



## NEWSLETTER

**AUG-SEPT  
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### 33rd ANNUAL GENERAL BODY MEETING OF BULK DRUG MANUFACTURERS ASSOCIATION (INDIA)

Dear All,

Greetings from the Bulk Drug Manufacturers Association (India)

Annual General Body Meeting of BDMA held on 21st of September 2024 at 6.30 PM at Hotel AVASA, Hi-Tech City, Hyderabad.

We are pleased to inform you of the outcome of the elections of BDMA Office Bearers for the term 2024-2025. Mr. RK Agrawal has been re-elected as the National President of the Bulk Drug Manufacturers Association (India). Please find attached herewith a list on the outcome of BDMA Office Bearers and Executive Committee Members elections for your ready reference.

#### BDMA OFFIE BEARERS- (2024-2025)

Name (Shri)	Position	Election Result
Rk Agrawal	National President	Re-Elected
Ch Ap Rameswara Rao	Sr.Vice President	Re-Elected
Br Sikri	Vice President (North Zone)	Re-Elected
Naresh Gupta	Vice President(West Zone)	Re-Elected
R. Srinivasa Raju	Vice President(South Zone)	Re-Elected
Lv Sunil	General Secretary	Elected
M. Vijay Kiran	Secretary	Re-Elected
P.Anup Veer	Treasurer	Elected

SINo	Name	Company Name (M/s)	DESIGNATION
1	SHRI V.V. KRISHNA REDDY	SRI KRISHNA PHARMACEUTICALS LTD	EXECUTICE COMMITTEE MEMBER
2	SHRI. K. NITYANANDA REDDY	AUROBINDO PHARMA LTD.,	EXECUTICE COMMITTEE MEMBER
3	Dr. V.V. SUBBA REDDY	SRI KRISHNA PHARMACEUTICALS LTD	EXECUTICE COMMITTEE MEMBER

4	Dr. B. PARTHASARADHI REDDY	HETERO DRUGS LTD	EXECUTICE COMMITTEE MEMBER
5	Dr N.VENKATA REDDY	VIRCHOW LABORATORIES LTD	EXECUTICE COMMITTEE MEMBER
6	SHRI VENKAT JASTI	SUVEN LIFE SCIENCES LTD	EXECUTICE COMMITTEE MEMBER
7	SHRI P.V.RANVEER	VEERCHEMIE AND AROMATICS PVT. LTD.,	EXECUTICE COMMITTEE MEMBER
8	SHRI B.DILIP KUMAR REDDY	COREY ORGANICS LTD.,	EXECUTICE COMMITTEE MEMBER
9	SHRI ANUP AGARWAL	SREEPATHI LABS PVT. LTD.,	EXECUTICE COMMITTEE MEMBER
10	SHRI. K. SUBBARAO	GLOCHEM INDUSTRIES LTD	EXECUTICE COMMITTEE MEMBER
11	SHRI G.MANIKYA REDDY	S.M. LABS PVT.LTD	EXECUTICE COMMITTEE MEMBER
12	SHRI.J.SANJEEVA REDDY	ALISTER PHARM CHEM PVT LTD	EXECUTICE COMMITTEE MEMBER
13	SHRI.K.RAJA RAO	KEKULE PHARMA LTD	EXECUTICE COMMITTEE MEMBER
14	SHRI P LAKSHMAN RAO	RASULA PHARMACEUTICALS & FINE CHEMICALS	EXECUTICE COMMITTEE MEMBER
15	SHRI.M.BALA SUBBA REDDY	VIRUPAKSHA LABORATORIES PVT LTD	EXECUTICE COMMITTEE MEMBER
16	SHRI V.VASUDEV GOUD	BALAJI FORMULATIONS PVT.LTD	EXECUTICE COMMITTEE MEMBER
17	SHRI SRINIVAS ISOLA	SREEPATHI PHARMACEUTICAL LTD.,	EXECUTICE COMMITTEE MEMBER
18	SHRI N.SRINIVASAN-DIRECTOR	PORUS LABORATORIES PVT LTD	EXECUTICE COMMITTEE MEMBER

19	SHRI TBNV SUNDER RAO	VISHNU CHEMICALS LTD.,	EXECUTICE COMMITTEE MEMBER
20	SHRI RAVI SEELAM SHETTY	KREATIVE ORGANICS PVT. LTD.,	EXECUTICE COMMITTEE MEMBER
21	Dr. GIRIDHAR THOTA	SHODHANA LABORATORIES LTD	EXECUTICE COMMITTEE MEMBER
22	SHRI M.V. RAMA RAJU	VASUDHA PHARMA CHEM LTD	EXECUTICE COMMITTEE MEMBER
23	SHRI. P. RAMESH KUMAR	GLAND CHEMICALS PVT. LTD.	EXECUTICE COMMITTEE MEMBER
24	Dr.PV APPAJI	MEENAXY PHARMA PVT LTD	EXECUTICE COMMITTEE MEMBER
25	SHRI M. JAYANT TAGORE	SYNTHOKEM LABS. PVT. LTD.,	EXECUTICE COMMITTEE MEMBER
26	Dr. S.SURESH BABU	ENAL DRUGS PVT LTD	EXECUTICE COMMITTEE MEMBER
27	SHRI DINESH DUA	NECTAR LIFE SCIENCES LTD	EXECUTICE COMMITTEE MEMBER
28	SHRI RAVI YERRA	RA CHEM PHARMA LTD	EXECUTICE COMMITTEE MEMBER
29	SHRI K. VAMSHIDHAR REDDY	EMMENNAR PHARMA PVT LTD	EXECUTICE COMMITTEE MEMBER
30	SHRI K.RAVINDRA REDDY	MSN LABORATORIES PVT LTD	EXECUTICE COMMITTEE MEMBER
31	SHRI C.S. RATNA PRASAD	VALENS MOLECULES PVT LTD	EXECUTICE COMMITTEE MEMBER
32	SHRI S.V.RAO	STYRAX PHARMA PVT LTD	EXECUTICE COMMITTEE MEMBER
33	SHRI V.MADHUKAR REDDY	S.M.LABS PVT LTD	EXECUTICE COMMITTEE MEMBER

