



TELANGANA STATE POLLUTION CONTROL BOARD

Phone: 23887500
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CONSENT ORDER FOR CFO RENEWAL

CONSENT RENEWAL ORDER BY REGISTERED POST WITH ACKNOWLEDGEMENT DUE

CONSENT ORDER NO. 16082261231 DATED: 25/06/2016.

(Consent Order for Existing/New or altered discharge of sewage and/or trade effluents/outlet under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and amendments thereof, Operation of the plant under section 21/22 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof.) Rules 2008 & Amendments thereof)

CONSENT is hereby granted under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974, under section 21/22 of Air (Prevention & Control of Pollution) Act 1981 and amendments thereof, and Authorisation under the provisions of HW (MH & TM) Rules, 2008 (hereinafter referred to as 'the Acts', 'the Rules') and amendments thereof and the rules and orders made there under to M/s. "**Glaxosmithkline consumer private limited ,GROUND FLOOR, BUILDING NO.1800, TAKSHILA TECHPARKS & INCUBATORS (INDIA), SURVEY NO 101,101/2, PLOT NO 4** " (hereinafter referred to as 'the Applicant /Industry') and the industry is authorized to operate the industrial plant to discharge the Effluents from the outlets and the quantity of Emissions per hour from the chimneys, by operating pollution control equipment, as detailed below,

i) Out lets for discharge of Effluents :

Outlet No.	Description of Outlet	Max Daily Discharge in KLD	Point of Disposal
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ii) Emissions from chimneys:

Chimney No.	Description of Chimney
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This consent order is valid for manufacture of the following products along with quantities only:

Products	Capacity
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This order is subject to the provision of 'the Acts' and amendments made thereunder and further subject to the terms and conditions incorporated in the schedule A and B enclosed to this order.

This combined order of consents is valid for a period ending with the (validity period recommended in the minutes). June 25, 2016

This order is subject to the provision of 'the Acts' and amendments made thereunder and further subject to the terms and conditions incorporated in the schedule A and B enclosed to this order.

This combined order of consents is valid for a period upto. June 25, 2016

MEMBER SECRETARY

To
The Director,
M/s.GLAXOSMITHKLINE CONSUMER PRIVATE LIMITED,
GROUND FLOOR, BUILDING NO.1800, TAKSHILA TECHPARKS & INCUBATORS (INDIA), SURVEY NO 101,101/2, PLOT
NO 4,
Pin: 500078

Copy to :

SCHEDULE – A

SCHEDULE - B

MEMBER SECRETARY

To
The Director,
M/s.GLAXOSMITHKLINE CONSUMER PRIVATE LIMITED,
GROUND FLOOR, BUILDING NO.1800, TAKSHILA TECHPARKS & INCUBATORS (INDIA),
SURVEY NO 101,101/2, PLOT NO 4,
Pin: 500078



TELANGANA STATE POLLUTION CONTROL BOARD
ZONAL OFFICE: HYDERABAD

R. Ravinder Reddy

Joint Chief Environmental Engineer (FAC)

H.No.6-3-1219, Sy.No.TS No.1 Part,
Block - C, Ward No.91,
Near Country Club, Uma Nagar,
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CONSENT & AUTHORIZATION ORDER

BY REGISTERED POST WITH ACKNOWLEDGEMENT DUE

Consent Order No : 1114-RR-II/TSPCB/ZOH/CFO/2016 - 429 **Date: 17.06.2016**

(Consent Order for Existing/New or altered discharge of sewage and/or trade effluents/outlet under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and amendments thereof, Operation of the plant under section 21 of Air (Prevention & Control of Pollution) Act, 1981 and amendments thereof and Authorization / Renewal of Authorization under Rule 5 of the Hazardous Wastes (Management, Handling and Transboundary, Movement) Rules, 2008 & amendments thereof.

