



TELANGANA STATE POLLUTION CONTROL BOARD

CONSENT ORDER FOR ESTABLISHMENT

ORDER NO. 240125305616

DATED: 12/08/2024.

SUB: TGPCB-Consent for Establishment-M/s. UNITED STATES PHARMACOEPIA INDIA PVT LIMITED, UNIT-II , S.F. No. Lab Nos 101 to 118 of 1st floor Lab No’s 201 to 205 and 209 of 2nd Floor, Turkapalle village, Shamirpet Taluk and Medchal ii District - Consent for Establishment of the Board under Sec.25 of Water(P & C of P) Act, 1974 and Under Sec.21 of Air (P&C of P) Act, 1981 - Issued - Reg.

REF:

1. In the reference cited, an application was submitted to the Board seeking Consent for Establishment (CFE) of the Board to establish, with a project cost of Rs. to manufacture following products/activity.

S.No.	Product	Capacity	Unit
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2. As per the application, proposed products are to be manufactured/activity to be carried out atUnited states pharmacopeia india pvt limited, unit-ii , S.F. No. Lab Nos 101 to 118 of 1st floor Lab No’s 201 to 205 and 209 of 2nd Floor, Turkapalle village, Shamirpet Taluk and Medchal ii District

3. The above site was inspected by & Asst. Environmental Engineer, Regional office,T.S Pollution Control Board and observed tha the site is surrounded by

NORTH	
SOUTH	
EAST	
WEST	

- 4.
5. This Consent Order now issued is subject to the conditions mentioned in Schedule 'A' and Schedule 'B'.
6. This order is issued from pollution control point of view only. Zoning and other regulations are not considered.

MEMBER SECRETARY

To
Senior Vice President & Site Head India Operations,M/s.UNITED STATES PHARMACOEPIA INDIA PVT LIMITED, UNIT-II,
Lab Nos 101 to 118 of 1st floor Lab No’s 201 to 205 and 209 of 2nd Floor, SME Hub (Catalyst), IKP Knowledge Park, Sy.
No’s.234/2, 234/3 & 235/2, Turkapally (V), Shameerpet (M), Medchal-Malkajgiri,
Pin: 500078

Copy to :

SCHEDULE 1½ A

SCHEDULE - B

MEMBER SECRETARY

To
Senior Vice President & Site Head India Operations,M/s.UNITED STATES PHARMACOEPIA INDIA PVT LIMITED, UNIT-II,
Lab Nos 101 to 118 of 1st floor Lab No’s 201 to 205 and 209 of 2nd Floor, SME Hub (Catalyst), IKP Knowledge Park, Sy.
No’s.234/2, 234/3 & 235/2, Turkapally (V), Shameerpet (M), Medchal-Malkajgiri,
Pin: 500078



TELANGANA POLLUTION CONTROL BOARD
ZONAL OFFICE: HYDERABAD

H.No.6-3-1219, TS No.1 Part, Block - C, Ward No.91, Near Country Club,
Uma Nagar, Begumpet, Hyderabad. Phone: 040-23402495
Email: jcee-zhyd-tspcb@telangana.gov.in

CONSENT ORDER FOR ESTABLISHMENT – RED CATEGORY

Order No. 1660 - RR-II/TGPCB/ZO-HYD/TG-iPASS/CFE/2024 - 749 Date:09.08.2024

Sub: TGPCB – ZOH – TG-iPASS - CONSENT FOR ESTABLISHMENT (CFE) For Expansion – M/s. United States Pharmacopeia India Pvt. Ltd., Unit 101 to 118 in 1st floor & 201 to 205 & 209 in 2nd floor of SME Hub (Catalyst), IKP Knowledge park, Sy.No's 234/2, 234/3 & 235/2, Turkapally (V), Shameerpet (M), Medchal-Malkajgiri District - Consent for Establishment of the Board under Sec.25 of Water (Prevention and Control of Pollution) Act, 1974 and under Sec.21 of Air (Prevention and Control of Pollution) Act, 1981 – Issued – Reg.