34	SHRI P.KIRAN KUMAR	Dr.REDDY'S LABS LTD	EXECUTICE COMMITTEE MEMBER
35	SHRI P.MADANMOHAN REDDY	AUROBINDO PHARMA LTD.,	EXECUTICE COMMITTEE MEMBER
36	SHRI RAHUL THOTA	SHODHANA LABORATORIES LTD	EXECUTICE COMMITTEE MEMBER
37	SHRI NIKHIL THOTA	SHODHANA LABORATORIES LTD	EXECUTICE COMMITTEE MEMBER
38	SHRI KARTHIK CHANDRA ISOLA	SREEAPTHI PHARMACEUTICALS LTD	EXECUTICE COMMITTEE MEMBER
39	SHRI S.SREENATH	STYRAX PHARMA PVT LTD	EXECUTICE COMMITTEE MEMBER
40	Dr Y.RAMACHANDRA REDDY	SRC LABORATORIES PVT LTD	EXECUTICE COMMITTEE MEMBER
41	G.HEMANTH REDDY	BALAJI AMINES LTD	EXECUTICE COMMITTEE MEMBER
42	SHRI HARDEV	METROCHEM API DIVISION PVT LTD	EXECUTICE COMMITTEE MEMBER
43	SHRI JAGAN MOHAN REDDY	S.M. RECOVERIES PVT.LTD	EXECUTICE COMMITTEE MEMBER
44	SHRI MAHAREDDY REVANTH REDDY	PRABHAVA ORGANICS	EXECUTICE COMMITTEE MEMBER
45	SHRI NAGARJUN CHAKILAM	MAITHRI DRUGS PVT LTD	EXECUTICE COMMITTEE MEMBER
45	SHRI K.SURAJ	VIRUPAKSHA LABORATORIES PVT LTD	EXECUTICE COMMITTEE MEMBER
46	SHRI V.ABHINAV KUMAR	BALAJI FORMULATIONS PVT.LTD	EXECUTICE COMMITTEE MEMBER
47	SHRI KVS R SESHU KUMAR	PURVIEW LIFESCIENCES P LTD	EXECUTICE COMMITTEE MEMBER







## **NATIONAL PRESIDENTS SPEECH FOR AGM 2024.**

Dear Friends,

Greetings and Good Evening to all.

It gives me immense Pleasure to welcome you all for this AGM - 33 RD Year of BDMA existence. Our Association has been effectively serving the API industry for last 33 years. I am indeed privileged to head one of the Oldest and prestigious association in Bulk Drug / Pharmaceutical sector.

The Detailed annual activity report of BDMAI will be presented by General Secretary. I take this opportunity to talk about other important subjects relating to API sector.

The biggest achievement for India in 2023 was Indian economy becoming 5th Largest economy, surpassing UK. Also India's exports figure of goods crossed \$ 400 billion. While the countries of the world are going through recessionary trends and inflation, Indian economy is insulated from external shocks and become fastest growing country in the world. Today, India has strong pharmaceutical sector and has very ambitious growth targets.

Indian exports of Pharmaceuticals grew at 9.6% during 2023-24 in spite of reduction in country's Merchandise exports by about 3% from 451 Bn \$ to about 437 Bn \$. The Exports of Pharmaceuticals now stands at 27.9 Bn \$ And including Domestic is estimated to be 58 Bn \$. The Ambitious future targets for Pharma sector is 130 Bn \$ by 2030 and 500 Bn \$ by 2047. US continues to remain top export destination with 31% contribution , followed by UK and Netherlands. With this performance India ranks 3rd in terms of Volume and 13th in terms of Value in field of Pharmaceurticals. We are therefore named as "Pharmacy of the World. "

We are all aware that India's journey of Growth in Pharma so far is driven by Generic Formulations with almost 40% generic drugs available in American Selves coming from India Origin. However to sustain our position in Global market & to achieve Future growth, other verticals have to grow exponentially. Making API manufacturing less dependent on China & Value Creation through R&D are now the focus areas that have potential to drive future growth.

Govt came out with two PLI schemes for Pharma Sector involving capital outlay of about Rs 21690/ Crore. As a result some of the critical API's are now on the verge of being produced locally. Govt also approved three Pharma Specific parks to promote API manufacturing. These parks are located in AP, Gujrat and Himachal Pradesh.

The Pharma associations are also persuing with Government to bring an additional PLI for promoting the manufacturing of KSM & Drug Intermediates for reducing Import Dependence .

In order to Promote Research and Innovation, the efforts are more towards Industry -Academia Collaboration. Both CSIR-IICT & NIPER have been in continuous discussion about how their services can be utilised in this Journey of Growth. You may be aware that NIPER has been nominated as Center of Excellence for API sector and are looking for Industry Inputs to make this Center industry oriented and be our partner in this journey of Growth. I request members to seriously think about how their services can be best utilised for Industry's future growth. NIPER has proposed to form a Task force with BDMA member units and set an agenda for a Collaborative approach. The Operations Head of Nipper Dr. Nandoori is here to talk about it later during the meeting.

I am extremely delighted to inform that Ist Phase of BDMA Technology and Training Centre at our Jeedimetla Building is now operational. This is first of its kind in the country where an association is coming forward to have a skill upgradation Centre to the employees as well as to the fresher's. The key beneficiaries of the project will be our member units. Currently 3 batches of 30 students each are under training and for 1 batch with 30 students has completed the training and has been successfully placed in the Industry. We aim to train about 2000 students each year to help Industry meet their growing Human Resource needs. Request Industry to avail this opportunity.

BDMA technology Development Center plans to offer technological support to MSME industry by providing software support for process monitoring, Equipment selection, utility



optimisation, Impurity assesment etc. We have procured Dynochem software for process optimisation to help units to improve their reaction efficiency and improve productivity. This service is now available and members are requested to avail this service.

We are also Closely working with USP and receiving their Technical support in improving quality standrads in MSME Units. They also partner with us in training programs and have provided a complimentary copy of USP monograpgh compendium to enable smaller companies to obtain upto 5 Monograpgh copies Free of cost from BDMA. More Suggestions to make this training and technology development Center are welcome from Members.

The BDMA training Center is built over 1 Acre land at Jeedimetla and the Building looks very promising. A separate presentation is planned to be shown here today. In order to make 2nd phase ready and operative, We need additional 5 Crore. This second phase also includes an 300 Seater Auditorium which can be named after Donor Industry. BDMAI training Center has received Approval of Ministry of Corporate affairs to receive CSR funds and thus contributions given to Training center are eligible for CSR qualification.

Happy to announce that Sri Krishna Pharma was First company to donate Rs 15 lacs to BDMA training Center under CSR.

Upskilling training & Certification Needs of Existing Employees :

I am pleased to inform you that the Ministry has approved LSSSDC's Up Skilling proposal inclusive of BDMAI demand for 2000 employees in alignment with the project guidelines. we would request re-confirmation from BDMAI to take up the Project of Upskilling Under PMKVY Branding.

The Details of scheme are already circulated and can also be provided by Mr Amrender Reddy - Cluster Head South India located in Hyderabad. He is also available here .