CONSENT is hereby granted under section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under section 21 of Air (Prevention & Control of Pollution) Act 1981 and Authorization under the provisions of HW (M,H&TM) Rules (hereinafter referred to as 'the Acts', 'the Rules') and the rules and orders made thereunder to:

M/s. GlaxoSmithKline Consumer Private Limited
(Formerly M/s. Novartis Healthcare Pvt., Ltd.,
Lab No's:12A & Lab No's:11,13 & 14, Ground floor, Building No.01,
Takshila Tech Parks & Incubators (India) Pvt Ltd.,
Plot No.4, Sy.No.101, APIIC Biotech Park,
Phase-II, Genome Valley, Lalagadi Malakpet(V),
Shameerpet(M), Rangareddy District

(Hereinafter referred to as 'the Applicant') authorizing to operate the industrial plant, to discharge the effluents from the outlets and the quantity of Emissions per hour from the chimneys as detailed below.

i) Outlets for discharge of effluents:

Outlet No.	Outlet Description	Max Daily Discharge	Point of Disposal	Limiting Standards
1	Process & Washings	4.0 KLD	Shall be sent to Common Effluent collection tank of M/s. Takshila Tech Parks & Incubators Pvt Ltd., After pretreatment shall be lifted to CETP, Jeedimetla for further treatment and disposal	Inlet parameters of CETP prescribed by the Board.
2	Domestic Effluents	2.5 KLD	After treatment in Common STP of M/s. Takshila Tech Parks& Incubators (India) Pvt. Ltd. the treated wastewater shall be used on land for gardening within the premises.	pH - 5.5 - 9.0, Total Suspended Solids - 200.0 mg /l, Oil & Grease - 10.0 mg /l, Biochemical Oxygen Demand (3 days at 27° C) - 100.0 mg /l

ii) Emissions from chimneys:

Chimney No.	Description of Chimney	Quantity of Emissions at peak flow	Emission Standards
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iii) Hazardous Waste Authorization: (Form – II) [See Rule 5(4)]:

M/s.GlaxoSmithKline Consumer Private Limited (Formerly M/s. Novartis Healthcare Pvt., Ltd., Lab No's:12A & Lab No's:11,13 & 14, Ground floor, Building No.01, Takshila Tech Parks & Incubators (India) Pvt Ltd., Plot No.4, Sy.No.101, APIIC Biotech Park, Phase-II, Genome Valley, Lalagadi Malakpet(V), Shameerpet(M), Rangareddy District is hereby granted an authorization to operate a facility for collection, reception, storage, transport and disposal of the following wastes with quantities as mentioned below:

Sl. No.	Name of the Hazardous Waste	Stream	Quantity of Hazardous waste	Disposal Option
1	R&D Process Residue	330 Kg/month	28.1 of Sch-I	Shall be disposed to M/s. HWMP (TSDF), Dundigal, Rangareddy District through M/s. TTP&IPL for incineration
2	R&D Process reject material	220 Kg/month	28.1 of Sch-I	
3	Discarded / Expired Chemicals	3 Kgs/month	28.4 of Sch – I	
4	PPE (used gloves, others) tissue papers and spilled chemicals, syringes	50 Kgs/annum	----	
5	Glass ware	102 Kgs/month	----	After complete detoxification, shall be sent to scrap vendors through TTP&IPL
6	Spent mixed solvents	2000 Ltrs/ month	20.2 of Sch-I	Shall be disposed to authorized solvent recovery units / M/s. HWMP (TSDF), Dundigal, Rangareddy District through M/s. TTP&IPL.
7	Paper / Card Board Boxes etc.,	330 Kgs/month	---	Shall be sent to scrap vendors through M/s.TTP&IPL

This consent order is valid for the manufacture of the following products with quantities mentioned below only:

Sl.No.	Name of the product & By product
1	R & D activity on • Method development and validation • Stability studies for drug products • Formulation development • GMP (Good Manufacturing Practices) Formulation and process scale up. • Provisions of GMP batches for sensory and clinical work. • Other related activities (No Commercial production)

This order is subject to the provisions of 'the Acts' and the Rules' and amendments made thereunder and further subject to the terms and conditions incorporated in the schedule A, B and C enclosed to this order.