- Ref:**
1. Industry's CFO Order No. 1660-RR-II/TGPCB/ZOH/TS-iPASS/CFO/2021-501, Dated: 25.01.2021 valid upto 30.11.2025.
 2. Industry's CFE (Expansion) application received through TG-iPASS online portal on 18.07.2024 at TGPCB, RO, Medchal.
 3. TGPCB, Regional Office, Medchal verification report dated 27.07.2024 and received by Zonal Office, Hyderabad on 27.07.2024.
 4. CFE Committee meeting held on 03.08.2024 at TGPCB, Zonal Office, Hyderabad.
 5. Industry's letter dt.09.08.2024 furnishing information.

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1. In the reference cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for expansion to setup R & D activity as mentioned below, with a proposed investment of **Rs.73.53 Crores for Expansion**.

S.No.	Name of the Product/Activity		
	(Existing as per CFO order dt.25.01.2021)	Proposed Expansion	Total (After Expansion)
1.	R & D (Bulk Drug and Bulk Drug intermediates, not for commercial purpose), capacity not exceeding 1 kg/day for all the products.	R & D (Bulk Drug and Bulk Drug intermediates, not for commercial purpose), capacity not exceeding 1 kg/day for all the products.	R & D (Bulk Drug and Bulk Drug intermediates, not for commercial purpose), capacity not exceeding 1 kg/day for all the products (Total built up area 22,221 sq ft.)

2. As per the application, the above activity is to be located in the existing premises at **Unit 101 to 118 in 1st floor & 201 to 205 & 209 in 2nd floor of SME Hub (Catalyst), IKP Knowledge park, Sy.No's 234/2, 234/3 & 235/2, Turkapally (V), Shameerpet (M), Medchal-Malkajgiri District with additional builtup area.**
3. The above site was inspected by the Asst. Environmental Engineer-II, Regional Office, Medchal, T.G.Pollution Control Board on 26.07.2024 and found that the industry is surrounded by **East:** Phase- I Parking area; **West:** IKP Admin Building; **North:** Internal road of IKP; **South:** Internal road of IKP.
4. The Board, after careful scrutiny of the application, verification report of Regional Office, Medchal, recommendation by the CFE Committee meeting held on **03.08.2024** at TGPCB, Zonal Office, Hyderabad, hereby issues **CONSENT FOR ESTABLISHMENT (CFE)** for expansion to the industry, under Section 25 of Water (Prevention and Control of Pollution) Act, 1974 and under Section 21 of Air (Prevention and Control of Pollution) Act, 1981 and the rules made there under. This Order is issued to manufacture the products mentioned at para (I) only.

5. This Consent Order now issued is subject to the conditions mentioned in Schedule 'A' and Schedule 'B'.
6. This order is issued from pollution control point of view only. Zoning and other regulations are not considered.

Encl: Schedules "A & B".

To

**M/s. United States Pharmacopeia India Pvt. Ltd.,
Unit 101 to 118 in 1st floor & 201 to 205 &
209 in 2nd floor of SME Hub (Catalyst), IKP Knowledge park,
Sy.No's 234/2, 234/3 & 235/2, Turkapally (V),
Shameerpet (M), Medchal-Malkajgiri District.
Email: girish.kapur@usp.org**

JOINT CHIEF ENVIRONMENTAL ENGINEER



Copy submitted to the Member Secretary, TGPCB, Board Office, Hyderabad for information.
Copy submitted to The General Manager, District Industries Centre, Near ORR, Keesara,
Medchal- Malkajgiri District, Collectorate Complex, Hyderabad-500083.
Copy to the Environmental Engineer, TGPCB, Regional Office, Medchal for information and
necessary action.

SCHEDULE – A

1. **This order is valid for a period of 5 years from the date of issue.** Progress on implementation of the project shall be reported to the concerned Regional Office, T.S. Pollution Control Board once in six months. The consent of the Board shall be exhibited in the factory premises at a conspicuous place for information of the inspecting officers.
2. The proponent shall obtain Consent for Operation (CFO) from TGPCB, as required Under Sec.25/26 of the Water (Prevention and Control of Pollution) Act, 1974 and under sec. 21/22 of the Air (Prevention and Control of Pollution) Act, 1981, before commencement of the activity.
3. The proponent shall ensure that there shall not be any change in the process technology and scope of working without prior approval from the Board.
4. The industry is liable to pay compensation for any environmental damage caused by it, as fixed by the Hon'ble Courts, Collector and District Magistrate as Civil liability.
5. The rules and regulations notified under Environmental Acts by the MOEF&CC and by the Ministry of Law and Justice, GOI, regarding the Public Liability Insurance Act, 1991 shall be followed.
6. 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.
7. Notwithstanding anything contained in this consent order, the Board hereby reserves the right and powers under Section 27(2) of the Water (Prevention & Control of Pollution) Act, 1974 and under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and amendments thereof, to review any and/or all the conditions imposed herein, to modify conditions or stipulate any further conditions and to take action including revocation of this order in the interest of public health and environment.
8. 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 the State Water Rules, 1976 and Air Rules, 1982, to such authority (hereinafter referred to as the Appellate Authority) constituted under Section 28 of Water (Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