BDMAI : i Wish to mention that BDMA(I) is your own organisation and has now created a important place for itself. Both Central and state level agencies communicate with BDMA and ask for inputs on various subjects. i am firmly of the opinion that a Industry Sector like ours , a strong and effective association is must for effective representation of Industry issues at National level.

However for BDMA to play that role effectively, it is important that members give their inputs . I request all members to please react for BDMA requests for inputs on various subjects as and when asked. BDMA has also collaborated with Association of European API producers based in Belgium & part of Active Pharma Ingradient Committee ( APIC ). This body has various publications on GMP Guidelines related to manufacturing of Pharmaceuticals.

Many of our members with their units in other states such as Andhra & Karnataka communicate with us about their problems in those states. I am of the opinion that BDMA members having units in Andhra needs to form a State forum in Andhra to have proper representation of their issues.

I also thank all members for your continued trust in this committee and look forward to their valued suggestions to make it more effective. Finally I thank all my managing committee members for their co-operation and support in running the organisation.

Thank you very much.

**R K Agrawal.**  
**National President.**

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Dear Sir,

Please find enclosed draft Notification of MoEF &CC dated 19th July, 2024 G.S.R. 423(E).—The - Guidelines relating to the Uniform Consent fee and Grant, Refusal or Cancellation of Consent to Establish or Consent to Operate.

The attached draft notification which the Central Government proposes to issue, in exercise of the powers conferred by section 21A of Air Act and section 27A of Water Act for bringing out regulations for issuing guidelines with regard to consent to operate and consent to Establish is hereby published for information of the public and other stakeholders likely to be affected. Further, notice is hereby given that the said notification will be taken into consideration by the Central Government on or after the expiry of sixty days from the date on which the draft notification is published in the Gazette of India;

Any person interested in making any objection or suggestion on the proposals contained in the draft notification may do so in writing within the period so specified through post to the Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, Aliganj, New Delhi-110003 or electronically at email address: mishra.vp@gov.in or prasoon.tripathi76@gov.in under copy to BDMA (info@bdmai.org)

We hereby request all our members to send their objections, if any, to MoEF&CC or to BDMA so that we can compile and submit to MoEF&CC.

**MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE  
NOTIFICATION New Delhi, the 19th July, 2024 G.S.R. 423(E).**—The following draft

notification which the Central Government proposes to issue, in exercise of the powers conferred by section 21A of Air Act and section 27A of Water Act for bringing out regulations for issuing guidelines with regard to consent to operate and consent to Establish is hereby published for information of the public and other stakeholders likely to be affected. Further, notice is hereby given that the said notification will be taken into consideration by the Central Government on or after the expiry of sixty days from the date on which the draft notification is published in the Gazette of India; Any person interested in making any objection or suggestion on the proposals contained in the draft notification may do so in writing within the period so specified through post to the Secretary, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, Aliganj, New Delhi-110003 or electronically at email address: mishra.vp@gov.in or prasoon.tripathi76@gov.in

DRAFT NOTIFICATION Whereas, the Air (Prevention and Control of Pollution) Act, 1981 and Water (Prevention and Control of Pollution) Act 1974 were amended with a view to Streamline Consent Mechanism by issuing guidelines; And whereas, the Ministry consulted the Central Pollution Control Board (CPCB) to prepare such guidelines; And whereas, this notification is intended not only to enhance ease of doing business, minimizing compliance burden of Industries, but also to reduce duplication in the work at the State Pollution Control Board (SPCB)/Pollution Control Committee (PCC) level; And whereas, due care has been taken, while preparing this notification, that appropriate monitoring and compliance of pollution is ensured. Now therefore, in exercise of powers conferred under Section 21A of the Air (Prevention and Control of Pollution) Act, 1981, and section 27A of Water (Prevention and Control of Pollution) Act, 1974, the Central Government, hereby notifies the Guidelines relating to Consent fee and Grant, Refusal or Cancellation of Consent to Establish & Consent to Operate: Guidelines relating to the Uniform Consent fee and Grant, Refusal or Cancellation of Consent to Establish or Consent to Operate CONTENTS Chapter Description 1.0 Guidelines for Uniform Consent Fee across SPCB / PCC Page 2.0 2 Guidelines relating to grant, refusal or cancellation of consent 2.1 3 Guidelines for Grant of Consent to Establish 2.2 3 Guidelines for Grant of Consent to Operate & its Renewal 2.3 4 Guidelines for Refusal and Cancellation of Consent 6 26

THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] Chapter Description 3.0 Page Timeline for processing of consent applications 4.0 7 Portal for implementation of these guidelines 5.0 8 Monitoring Committees Annex I 8 Model Template for Common Consent & Authorization Annex II 9 Model Template for Endorsement for White Category Industry Appendix 18 Uniform Consent Fee Mechanism 19 1.0 1.1 1.2 1.3 1.4 1.5 2.0 2.1 GUIDELINES

FOR UNIFORM CONSENT FEE ACROSS SPCB / PCC The guidelines for rationalized / uniform consent fee across the State Pollution Control Boards (SPCBs) / Pollution Control Committees (PCCs) under the Water (Prevention and Control of Pollution) Act, 1974 (as amended to date), Air (Prevention and Control of Pollution) Act, 1981 (as amended to date) and Authorization under various Environmental Protection Rules, 1986 (as amended to date) are as follows: Capital Investment

(a) The investment made on fixed assets i.e. Land, Buildings including Staff Quarters, Guest Houses, etc. within industrial premises (or) townships, plants and machinery or equipment including the cost of investment on Pollution Control without depreciation.

(b) In the case of an industry operating on lease land and / or building or any other assets, ten (10) times the annual lease value is to be taken as equivalent to Capital Investment (or) Guidance Value of property / land, whichever is higher. Validity period of Consent to Establish & its Consent fee (a) The validity period of Consent to Establish (CTE) shall be as per the Environment Clearance (EC) issued by the Ministry of Environment, Forest and Climate Change (MoEF&CC) / State Environment Impact Assessment Authority (SEIAA) in case of a project attracting prior Environment Clearance. (b) In case the project / activity does not attract EC, then CTE shall be given for a minimum of five (05) years period initially and may be further extended by a maximum period of two (02) years on request of the project proponent, thereby making the outer limit for validity seven (07) years from the issue of CTE.

(c) The consent fee for CTE shall be twice the Annual Consent fee under the Water Act and / or Air Act, as applicable to the project activities for the entire period of establishment of the project. Estimation of Consent fee for various activities The capital investment slabs, categorization of industry, consent fee for industrial sectors, local bodies, mining projects, coffee pulping, aqua culture and Diesel Generator (DG) set as single air pollution source, rebate & late fee for renewal of consent, incentives to the industry, revision of consent fee and authorization fee, are given as Appendix. Higher Consent fee by SPCBs / PCCs SPCBs / PCCs may decide the quantum of consent fee which may be maximum up to 20% higher than the estimated consent fee based on the methodology suggested in this guideline, taking into account local environmental issues and local conditions. However, SPCBs / PCCs can charge any consent fee lower than that. Common Consent and Authorization Form SPCBs / PCCs shall adopt a single-step procedure for issuing Common Consent and Authorization (CC&A) under the Water Act, the Air Act and Authorization under the EPA Rules. Accordingly, a model template for Common Consent and Authorization form is given at Annexure I.