This combined order of Consent and Authorizations shall be valid for a period ending with the 31.03.2021

17/8/2016
JOINT CHIEF ENVIRONMENTAL ENGINEER (FAC)

To

M/s.GlaxoSmithKline Consumer Private Limited
(Formerly M/s. Novartis Healthcare Pvt., Ltd.,
Lab No's:12A & Lab No's:11,13 & 14, Ground floor, Building No.01,
Takshila Tech Parks & Incubators (India) Pvt Ltd.,
Plot No.4, Sy.No.101, APIIC Biotech Park,
Phase-II, Genome Valley, Lalagadi Malakpet(V),
Shameerpet(M), Rangareddy District

Copy submitted to the Member Secretary, TSPCB, Board Office, Hyderabad for information.
Copy to the JCEE(CESS), TSPCB, Board Office, Hyderabad for information.
✓ Copy to the Environmental Engineer, TSPCB, Regional Office-II, Rangareddy District for information.

SCHEDULE – A

1. The applicant shall make applications **through online** for renewal of consent (under Water and Air Acts) and Authorization under HWM Rules **atleast 120 days before the date of expiry of this order**, along with prescribed fee under Water and Air Acts for obtaining consent of the Board **along with detailed compliance to the conditions stipulated in the CFO**.
2. The industry shall immediately submit the revised application for consent to this Board in the event of any change in the raw material used, processes employed, quantity of trade effluents & quantity of emissions etc.
3. a) All the fugitive emissions shall be controlled with proper measures.
b) The applicant shall also install the equipment such as wind speed recorder and wind direction recorder.
4. The applicant shall not change or alter either the quality or the quantity or the rate of the discharge or the route of discharge and shall not change or alter either the prescribed quality or the rate of emission without the previous written permission of the Board.
5. The applicant shall, not later than 30 days from the date of issue of this consent order, certify in writing to the Board that the applicant has installed or provided for an alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent. In absence of alternative electric power source sufficient to operate all facilities installed by the applicant, to comply with the terms and conditions of this consent, production shall be stopped.
6. Any up-set condition in any plant/plants of the industry, which result in, increased effluent discharge and/ or violation of standards stipulated in this order or the emission of any Air Pollutant into the environment in excess of the standards laid down by the Board, occurs or is apprehended to occur due to accident, or other unforeseen act or event, the person-in-charge of the premises, from where such discharge / emission occurs or is apprehended to occur shall forthwith intimate the fact of such occurrence or the apprehension of such occurrence to this Board, by fax / email under intimation to the Collector and District Magistrate.
7. In case of such episodal discharges / emissions mentioned in item 6 above, the industry should take immediate action to bring down the discharge / emission below the limits prescribed in this order.
8. A good house keeping shall be maintained both within the factory and in the premises. All hoods, pipes, valves, sewers and drains shall be leak proof. Floor washings shall be admitted into the effluent collection system only and shall not be allowed to find their way into storm drains or open areas.
9. a) The industry shall carryout analysis of waste water discharges or emissions through chimneys, for the parameters mentioned in Schedule – B of this order at regular intervals.
b) The industry shall maintain following records to accessible to the Board, whenever required.
 1. Analysis reports of waste water/ emissions.
 2. Log book for operation of pollution control systems.
 3. Inspection book
10. The applicant shall set up THREE Ambient Air Quality Monitoring Stations for continuous recording of relevant critical parameters mentioned in Schedule - B as per the CPCB guidelines and submit monthly reports.
11. Separate power connection with energy meter shall be provided for the Pollution Control Equipment and record of power consumption and chemicals consumption for the operation of pollution control equipment shall be maintained separately.
12. The applicant shall submit Environment statement in Form V before 30th September every year as per Rule No.14 of E (P) Rules, 1986 & its amendments thereof.
13. The applicant shall comply with the directives/orders issued by the Board in this consent order and at all subsequent times without any negligence on his part. The applicant shall be liable for such legal action against him as per provisions of the Law/Act in case if non-compliance of any order/directive issued at any time and/or violation of the terms and conditions of this consent order.