SCHEDULE – B

1. **The industry shall not provide pilot plant activity and shall not go for commercial production without permission of the Board.**
2. The source of water is M/s. IKP Knowledge Park and the maximum permitted water consumption shall not exceed the following quantities:

S. No.	Purpose	(Existing Quantity as per CFO order dt.25.01.2021)	Proposed Expansion	Total Consumption (After Expansion)
1.	Process & Washings	5.0 KLD	4.0 KLD	9.0 KLD
2.	Domestic	2.0 KLD	3.0 KLD	5.0 KLD
	Total	7.0 KLD	7.0 KLD	14.0 KLD

3. **The industry shall obtain NOC from CGWA for drawl of ground water within One month and submit a copy of the same at TGPCB Regional Office, Medchal.**
4. The maximum waste water generation (KLD) shall not exceed the following:

S. No.	Wastewater generation	(Existing Quantity as per CFO order dt.25.01.2021)	Proposed Expansion	Total Generation (After Expansion)
1.	Process & Washings	3.5 KLD	3.0 KLD	6.5 KLD
2.	Domestic	2.0 KLD	2.5 KLD	4.5 KLD
	Total	5.5 KLD	5.5 KLD	11.0 KLD

Effluent source	Total Quantity (After Expansion)	Standards to be complied	Mode of final disposal
Process & Washings	6.5 KLD	Inlet standards of CETP as prescribed by the Board.	Shall be sent to common collection tank provided by M/s. IKP Knowledge Park. (After pretreatment, treated effluents shall be sent to M/s. JETL, Jeedimetla for further treatment and safe disposal by M/s. IKP Knowledge Park).
Domestic	4.5 KLD	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 ⁰ C) - $\leq$ 10 mg/lit.	Shall be sent to common Sewage Treatment Plant (STP) provided by M/s. IKP Knowledge Park. (After treatment, the treated water shall be used on land for gardening purpose within the premises by M/s. IKP Knowledge Park).

- The industry shall send the process & washings effluents to common collection tank provided by M/s. IKP Knowledge Park. After pretreatment, treated effluents shall be sent to M/s. JETL, Jeedimetla for further treatment and safe disposal by M/s. IKP Knowledge Park, duly meeting the inlet standards of CETP as prescribed by the Board.
- The industry shall send the domestic effluents to the common Sewage Treatment Plant (STP) provided by M/s. IKP Knowledge Park. After pre-treatment shall be used on land for gardening by M/s. IKP Knowledge Park within the premises duly meeting the prescribed standards of the Board.
- 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. IKP Knowledge Park and shall maintain the register.
- The industry shall suck the fumes emanated during the various chemical reactions in the fume cupboards and pass them through a wet scrubber before letting into atmosphere through common stack.
- The industry shall not discharge any waste water to outside the factory premises.
- The Solid wastes generated shall not exceed the following breakup quantities:

S. No.	Name of the Hazardous / Solid waste	Hazardous / as defined under HWM Rules, 2016	Existing quantity	Proposed Expansion	Total quantity (after expansion)	Method of Disposal
1.	Expired Chemicals	28.5 of Sch -I	25 Kgs/Month	22 Kgs/Month	47 Kgs/Month	Shall be disposed to M/s TSDF, Dundigal, Medchal-Malkajgiri District through M/s. IKP Knowledge Park.
2.	Discarded Tablets & Gels	28.4 of Sch-I	25 Kgs/Month	2 Kgs/Month	27 Kgs/Month	
3.	Spent Catalyst, Palladium Carbon and Raney Nickel	28.2 of Sch -I	16 Lit/Month	--	16 Lit/Month	
4.	Used PPEs & other plastic material which contacts with Hazardous material	33.3 of Sch -I	40 Kgs/Month	76 Kgs/Month	116 Kgs/Month	

