

(Member Secretary/ Sr. Env. Engr./ Asst. Secy/ Asst. Secy)

**Senior Environmental Engineer
West Bengal Pollution Control Board
Barrackpore Regional Office**



ANNEXURE

Consent to Presenius Kabi Oncology Limited,
 for its unit at D-35, Industrial Area, Vill, P.O. & P.S: Kalyani,
Dist. Nadia, Pin - 741235.

Conditions :

1. This Consent is valid for the manufacture of :— See Annexure -I attached herewith.

Sl. No.	Name of major products and by-products	Quantity manufactured per month
01		
02		
03		
04		
05		
06		
07		
08		
09		
10		
11		
12		

- 02. The Applicant shall remain responsible for quantity and quality of liquid effluent and air emissions.
- 03. Daily discharge of industrial liquid effluent shall not exceed 220.0 KL.
- 04. Daily discharge of domestic liquid effluent shall not exceed 77.0 KL.
- 05. Daily discharge of mixed (industrial & domestic) liquid effluent shall not exceed Nil KL.
- 06. The Applicant shall discharge liquid effluent to 1) Domestic - to Kalyani Municipal sewer.
2) Industrial - partly to Kalyani Municipal Sewer and Party for
 through -- nos. outlets/outfalls, gardening as and when required
- 07. To being into any altered or new outlet/ourfall or to change the place of discharge, the Applicant shall have to inform the Board and obtain prior permission of the Board in this effect.
- 08. The Applicant shall provide comprehensive facility for treatment of industrial liquid waste and domestic liquid waste (sewage, sullage and liquid effluent generated from canteen), and operate and maintain the same continuously so that the quality of final effluent conforms to the Standard as given in Table-I in page 03.



[Signature]
 26/11/18
 (Member Secretary) / Sr. Env. Engr./BCC/Engr./Asst./BCC/Engr.
Senior Environmental Engineer
West Bengal Pollution Control Board,
Barrackpore Regional Office Continued P/3

Consent to Presenius Kabi Oncology Limited,
for its unit at D-35, Industrial Area, Vill, P.O. & P.S: Kalyani,
Dist. Nadia, Pin - 741235.

Table - I

Outlet No.	Nature of effluent	Parameters	Standard	Frequency of effluent sampling
01. Industrial		pH	Between: 6.0 to 8.5	Yearly
		Total Suspended Solids	Not to exceed: 100 mg/l.	
		Biochemical Oxygen Demand (3day at 27°C)	Not to exceed: 30 mg/l.	
		Chemical Oxygen Demand	Not to exceed: 250 mg/l.	
		Oil & Grease	Not to exceed: 10 mg/l.	
		Mercury Mg	" 0.01 mg/l	
		Arsenic As	" 0.20 mg/l	
		Hexavalent Chromium	" 0.10 mg/l	
		Lead	" 0.10 mg/l	
		Cyanide	" 0.10 mg/l	
		Phenolics (C ₆ H ₅ OH)	" 1.0 mg/l	
		Sulfides (as S)	" 2.0 mg/l	
		Phosphate (as P)	" 5.0 mg/l	
02. Domestic		pH	6.0 to 8.5	
		Total Suspended Solids	100 mg/l	
		Biochemical Oxygen Demand	30 mg/l	
		Chemical Oxygen Demand	250 mg/l	
		Oil & Grease	10 mg/l	

09. The Applicant falls in the Category of the Water (Prevention and Control of Pollution) Cess Act, 1977 and Rules made thereunder and the Applicant shall comply with the provisions of the said Act and Rules made thereunder.

10. Daily water consumption for the following purposes should not exceed :-

- Industrial cooling, spraying in mine pits and boiler feed water → 121.0 KL
(Water used for gardening should be included in this category of use)
- Domestic purpose → 100.0 KL
- Processing whereby water gets polluted and the pollutants are easily biodegradable → 220.0 KL
- Processing whereby water gets polluted and the pollutants are not easily biodegradable → Nil KL

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.



Sr. Env. Engr./Sr. Engr. (W. B. Pollution Control Board)

[Signature]
26/11/18
Senior Environmental Engineer
West Bengal Pollution Control Board
Barrackpore Regional Office

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Consent to Presenius Kabi Oncology Limited,
 for its unit at D-35, Industrial Area, Vill, P.O. & P.S: Kalyani,
Dist. Nadia, Pin-741235.