GUIDELINES RELATING TO GRANT, REFUSAL OR CANCELLATION OF CONSENT : Guidelines for grant of Consent to Establish (CTE)

(a) Information related to the CTE application (common consent form) shall be filled up by the applicant with prerequisite information / documents as per the procedures specified. [□□□ II—□□□ □ 3(i)] □□□□ □□ □□□□□□□□ : □□□□□□□□ 27

(b) Adequate fees prescribed for obtaining CTE shall be paid along with the application online / offline as per the rates prescribed by the State Government / UT.

(c) Siting Criteria: i. The industrial establishment shall comply with the sector-specific siting criteria of the Central / State / UT as applicable, orders passed by the Hon'ble National Green Tribunal (NGT) / Courts, and Guidelines issued in compliance with such orders / rules issued by MoEF&CC / CPCB / SPCB / PCC. ii. iii. iv. v. vi. vii. In case of non-availability of sector specific siting criteria, the General Guidelines framed by the respective State / UT shall be followed, otherwise, the following criteria (minimum distance) shall be maintained

a) From the nearest boundary of surface water body (flood plain/ HFL / Red line) as per the revenue sketch: • Red Category • Orange Category ✓ With effluent generation : Beyond 500 meters : : Beyond 75 meters ✓ Without effluent generation : Beyond 30 meters • Green Category : Beyond 30 meters

b) From the Settlement, Educational Institute, Worship place, Archaeological Monuments, National Park, Reserve Forest, Heritage site, interstate boundary shall be maintained: • Red Category • Orange Category • Green Category : Beyond 500 meters : Beyond 250 meters : Beyond 100 meters (Having noise/vibration generating machineries) Note: Other than the above criteria, the respective SPCB /PCC shall follow the distance from the water bodies / above-mentioned places, as per their existing rules / norms if any specified by the concerned departments of State Governments / UT or Central Govt. Department. The above distance criteria shall not be applicable to Special Economic Zones / Doon Valley / Dhanuka / Taj–Trapezium, Aravalli Range, etc. where it shall be governed as per provisions laid down under the respective notification.

C) No industry will be allowed to set up in non-conforming areas or restricted / prohibited areas pertaining to Eco-Sensitive Areas, Wetland areas, etc. as notified under Coastal Regulation Zone (CRZ) Regulations, Wet Land Rules, other notifications notified under the Environment (Protection) Act, 1986 or other laws / rules / notifications issued therein from time to time. Applicability of other prevalent laws, rules, and regulations, as applicable shall be verified and complied with. The natural / storm drain passing through any proposed site shall not be disturbed. The applicability of EC as per the provisions of Environmental Impact Assessment (EIA) Notification 2006, as amended from time to time, shall be verified and complied with.

(d) Site verification: i. ii. iii. The respective officer of SPCB / PCC, as per the delegation of power, shall conduct inspection of the proposed site and verify the suitability of the site for establishing proposed activity with respect to present environmental conditions of location, human habitation, historical monument, and sensitive area, if any. Inspection may also be carried out to capture surrounding environmental settings, and verification of information submitted in the application / proposals. Accordingly, the detailed observations report will be submitted to the designated officer of the Board / Committee for taking decision. The reasons for violations / non compliances are to be recorded in writing and communicated to the industry by the inspecting officer.

THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)]

(e) Grant of CTE: Based on the verification report and recommendations of the designated officer / consent committee, CTE shall be issued to the unit under Section 25 / 26 of the Water Act and under Section 21 of the Air Act, along with general conditions and specific conditions, as applicable based on the proposed activities and site location.

(f) 17 categories of Highly Polluting Industries i.e. Pulp & Paper, Distillery, Sugar, Tanneries, Power Plants, Iron & Steel, Cement, Oil Refineries, Fertilizer, Chloral Alkali Plants, Dye & Dye Intermediate Units, Pesticides, Zinc, Copper, Aluminum, Petrochemicals, and Pharma Sector, and Common Effluent Treatment Plants (CETP), Sewage Treatment Plants (STPs), Common Bio-Medical Waste and Common Hazardous Waste Incinerators will have to install Online Continuous Effluent Quality and Emission Monitoring Systems (OCEMS).

(g) White Category: These are exempt from CTE/CTO procedure. However, One-time endorsement shall be issued to the White Category Industries based on self-declaration, as per the procedure laid down. A model template for endorsement is given in Annexure II. Note: The industry shall also obtain CTE in case of expansion / modernization / change of products or processes from the respective SPCB / PCC before commissioning. 2.2 Guidelines for Grant of Consent to Operate & its Renewal Once the industry or process plant is established with the requisite pollution control systems and ready to operate, the occupier is required to obtain Consent to Operate. Accordingly, the guidelines for Grant of Consent to Operate & its Renewal under the Water Act and Air Act are as follows: 2.2.1 Consent to Operate (CTO): The following procedure shall be followed for issue of CTO: a. b. c. d. e. Information related to the CTO application (common consent form) shall be filled up by the applicant with prerequisite information / documents. Adequate fees along with penalty / late fee, if any prescribed for obtaining CTO shall be paid as per the rates prescribed by the SPCB / PCC. Compliance with the conditions stipulated in CTE issued by the SPCB / PCC shall be submitted along with the self-regulation mechanism Online Continuous Effluent Monitoring System (OCEMS) implemented by the occupier, as applicable. Compliance with the conditions stipulated in EC as applicable and issued by the concerned authorities shall be submitted. Verification : i. ii. The respective officer of SPCB / PCC, as per delegation of power, shall inspect and verify the industry w.r.t. compliance of CTE and installations of various plants & machineries, pollution control devices, waste management facilities and other infrastructures required to ensure compliance of stipulated discharge / emission / waste management norms, OCEMS, etc. The detailed report of compliance of monitoring with CTE conditions / EC conditions will be submitted to the designated officer of the SPCB / PCC for taking a decision. The reasons of violations / non-compliances are to be recorded in writing to the industry by the inspecting officer. f. Issue of CTO : i. ii.