5.	Silica gel, Celite Gel, Dalda	28.1 of Sch-I	25 Kgs/Month	25 Kgs/Month	50 Kgs/Month	Shall be disposed to M/s TSDF, Dundigal, Medchal-Malkajgiri District through M/s. IKP Knowledge Park.
6.	Spent solvent	28.6 of Sch-I	1600 Lit/Month	2510 Lit/Month	4110 Lit/Month	Shall be sent to authorized solvent recovery units through M/s. IKP Knowledge Park
7.	Detoxified empty chemical / Plastic Bottles	33.1 of Sch -I	250 Nos/Month	310 Nos/Month	560 Nos/Month	After Detoxification shall be sent to authorized agencies /dealers for preprocessor's /Recycling units through through M/s. IKP Knowledge Park
8.	Broken Lab glassware	33.1 of Sch -I	20 Kgs/Month	14.5 Kgs/Month	34.5 Kgs/Month	Sold to Preprocessors / recyclers/ Scrap Vendors
9.	Plastic Material Unused Consumables (Non-Hazardous)	--	25 Kgs/Month	10 Kgs/Month	35 Kgs/Month	
10.	General waste, Other Cartoon Boxes etc.,	--	30 Kgs/Month	150 Kgs/Month	180 Kgs/Month	
11.	Used Oil from Vacuum Pumps	--	0.3 KL/Annum	--	0.3KL/Annum	Shall be sent to authorized recovery units through M/s. IKP Knowledge Park
12.	Organic & Inorganic residues, failed batches	28.1 of Sch-I		8.5 Kgs/Month	8.5 Kgs/Month	Shall be disposed to TSDF, Dundigal, Medchal-Malkajgiri District.
13.	Used Batteries	--		150 Nos/Annum	150 Nos/Annum	Shall be sent to back to the dealers / Manufacturers on buy back basis.
14.	E-Waste	--		30 Kgs/Month	30 Kgs/Month	Shall be sent to authorized E-waste recyclers.

11. The industry shall collect hazardous waste i.e., Expired Chemicals, Discarded Tablets & Gels, Spent Catalyst, Palladium Carbon and Raney Nickel, Used PPEs & other plastic material which contacts with Hazardous material, Silica gel, Celite Gel, Dalda & Organic &

Inorganic residues, failed batches and lift the waste as per the disposal option through M/s. IKP Knowledge Park.

12. The industry shall not discharge any waste water to outside the industry premises under any circumstances.
13. The industry shall not cause any air pollution/odour nuisance to the surrounding environment.
14. The industry shall not dispose the solid waste outside the factory premises.
15. 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.
16. 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 and other Wastes (Management, Transboundary Movement) Rules, 2016.
17. The industry shall not manufacture any extra products or extra capacities without obtaining CFE/CFO of the Board.
18. The industry shall not take up trial production without obtaining Consent for Operation of the Board.
19. Rain Water Harvesting (RWH) structure (s) shall be established on the plant site so that the ground water is recharged by the storm water.
20. The following rules and regulations notified by the MoE&F, GoI shall be implemented:
 - a) Solid Waste Management Rules, 2016.
 - b) Construction and Demolition Waste Management Rules, 2016.
 - c) Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 & its amendments.
 - d) Battery Waste Management Rules, 2022.
 - e) E-Waste Management Rules, 2022.
 - f) Bio-Medical Waste Management Rules, 2016 & its amendments.
 - g) Plastic Waste Management Rules, 2016 & its amendments.
21. The industry shall comply with Rules & Regulations notified by Ministry of Law and Justice, Govt. of India, regarding the Public Liability Insurance Act, 1991.
22. The industry shall comply with all the directions issued by the Board from time to time.
23. The Board reserves its right to modify above conditions or stipulate any further conditions and to take action including revoke of this order in the interest of environment protection.
24. This Order is issued to the industry without prejudice to the action taken by the Task Force of the Board.

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JOINT CHIEF ENVIRONMENTAL ENGINEER



To
M/s. United States Pharmacopeia India Pvt. Ltd.,
Unit 101 to 118 in 1st floor & 201 to 205 &
209 in 2nd floor of SME Hub (Catalyst), IKP Knowledge park,
Sy.No's 234/2, 234/3 & 235/2, Turkapally (V),
Shameerpet (M), Medchal-Malkajgiri District.