11. The Applicant shall install suitable device for measuring the volume of water consumed for different purposes as mentioned above giving correct result to the satisfaction of the State Board.
12. All the stacks connected to various sources of emissions must be designated by numbers such as S-1, S-2, S-3, etc., and this must be painted/displayed to facilitate identification.
13. The Applicant shall install comprehensive control system consisting of pollution control equipment as is warranted with reference to generation of air emissions and operate and maintain the same continuously so as to achieve the level of pollutants of the Standard as given in Table-II below :

Table - II

Stack No.	Stack height from G.L. (in mts.)	Stack attached to (sources and control system, if any) :	Volume Nm ³ /hr.	Velocity of gas emission m/sec	Concentrations of parameters not to exceed					Frequency of emission sampling
					SPM (mg/Nm ³)	CO (% v/v)				
S-1	21	Solvent Recovery Unit (SRU)-1	-	-	-	-	-	-	-	-
S-2	21	SRU - 2	-	-	-	-	-	-	-	-
S-3	21	SRU - 3	-	-	-	-	-	-	-	-
S-4	21	SRU - 4	-	-	-	-	-	-	-	-
S-5	21	SRU - 5	-	-	-	-	-	-	-	-
S-6	21	SRU - 6	-	-	-	-	-	-	-	-
S-7 S-7A	26.55 each	2x1250 KVA D.G. Set	-	-	150	1%	-	-	-	Yearly
S-8	7.90	1x1000 KVA D.G. Set	-	-	150	1%	-	-	-	-do-
S-9	30.48	P.O.fired Boiler Capacity - 2 Ton/day - 1 No.	-	-	150	-	-	-	-	-do-
S-10	40.00	P.O.fired Boiler Capacity - 5 Ton/day - 1 No.	-	-	150	-	-	-	-	-do-



(Member Secretary) / Sr. Env. Engr. / Secy. Engr. / Sr. Env. Engr.

Senior Environmental Engineer
 West Bengal Pollution Control Board
 Barrackpore Regional Office

Continued... P/5

Consent to Fresenius Kabi Oncology Limited,
 for its unit at D-35, Industrial Area, Vill, P.O. & P.S: Kalyani,
Dist. Nadia, Pin- 741235.

11. The Applicant shall provide ports in the stack(s) and other necessary permanent facilities such as ladder, platform, etc. for monitoring/sampling the air emissions and the same shall be made available for inspection and use by the State Board's staff as well as State Board's authorised agencies.
15. The Applicant shall observe the following fuel consumption pattern :-

Sl. No.	Type of fuel	Quantity consumed per day	Fuel burning operation where the fuel is used
01	Furnace Oil	180 KL/month	Boiler.
02	HSD	1.50 KL/month	D.G. Sets.
03			
04			
05			

16. The Applicant shall maintain the generation and treatment / disposal of non-hazardous solid waste as specified below : See Annexure - II attached herewith.

Type of waste	Quantity	Treatment	Disposal

17. The Applicant shall take adequate measures for control of noise levels from its own sources within the premises within the limit given below :-

Time	Limit in dB(A) L ₉₀
Day Time (06 a.m. to 10 p.m.)	75
Night Time (10 p.m. to 06 a.m.)	70

18. The Applicant shall at all times maintain good house-keeping, proper working order, and operate efficiently for control of pollution from all sources so as not to cause nuisance to surrounding areas/inhabitants and to achieve compliance with the terms and conditions of the consent.
19. The Applicant shall bring about at least 33% of the available open land under the green coverage/plantation.
20. 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 absence of such an alternate electric power source, the Applicant shall stop, reduce or otherwise control production to abide by the terms and conditions of the Consent regarding pollution level.
21. The Applicant shall install a separate energy meter showing the consumption of energy for operation of pollution control devices.
22. The Applicant shall ensure that fugitive emissions from the activity are controlled so as to maintain clean and safe environment in and around the factory premises.
23. The Applicant shall provide drainage system for conveying industrial and domestic liquid waste. Storm-water drain shall be kept separate from the drainage system meant for industrial and domestic liquid waste.



(M) (Date: 24/11/18) /Sr. Env. Engr./Sr. Engr./Asst. Engr./Engr.

Senior Environmental Engineer
 West Bengal Pollution Control Board
 Barrackpore Regional Office p/6
 Continued:...

Consent to **Fresenius Kabi Oncology Limited,**
 for its unit at **D-35, Industrial Area, Vill, P.O. & P.S: Kalyani,**
 **Dist. Nadia, Pin- 741235.**.....