14. The applicant shall furnish to the visiting officer and / or the Board any information regarding the construction, installation or operation of the effluent treatment system/ air pollution control equipment and such other particulars as may be pertinent for preventing and controlling pollution.
15. The industry is liable to pay compensation for any environmental damage caused by it, as fixed by the Collector and District Magistrate as Civil liability.
16. All the rules & regulations notified by Ministry of Environment and Forests, Government of India in respect of management, handling, transportation and storage of hazardous chemicals and wastes shall be followed.
17. All the rules & regulations notified by Ministry of Law and Justice, Government of India regarding Public Liability Insurance Act, 1991 shall be followed.
18. The occupier shall educate the workers and nearby public of possible accidents and remedial measures.
19. For any accident or spillage of hazardous wastes causing damage to the Environment, the occupier or the transporter as the case shall be held responsible.
20. In case of closure of industry, the un-used/not consumed raw materials falling under the category of Hazardous Chemicals and mentioned in Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 and Amendment Rules, 2003 shall be removed and sold to other units within 90 days from the date of closure to prevent any possibility of occurrence of an accident. In case the above hazardous chemicals have lost their properties originally acquired, then they shall be treated as Hazardous Waste and they should be disposed off only to the authorized agencies of TSPCB in a safe manner.
21. The occupier shall prepare / update an emergency preparedness plan for safe handling of hazardous waste from time to time and submit the same to TSPCB. Emergency preparedness plan must be implemented immediately whenever there is fire, explosion or release of hazardous waste or hazardous waste constituents, which could endanger to human health or environment.
22. Packaging, labeling and transportation of Hazardous Wastes shall be in accordance with the provisions of the rules issued by the Central Govt. under the Motor Vehicles Act, 1988 and other guidelines issued from time to time. The packaging and labeling shall be based on the composition and hazardous constituent of the waste, however all Hazardous Waste containers should be provided with a general label.
23. The driver who transports Hazardous Waste should be well acquainted about the procedure to be followed in case of an emergency during transit. The transporter shall carry a Transport Emergency (TREM) card (as given in the guidelines for management and handling of hazardous wastes) duly filled by the Hazardous Waste generator.
24. Containers / Container Liners of Hazardous Chemicals and Hazardous Wastes should be thoroughly detoxified before selling to agencies authorized by TSPCB. Proper records, specific to each Hazardous Chemical / Hazardous Waste Containers / container Liners should be maintained in the following way:
 - i . Number of containers received.
 - ii . Date and method of detoxification.
 - iii . Name of agencies to whom containers were sold with quantities.
 - iv . Transportation particulars.
25. No Hazardous Wastes shall be mixed with any other waste or shall be discharged to a common, other internal, external sewerage or other drainage system without prior approval of TSPCB.
26. If HDPE bags are used for storing Hazardous Wastes, it should be ensured that they are perfectly sealed mechanically or double hot sealed. If MS / HDPE bags or drums are used for Hazardous Wastes, these drums / bags should be ensured that they are perfectly sealed.
27. The person authorized shall not rent, lend, sell, transfer their industrial premises without obtaining prior permission of State Pollution Control Board.
28. Any Unauthorized change in personnel, equipment and working condition as mentioned in the application by the person authorized shall constitute a breach of this authorization.