g. Based on the inspection report and recommendations of the designated officer / consent committee, CTO shall be issued to the Unit under Section 25 & 26 of the Water Act and under Section 21 of the Air Act. The CTO will contain general conditions and relevant specific conditions in view of variation in process, operations, effluent disposal, environment standards,



guidelines, siting criteria, court directions, notification, etc. taking into account required pollution control measures and safeguard of environment for respective industrial sector and area. CTO shall be issued to the Unit under Section 25/26 of the Water Act and under Section 21 of the Air Act, for a specific period based on the category of industry, as decided from time to time.

h. The frequency of compliance monitoring and sampling of the Red, Orange and Green category industry shall be half yearly, annually, and once in two (02) years respectively by the SPCBs / PCCs. [□□□ II—□□□ □ 3(i)] □□□□ □□ □□□□□□□ : □□□□□□□ 29 2.2.2

Consent for Renewal: The following procedure shall be followed for renewal of CTO: a. Compliance status to the conditions stipulated in previous CTO / Conditions of Bank Guarantee (if any) / Directions (if any) issued by CPCB / respective SPCB / PCC for time-bound compliance shall be observed. b. c. d. e. f. g. h. 2.3 Submission of Environmental Statement (Form V) as per Environment (Protection) Rules, 1986 and Annual Returns (Form- 4) as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 shall be ensured. Declaration on no Change in the Manufacturing Process, Production capacity Pollution Load, Quantity, and mode of discharge of effluent and emissions shall be obtained and ensured. The respective officer of SPCB / PCC, as per delegation of power, shall verify the industry w.r.t. compliance of CTO conditions which includes verification of relevant records on water consumption and waste water management, operation of Effluent Treatment Plants (ETP) / Air Pollution Control Devices (APCD), Records of generation and disposal of hazardous wastes, functioning of OCEMS and its data logging, record of exceedance of stipulated standards of source emission and effluent discharge, addressing Public / VIP complaints etc. and submit the detailed observations report to the designated officer of the Board / Committee for taking decision. In case of non-compliance of effluent and emission discharge norms as per the compliance monitoring and sampling carried out, the details of pollutants / emissions (chemical reaction / material balance), design and operating conditions of ETPs and APCDs / System to be verified by the respective officer and upgradation / modification of environmental management systems required to be incorporated while renewing consent to meet the norms prescribed. The reasons for violations / non-compliances to be recorded. The inspection report shall record, the observations of the compliance monitoring, findings of the records and his / her view on the compliance of consent conditions. Based on the inspection report, the decision-making authority will initiate appropriate action as contemplated in the statute. CTO will be renewed to the Unit under Section 25/26 of the Water Act and under Section 21 of the Air Act, for a specific period based on the category of industry, as decided from time to time. In order to minimize inspection of industries, the frequency of compliance monitoring and sampling of the Red, Orange and Green category industry shall be half yearly, annually, and once in two (02) years respectively by the SPCBs / PCCs. Guidelines for Refusal and Cancellation of Consent Refusal or Cancellation / Withdrawal of consent (before the expiry of the period for which it is granted or refusing further consent after such expiry) is done as per Section 27 of the Water Act and Section 21 of the Air Act, for non-compliance with consent conditions imposed by the SPCB / PCC. The refusal of consent may be effected /considered for the following reasons: a) Violation of siting criteria, the industry does not satisfy the sitting criteria of the Central / State in the

case of CTE. b) Non-compliance of Consent and EC conditions. c) Variation in their process and its operations. d) Not meeting the effluent disposal / emission standards and failure to upgrade the ETP / APCDs / Fugitive Emission Control Systems or any other prescribed equipment. e) Non-compliance of Court directions, Guidelines, and Notifications and Standard Operating Procedures (SOPs) f) Accidental discharges of effluent / emission causing grave injury to the environment and human health. g) Occurrence of accident resulting in damage to the existing ETP / APCD systems. h) Non-payment of requisite consent fee, Environmental Compensation / Late fee / Bank Guarantee imposed by the CPCB and respective SPCB / PCC.

i) j) Industries proposed in the ban areas notified by the Central / State Government. Submission of incomplete information or false information or concealment of any material facts pertaining to the proposed plant. 30 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)]

k) Violation of any prevailing rules/regulations. No application for grant of consent will be refused without giving an opportunity of being heard and the reasons for refusal recorded in writing and duly communicated to the applicant with necessary directions, as deemed fit. 3.0

**TIMELINE FOR PROCESSING OF CONSENT APPLICATIONS:**

3.1 3.2 The Water Act and the Air Act provide for obtaining Consent to Establish / Operate by Activities / Industries. Subject to the provisions of the amended Air and Water Act, the timeline for issuing consents will be governed by this para. The maximum time limit for processing of the applications received from the date of receipt in all respects for issue of consent to establish, consent to operate, renewal of consent, consent for expansion activity, amendment, extension of consent by the SPCB/PCC will be as follows:

S. No.	Application	Red#	Orange#	Green#
1.	Grant / Refusal of Consent to Establish	Time Line (Days)*	60	2.
Grant / Refusal of 1st Consent to Operate	45	30	3.	
Grant / Refusal of Renewal of Consent / Expansion / Amendment	120	60	60	

30 \* From the date of receipt of the application complete in all respects. # As categorized by CPCB from time to time. 3.3 The consent shall be granted or refused within the timeline specified as above. 30 3.4 In case, SPCB / PCC fails to grant or refuse the consent within the above timeline, the application will be presented to the State Level Monitoring Committee (SLMC) referred in para 5.2 below. This Committee shall dispose of the application within 30 days of such presentation, or the overall limit provided in the Air and Water Acts, whichever is earlier. The Member Secretary of the concerned SPCB / PCC will present the case before the Committee. 3.5 While deciding on such application, the committee will also look into causes of delay in grant / refusal of the consent by SPCB / PCC. If it is found that the reasons of delay are not justified, the Committee may recommend appropriate disciplinary action against the responsible officer(s) of the SPCB / PCC. The Committee may also recommend presenting the case for contravention of the Air / Water Act before concerned adjudicating officer under Section 48 (2) of the Water Act and Section 38 A (2) of the Air Act, as amended. 3.6 The decision of the Committee shall be binding on the concerned SPCB / PCC. The Committee will have at least one meeting in a month's period. 3.7 The above committee will also monitor the SPCBs / PCCs with regard to adherence of these guidelines and take appropriate action wherever required. 3.8 Any policies framed by SPCBs / PCCs regarding consent mechanisms will