24. The Applicant shall maintain a separate register showing consumption of chemicals used in pollution control systems.
 25. The Applicant Shall get the samples of hazardous wastes/leachates analysed at least once in
 from the laboratory recognised of the West Bengal Pollution Control Board and ensure that they conform to the limits stipulated. Test reports shall be sent to the Board.
 26. The Applicant shall provide adequate and safe facility for collection of air, waste water and solid waste samples by the State Board's staff as well as State Board's authorised agencies.
 27. The Applicant shall submit to the State Board by the 30th September of every year the Environmental Statement Report for the financial year ending 31st March of the current year in the prescribed form (Form - V) as required under the provisions of rule 14 of the Environment (Protection) [Second Amendment] Rules, 1992.
 28. The Applicant shall allow the Officers of the State Board to enter into the applicant's premises at any reasonable time to inspect the pollution control systems as well as monitoring and measuring devices in connection with prevention & control of pollution.
 29. The Applicant shall maintain an Inspection Book in the factory premises which shall be made available to Officers & employees of the State Board for inspection, review and to write down any direction or observation as is deemed necessary during the inspection from time to time.
 30. The Applicant shall furnish to the State Board all information in respect of quality, quantity, rate of discharge, place of discharge of liquid effluent and air emissions.
 31. The Applicant shall maintain adequate number of qualified and trained personnel among his staff for proper maintenance and operation of the effluent treatment and / or emission control devices and for overall environment management of the industry.
 32. The Applicant shall have to make registration for the use of groundwater if any, with Central Ground Water Authority.
 33. The Applicant shall intimate to the State Board immediately of any occurrence or apprehension of occurrence of discharge of any poisonous, noxious or pollutants in excess of quality as well as quality as mentioned earlier to any receiving water body/receiving system or to atmosphere owing to accident or other unforeseen incident/event including natural disaster. The Applicant Shall (i) take all steps adequate to prevent such accident discharge/release of poisonous, noxious or pollutants and to limit their consequences to persons and the environment. (ii) provide to the persons working on the site with the information, training and equipment including antidotes necessary to ensure their safety and mitigate the accidental release of poisonous, noxious or pollutants to the environment.
 34. The Applicant shall make an application to the State Board in the prescribed form for renewal of the consent at least 60 (sixty) days before the date of expiry of this Consent.
 35. The Applicant shall not make any alternation/modification/expansion in the existing manufacturing process and equipment as well as the pollution control system without prior approval of the Board.
- Applicant shall comply with the conditions as laid down in the Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 and Hazardous Wastes (Management & Handling) Rules, 1989.



- P. T. O.

(Signature)
 Sr. Env. Engr./Barrackpore Regional Office
 Senior Environmental Engineer
 West Bengal Pollution Control Board
 Barrackpore Regional Office

Additional Conditions :

- 1) The occupier shall obtain all the statutory permission(as applicable) from the competent Authority to run the unit.
- 2) Hazardous Waste to be managed as per the Guideline of the State Board.
- 3) One time Authorisation as required to be obtained from the State Board under Bio-Medical Waste Management Rules, 2016.
- 4) This Consent may be revoked in case of any valid public complaint lodged against the unit for creating environmental pollution.



[Handwritten signature]
24/1/18

Senior Environmental Engineer,
Barrackpore Regional Office.

Senior Environmental Engineer
West Bengal Pollution Control Board
Barrackpore Regional Office



West Bengal Pollution Control Board
Barrackpore Regional Office
Panpur More, P.O.-Narayanpur, Kankinara,
Dist.: 24-Pgs (N), Pin-743 126
☎ - 2580-0573

Annexure - I

Annexure to Consent letter no.: CO83563

Additional conditions issued to : M/s. Fresenius Kabi Oncology Limited,
D-35, Industrial Area, Vill, P.O. & P.S: Kalyani, Dist. Nadia, Pin - 741235.

Sr. No.	Name of Product	Installed Production Capacity (Kg/year)
1	10 - DAB	1000
2	Altretamine	100
3	Amifostin	10
4	Anastrozole	50
5	Bicalutamide	1000
6	Bufflomedil Hydrochloride	18000
7	Busulfan	100
8	Carboplatin	750
9	Cisplatin	100
10	Cladribine	10
11	Cremophor	50000
12	Disodium Pamidronate	200
13	Docetaxel	200
14	Fludrabine Phosphate	100
15	Gemcitabine Hydrochloride	2000
16	Irinotecan Hydrochloride	1000
17	Letrozole	50
18	Lomustine	10
19	Melphalan	100
20	Metaxalone	30000
21	Mitoxantrone Hydrochloride	10
22	Oxaliplatin	500
23	Paclitaxel	1000
24	Temozolamide	50
25	Thalidomide	300
26	Topotecan	10
27	Vinorelbin Tartarate	10
28	Ambroxol Hydrochloride	19000
29	Azacytidine	500




26/11/18
Senior Environmental Engineer
West Bengal Pollution Control Board
Barrackpore Regional Office

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