29. The industry shall comply with the provisions of Batteries (Management and Handling) Rules, 2001.
30. The applicant shall put up two black boards of size 6 ft by 4 ft. at the main entrance to their plant. One board shall contain the specific CFE and CFO conditions, in sufficiently large font size so that it can be read easily from a distance of 10 ft to a normal eye, and other board shall carry, again in sufficiently large font size so as to be able to read from a distance of 10 ft, the latest Water, Air, Noise and solid waste monitoring data as well as the maximum vulnerable zone.
31. The applicant shall exhibit the Consent & HW Authorization order of the Board in the factory premises at a prominent place for the information of the inspecting officers of the different departments.
32. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves to it the right and powers under Section 27(2) of the Water (Prevention & Control of Pollution) Act, 1974 and its amendments thereof and under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and its amendments thereof to review any and/or all the conditions imposed herein above and to make such variations as deemed fit for the purpose of the Acts by the Board.
33. The authorization issued under Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008, shall comply with the provision of the Environment (Protection) act, 1986.
34. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Telangana State Water rules, 1976 and Air Rules 1982, to such authority (herein after referred to as the Appellate Authority) constituted under Section 28 of the Water (prevention and Control of Pollution) Act, 1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

SCHEDULE - B

Special Conditions

1. The industry shall take steps to reduce water consumption to the extent possible and consumption shall NOT exceed the quantities prescribed below:

Sl. No.	Purpose	Total quantity
1.	Process & Washings	4.0 KLD
2.	Domestic	3.5 KLD
	Total	7.5 KLD

The Industry shall maintain separate water meters for the above areas and maintain records.

2. The industry shall file the water Cess returns in Form-I as required under section (5) of Water (Prevention and Control of Pollution) Cess Act, 1977 on or before the 5th of every calendar month, showing the quantity of water consumed in the previous month along with water meter readings. The industry shall remit water Cess as per the assessment orders as and when issued by Board.
3. The emissions shall not contain constituents in excess of the prescribed limits mentioned below.

Chimney No.	Parameter	Emission Standards (mg/Nm ³)
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4. The industry shall comply with emission limits for DG sets upto 800 KW as per the Notification G.S.R.520 (E), dated 01.07.2003 under the Environment (Protection) Amendment Rules, 2003 and G.S.R.448(E), dated 12.07.2004 under the Environment (Protection) Second Amendment Rules, 2004. In case of DG sets more than 800 KW shall comply with emission limits as per the Notification G.S.R.489 (E), dated 09.07.2002 at serial no.96, under the Environment (Protection) Act, 1986.
5. The industry should comply with the National ambient air quality standards as per MoEF, GoI notification dated. 18.11.2009 along the premises of the factory as prescribed below.

S. No.	Parameters	Standards in $\mu\text{g}/\text{m}^3$
1	Particulate Matter (PM_{10})	100
2	Particulate Matter ($\text{PM}_{2.5}$)	60
3	SO_2	80
4	NO_x	80

Noise Levels: Day time (6 AM to 10 PM) - 75 dB (A)
Night time (10 PM to 6 AM) - 70 dB (A).