be subject to these guidelines. 4.0. Portal for implementation of these guidelines: 4.1. CPCB, in consultation with SPCBs / PCCs, develop an online portal for implementation of these guidelines, preferably within six (06) months, and not later than one (01) year from the date of this notification. 4.2 4.3 4.4 The portal will be exclusive interface between all the stakeholders and will be used for grant, refusal and withdrawal of CTE / CTO under the Water Act and Air Act, monitoring the process and by SLMC for disposal of cases presented before them. The portal shall act as single point data repository with respect to management and implementation of these guidelines. Unless otherwise provided, all the procedures and processes pertaining to CTE / CTO in respect of the Air and Water Act will be done through this portal only, in all the States / UTs. However, until the portal becomes operational, the alternative mode may be used for processing the applications for CTE / CTO. 5.0 Monitoring Committees: [ ] II—[ ] 3(i)] : [ ] 31 5.1 There will be a Monitoring Committee at the National Level to oversee and monitor the implementation of these guidelines and remove any difficulties in this regard. The Committee will consist of following Members: a) Joint/ Additional Secretary, CP Division, MoEFCC - Chairman b) Member Secretary, CPCB - c) Member Secretaries of any three (03) SPCBs / PCCs by rotation for three (03) years, nominated by MoEFCC - Member Member 5.2 There will also be a State Level Monitoring Committee to oversee the implementation of these guidelines and also to dispose of the matters presented to it under para 3.4 above. The committee will consist of following Members: a) Secretary in-charge, Dept. of Environment of State / UT b) Member Secretary of concerned SPCB/PCC c) Regional Director, CPCB of the jurisdiction - - Chairman Member - Member [F. No. F No. Q-15012/1/2022-CPW] NARESH PAL GANGWAR, Addl. Secy.

## Annexure I

MODEL TEMPLATE FOR COMMON CONSENT & AUTHORIZATION Application for Common Consent and Authorization (CCA) for establishment of the industry operation process or any treatment disposal system for discharge or continuation of discharge under Section 25 or Section 26 of the Water (Prevention and Control of Pollution) Act, 1974; Consent for emission / continuation of emission under section 21 of the Air (Prevention and Control of Pollution) Act, 1981 and Authorization under Hazardous And Other Wastes (Management And Transboundary Movement) Rules, 2016 From To Sir, \_\_\_\_\_

\_\_\_\_\_ The Member Secretary \_\_\_\_\_ State Pollution Control Board / Committee \_\_\_\_\_

\_\_\_\_\_ I / We hereby apply for -----

-----: 1. Consent / Renewal of Consent under Sections 25 and 26 of the Water (Prevention & Control of Pollution) Act, 1974 (Central Act 6 of 1974), as amended for establishing / operating or taking any steps for establishment / operation of industry / operation process, or ally treatment and disposal system to bring into use any new /altered outlet for discharge or continuation of discharge of sewage / trade effluent; 2. Consent / Renewal of Consent under Section 21 of Air (Prevention & Control of Pollution) Act, 1981,

(Central Act 14 of 1981) and as amended for establishing /operating industry, operation or process, or treatment and emission or continuation of emission of air pollutants;

THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] 3. Grant / Renewal of Authorization under Section 6 (1) of the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and as amended, for generation or collection or storage or transport or reception or recycling or reuse or recovery or pre-processing or co-processing or utilization or treatment or disposal of hazardous and other wastes from a land / premises owned by M/s.\_\_\_\_\_ at location \_\_\_\_\_

\_\_\_\_\_ as per

the details given below: S. No. Required Details TO BE FILLED IN BY THE APPLICANT PART A:

GENERAL 1.0 : Project Details : 1.1 Name of the Project / Industry / TSDF : 1.2 Project Proposal :

New / Expansion / Renewal / Validity Extension / Transfer 1.3 Details of Environment Clearance

: 1.4 Address of the Site / Unit : Plot / Survey No : Village : Tehsil : District : State/UT : Pin code :

2.0 Applicant / Occupier Details : 2.1 Name of the Applicant / Occupier Designation : 2.2 : 2.3

Nationality of the Occupier 2.4 Correspondence Address : Plot / Survey No/ Street Name :

Village / Town / City : Tehsil /Taluk : District : State / UT : Pin code : 2.5 Contact Details of Plant

Head with Alternate details : Name & Designation: : 1. 2. e-mail address 1. 2. Mobile Number :

1. 2. Landline Number : : 1, [□□□ II—□□□ □ 3(i)] □□□□ □□ □□□□□□□ : □□□□□□□

2. 3.0 Legal Status of the Company : 3.1 Individual / Proprietary concern / Partnership firm/

Joint family concern / Private Limited Company / Public Limited Company / Foreign Company /

Limited Liability Partnership. Note: Registration Number and Authority shall be mentioned. : 3.2

Central Govt. / State Govt./ Central PSU / State PSU / Joint Venture (Pvt. + Govt.), (Govt.+

Govt.), (Pvt.+ Pvt.) 4.0 Location of the Project / Industry / Activity : 4.1 Location : Upload KML

4.2 Bounded Latitudes (North) ( 8 digit after decimal) : From : To : 4.3 Bounded Longitudes

(East) ( 8 digit after decimal) : From : To : 4.4 Located in Eco-Sensitive Zone of Protected Area,

Coastal Regulation Zone, Biosphere, Reservoir, Forests, Mangroves, Rivers, Archeological

monuments, Critically Polluted Area, Non-attainment Cities, Polluted River Stretch, Hill stations

(altitude > 600 M), Major towns and Cities : 4.4 Survey of India Topo Sheet Number : 4.5 Land

details (as per Panchayat, Tehsil, District) : Owned / Leased : Total Area in Ha : a) Non – Forest

in Ha : b) Forest in Ha : Annual Lease Value, in case of Leased in Rs. : Build up Area in Sq. M. :

Green Belt cover in % of total area : 4.6 Extent of Land in Sq. m : Own-Agricultural : Industrial :

Converted : Industrial Area : c) Applied and not allotted : d) Applied and allotted : e) Leased : 3

THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] 5.0 Category & Classification of the Project / Industry / Activity : 5.1 Category of Industry (Red, Orange, and Green) : Category :

Pollution Index : 5.2 Industrial Sector /Type : 5.3 Grossly Polluting / 17 Category / Others : 5.4

Scale of Industry based on Capital Investment (Micro/ Small / Medium / Large) : Total Capital

Investment (Rs.) : Scale / Classification : 5.5 Products / By-Products manufacturing capacity