6. The industry shall comply with all the Rules and Regulations specified in Water (P&C of P) Act, 1974, Air (P&C of P) Act, 1981 and Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 and their amendments issued thereof.
7. The industry shall not provide pilot plant activity and shall not go for commercial production without permission of the Board.
8. The industry shall send the process and wash effluents to common effluent collection tank of M/s. Takshila Tech Parks & Incubators (India) Pvt. Ltd., (M/s.TTP&IIPL). After pretreatment, the effluents shall be lifted to CETP, Jeedimetla for further treatment and disposal by M/s.TTP&IIPL by duly complying with the inlet standards of CETP prescribed by the Board.
9. The industry shall send the domestic effluents to the common sewage treatment plant provided by M/s.TTP&IIPL. After treatment, the treated wastewater shall be used for on land for gardening by duly complying with the standards stipulated by the Board.
10. The industry shall provide digital flow meter with totalizer for assessing the quantity of waste water disposed in to common effluent collection tank of M/s.TTP&IIPL and shall maintain the register.
11. The industry shall suck the fumes emanated during the various chemical reactions in the fume hoods and pass them through a wet scrubber before letting into atmosphere through common stack.
12. The industry shall collect R&D Process Residue, R&D Process reject material, Discarded / Expired Chemicals and PPE (used gloves, others) tissue papers and spilled chemicals, syringes properly and lift these hazardous waste to TSDF, Dundigal, RR district through M/s.TTP&IIPL.
13. The industry shall not discharge any waste water to outside the factory premises.
14. The industry shall not cause any air pollution / odour nuisance to the surrounding environment.
15. The industry shall not dispose the solid waste outside the factory premises.
16. The industry shall develop 33% of the total area as thick green belt all along the boundary of the unit and also in the vacant places with all tall growing trees with wide leaf area.
17. The industry should maintain the following records and the same should be made available to the Board Officials during the inspection.
 - a) Daily production details, RG-I records and Central Excise Returns.
 - b) Quantity of effluent generated and sent to M/s.TTP&IIPL.
 - c) Log Books for pollution control systems.
 - d) Daily solid waste generated and disposed to TSDF through M/s.TTP&IIPL.
18. The industry shall maintain good housekeeping & maintain proper records for hazardous waste stated in the authorization.
19. The industry shall submit Environmental Statement in Form V before 30th September every year as per Rule No.14 of Environmental (Protection) Act, 1986.
20. The industry shall take necessary measures to control fugitive emissions.
21. The industry shall take all precautionary and safety measures during process operations.
22. The industry shall comply with the ambient air quality standards in respect of noise, as stipulated in the Environment (Protection) Rules, 1986.
23. The industry shall comply with all the directions issued by the Board from time to time.

24. Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order may result in withdrawal of this order and attract action under the provisions of relevant pollution control Acts.
25. The Board reserves its right to modify above conditions or stipulate any further conditions in the interest of environment protection.
26. This Order is issued to the industry without prejudice to the action taken by the Task Force of the Board.

SCHEDULE - C

(See Rule 5(4))

(Conditions of Authorization for occupier or operator handling hazardous wastes)

1. The industry shall give top priority for waste minimization and cleaner production practices.
2. The industry shall not store hazardous waste for more than 90 days as per the Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 and amendments thereof.
3. The industry shall store Used / Waste Oil and Used Lead Acid Batteries in a secured way in their premises till its disposal.
4. The industry shall not dispose Waste oils to the traders and the same shall be disposed to the authorized Reprocessors/ Recyclers.
5. The industry shall dispose Used Lead Acid Batteries to the manufacturers / dealers on buyback basis.
6. The industry shall take necessary practical steps for prevention of oil spillages and carry over of oil from the premises.
7. The industry shall maintain 6 copy manifest system for transportation of waste generated and a copy shall be submitted to Board Office and concerned Regional Office.
8. The industry shall maintain good housekeeping & maintain proper records for Hazardous Wastes stated in Authorisation.
9. The industry shall maintain proper records for Hazardous Wastes stated in Authorisation in FORM-3 and file annual returns in Form- 4 as per Rule 22(2) of the Hazardous Wastes (Management, Handling & Transboundary Movement) Rules, 2008 and amendments thereof.
10. The industry shall submit the condition wise compliance report of the conditions stipulated in Schedule B & C of this Order on half yearly basis to Board Office, Hyderabad and concerned Regional Office.
11. The industry shall dispose the e-waste to authorised recyclers / re-processors only.

Handwritten signature
17/6/2016

JOINT CHIEF ENVIRONMENTAL ENGINEER (FAC)

To

M/s.GlaxoSmithKline Consumer Private Limited
(Formerly M/s. Novartis Healthcare Pvt., Ltd.,
Lab No's:12A & Lab No's:11,13 & 14, Ground floor, Building No.01,
Takshila Tech Parks & Incubators (India) Pvt Ltd.,
Plot No.4, Sy.No.101, APIIC Biotech Park,
Phase-II, Genome Valley, Lalagadi Malakpet(V),
Shameerpet(M), Rangareddy District