(TPD/ TPA) : Products / By-products : Capacity : : : 5.6 Raw Materials / Chemicals Consumption

for manufacturing capacity (TPD & TPA) : Raw Materials : Consumption : : : 5.7 Brief

manufacturing Process with process flow chart and Material Balance, Advantage of Technology,

etc. : To be Annexed 5.8 Date / Expected date of commencement of production : 5.9 Number of people to be employed / employed : 5.10 Industry Shifts / Weekly off : Shifts (I / II / III ) & in Hours : Weekly off in days : 5.11 Use of Hazardous Chemicals as per MSIHC Rules : S. No Chemicals HS Code Storage capacity Daily consumption 1. 2 3. PART B: WASTEWATER ASPECTS 6.0 Water Consumption and Wastewater Generation 6.1 Source of Water : Ground Water / River / Industrial Estate Supply / Private Tanker / Sea / Recycled / Any other, if any 6.2 Authority Granting permission & Quantity permitted : Authority: Quantity : 6.3 Water Consumption (KLD) for manufacturing capacity : 6.4 Water Usage for manufacturing capacity. : Purpose : KLD [PART II—SEC. 3(i)] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] : [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] 35 (Attach Water Balance showing quantity with TDS at different points) Domestic : Process : Boiler : Other Utilities (pl. specify) : 6.5 Wastewater Generation (KLD) for the manufacturing process : KLD Wastewater from various sources : Purpose : KLD Domestic : Process : Boiler : Other Utilities (pl. specify) : 6.6 Wastewater Treatment systems : Type of Effluent : KLD Treatment System Bio-degradable : Non- Biodegradable : Boiler blowdown : Others Utilities : Any other Total : 6.7 Details Sewage Treatment Plant(s) : S. No. Capacity of STPs : KLD 1. 2. Mode of disposal of treated effluent 6.8 Details Effluent Treatment Plant (s) : S. No. Capacity of ETPs : KLD 1. 2. Mode of disposal of treated effluent : 6.9 Capacity of treated effluent sump, Guard Pond, if any : 6.10 Schematic diagram of the treatment scheme with inlet / outlet characteristics of each unit operation / process : To be Annexed 6.11 Quality of Effluent before & after treatment (at the final outlets) in respect to pH, SS, TDS and constituting major ions, BOD/COD, Oil & Grease, and relevant metals and nutrients as per the process/ standards. (Attach analysis report of untreated and treated effluent from the EPA recognized Lab) Note: For the proposed unit furnish the expected characteristics of the effluent : To be Annexed. 36 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] 6.12 Name of River / Creek, Estuary / Drain (owner of sewer) / Sea / Land / connected to CETP : 6.13 Details of Solid Wastes separately for 'Hazardous' and 'Other' wastes covered under H&OW Rules, 2016 and other solid wastes not covered under H&OW Rules, 2016, including their management system : To be Annexed 6.14 Details of treatment-performance and environmental-compliance monitoring and reporting system : To be Annexed 6.15 Any relevant information not covered in the above items : PART C: AIR EMISSION ASPECTS (Information required in case of industrial establishments having chimneys) 7.0 Type of Fuels 7.1 Fuel Consumption per Hour and TPD for manufacturing capacity : S. No Fuel Quantity Ash% S% 1. Coal 2 Diesel 3. Furnace Oil 4. Natural Gas 5. Wood 6. Others, if any 7.2 Details of Stack (Process, fuel, D.G): a) Number of stacks and vents with height and dia (m) b) Quality and quantity of stack emissions from each stack and vent c) Major industrial processes / sources of fugitive emission d) A Brief account of air pollution control units to deal with the emission Stack Attached to Fuel Height (m) Diameter (m) Pollutants Control system Port Hole & Platform 7.3 D.G. Sets : S. No. KVA Acoustic status Height (m) 7.4 Quality of source emission (before treatment/ control) and after treatment/ controlled emission (at stacks/vents) in respect of PM, SO<sub>2</sub>, : To be Annexed [PART II—SEC. 3(i)] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] : [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] 37 NO<sub>x</sub>, and other relevant air pollutants as per the process/ standards (Attach analysis reports of stack emissions from the EPA recognized Lab) Note: For the proposed unit furnish the expected characteristics of the emissions 7.5 Odorous compounds, if any and, control measures provided : 7.6 Details of treatment/control performance and environmental

compliance monitoring and reporting system : 7.7 Any relevant information not covered in the above items : PART D: HAZARDOUS WASTE ASPECTS (Information required in case of industrial establishments generating Hazardous Waste) 8.0 Hazardous Waste Management 8.1 Process generating Hazardous waste : S. No. Process Clause of Schedule I Quantity/ Annum 8.2 Authorization required for : S. No. Activity : Please tick 1. Generation : 2. Collection : 3. Storage : 4. Transportation : 5. Reception : 6. Reuse : 7. Recycling : 8. Recovery : 9. Pre-processing : 10. Co-processing : 11. Utilization : 12. Treatment : 13. Disposal : 14. Incineration :

THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] 8.3 Technical Capabilities / Facilities : S. No. Capabilities : 1. Storage Area : 2. Storage Quantity : 3. Method of storage : 4. Special handling requirement, if any : 5. Emergency Response Procedure : 6. Leachate treatment : 8.4 Nature (Characteristics of wastes) and quantity of waste : a) Handled per annum: b) Stored at any time: 8.4 Mode of Management / Disposal of above Wastes : S. No. Disposal : Please tick 1. Secured storage within the industrial unit : 2. Utilization within the plants (if not, please provide details of utilization) : 3. Common TSDF : Within the State : Outside the State : 4. Others : 8.5 Arrangement for transportation of H.W. to actual users / TSDF : 8.6 Details of the environmental safeguards and environmental facilities provided for safe handling of all the wastes at point (c) above; 8.7 Hazardous and other wastes generated as per these rules from the storage of hazardous chemicals as defined under the Manufacture, Storage, and Import of Hazardous Chemicals Rules, 1989. 8.8 For Treatment, storage and disposal facility (TSDF) operators : 1. Please provide details of the facility including: a) Location of the site with a layout map b) Safe storage of the waste and storage capacity c) Treatment processes and their capacities d) Secured landfills e) Incineration, if any f) Leachate collection and treatment system g) Firefighting systems h) Environmental management plan including monitoring and i) Arrangement for transportation of waste from generators. 2. Please provide details of any other activities undertaken at the TSDF site:

[PART II—SEC. 3(i)] Note: 1. In case of renewal of authorization previous authorization numbers and dates and provide copies of annual returns of the last three years including the compliance reports with respect to the conditions of Prior Environmental Clearance, wherever applicable.

2. Provide a copy of the Emergency Response Plan (ERP) which should address procedures for dealing with emergency situations (viz. Spillage or release or fire) as specified in the guidelines of CPCB. Such ERP shall comprise the following, but not limited to:

➤Containing and controlling incidents so as to minimise the effects and to limit danger to the persons, environment and property;

➤Implementing the measures necessary to protect persons and the environment;

➤Description of the actions which should be taken to control the conditions at events and to limit their consequences, including a description of the safety equipment and resources available; ➤Arrangements for training staff in the duties which they are expected to perform;



➤Arrangements for informing concerned authorities and emergency services; and

➤Arrangements for providing assistance with off-site mitigatory action.

3. Provide undertaking or declaration to comply with all provisions including the scope of submitting bank guarantee in the event of spillage, leakage, or fire while handling the hazardous and other waste 8.9 For Recyclers or pre-processors or co-processors or users of hazardous or other wastes : a) Nature and quantity of different wastes received per annum from domestic sources or imported or both b) Installed capacity as per registration issued by the District Industries Centre or any other authorized Government agency. c) Provide details of secured storage of wastes including the storage capacity. d) Process description including process flow sheet indicating equipment details, inputs and outputs (input wastes, chemicals, products, by-products, waste generated, emissions, waste water, etc.). e) Provide details of end users of products or by-products. f) Provide details of pollution control systems such as Effluent Treatment Plants, scrubbers, etc. including the mode of disposal of waste g) Provide details of occupational health and safety measures: h) Has the facility been set up as per Central Pollution Control Board guidelines? If yes, provide a report on the compliance with the guidelines. i) Arrangements for transportation of waste to the facility: 8.10 Any relevant information not covered in the above items : PART E: PAYMENT DETAILS 9.0 Payment Details 9.1 Payment Mode : Online / Offline 9.2 Transaction Details in case of online : Transaction No: Date: Status:

THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] 9.3 Draft details in case of offline : Amount (Rs): Draft No: In favour of: Bank Name: Date: 9.4 Consent and Authorization Fee break-up : 1. 2. Consent Fee under the Water Act: Consent Fee under the Air Act: 3. Authorization Fee under HW Rules: DECLARATION a) I / We declare that the above furnished information is true and correct to the best of my / our knowledge. I / We am/are aware that furnishing any wrong information is punishable under Section 42(f) of the Water (Prevention & Control of Pollution) Act, 1974 and Section 38(f) of the Air (Prevention & Control of Pollution) Act, 1981. b) I / We hereby submit that in case of any change from what is stated in this application in respect of raw materials, products, processes of manufacture and treatment and/or disposal of effluent, emission, hazardous wastes, etc. in quality and quantity; a fresh application for Consent / Authorization shall be made and until the grant of fresh Consent / Authorization is granted, no change shall be made. I/ We am/are aware that the violations of Section 25 of the Water Act, Section 21 of the Air Act attracts penal provisions under the relevant provisions of the Water and Air Act. c) I / We herewith submit an affidavit on the basis of which consent for the establishment will be issued to me/us and I/ We will be held responsible under Section 45 (A) of Water Act and / or Section 39 of the Air Act for any misleading / wrong representation. d) I / We undertake to furnish any other information within one month of its being called by the Board / Committee Date: Place: Enclosures: As above Name & Signature of the Occupier/ Authorized Signatory Note: The section 6.11, 6.13, 6.14, 7.4, 7.5, 7.6, 8.2, 8.4, 8.5, 8.6, 8.7, 8.8, and 8.9 are not applicable in the case of Consent to Establish for the industry. Annexure II MODEL TEMPLATE FOR ENDORSEMENT FOR WHITE CATEGORY INDUSTRY To \_\_\_\_\_ Subject: Request for issue of

endorsement for grant of exemption from Consent Mechanism under Water Act, 1974 & Air Act 1981 - reg. Ref.: 1. Directions issued by CPCB under Section 18(1) (b) of the Water Act & Air Act 2. SPCB / PCC Notification No\_\_\_\_\_ dated \_\_\_\_\_on re-categorization 3. Provisions of the Jan Vishwas (Amendment of Provisions) Act, 2023 4. Your letter dated \_\_\_\_\_ [PART II—SEC. 3(i)] \_\_\_\_\_ : \_\_\_\_\_ 41 Sir, The \_\_\_\_\_ State Pollution Control Board (SPCB) / Pollution Control Committee (PCC) in receipt of your intimation / undertaking dated \_\_\_\_\_ for \_\_\_\_\_ activity for the issue of endorsement regarding exemption of your industry / activity from Consent mechanism under the Water (Prevention and Control of Pollution) Act, 1974 and the Air ((Prevention and Control of Pollution) Act, 1981. The documents, undertaking and affidavit, and the production process flow sheet submitted by you have been examined and noted that you are engaged / propose to engage in the production of ..... and as such your activity proposed / followed has been categorized under the White Category and exempted from the purview of consent. In view of the facts stated above, M/s \_\_\_\_\_ located \_\_\_\_\_ is not required to apply for and obtain CTE/CTO of the Board / Committee under the provisions of the Water Act and the Air Act, as long as there is no change in the activity proposed / prevailing activity being indicated above. Date: \_\_\_\_\_ Place: \_\_\_\_\_ (Authorized Signatory) Note: This endorsement is subject to random verification by CPCB/SPCB/PCC

**UNIFORM CONSENT FEE MECHANISM**

a) Capital Investment Slabs: Appendix The Capital Investment is considered for the estimation of the consent fee; accordingly, the suggested slabs are as follows: a) Rs. 1 Crore and below b) Exceeding Rs. 1 Crore but not exceeding Rs.10 Crore c) Exceeding Rs. 10 Crore but not exceeding Rs.50 Crore d) Exceeding Rs. 50 Crore but not exceeding Rs.250 Crore e) Exceeding Rs. 250 Crore but not exceeding Rs.500 Crore f) Exceeding Rs. 500 Crore but not exceeding Rs.1000 Crore g) Exceeding Rs. 1000 Crore

b) Categorization of industry: The industries are categorised Red, Orange, Green, and White based on the Pollution Index (PI) of any industrial sector is a number from 0 to 100 to ensure that the industry is established in a manner which is consistent with the environmental objectives. Accordingly, the categorization based on PI as follows: Categorization of Industry S. No. Categorization 1 Red Pollution Index Score of 60 and above 2 Orange Score of 41 to 59 3 Green Score of 21 to 40 4 White Score including & up to 20 The consent shall be issued to the Red, Orange, and Green categories of industries only. The consent fee collection for Red, Orange and Green Category Industries for a period of 5, 10 & 15 years respectively, as recommended in the document of classification of the industrial sectors by CPCB. 42 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)]

c) Consent Fee for Industrial Sectors: The consent fee is estimated based on capital investment and categorization of industry only. Accordingly, the formula to estimate the Annual Consent Fee (CF) for the industry is:  $CF = CI * SF * PIF$  Where • CF : Annual Consent Fee (in Rs. / Annum) • CI • SF • PIF : Capital Investment (in Rs.) : Scale Factor (based on CI) : Pollution Index Factor (based on Category) The Scale Factor (SF) according to capital investment slabs are: Capital Investment Rs. 1 Crore and below Factor (SF) Exceeding Rs. 1 Crore but not exceeding Rs.10 Crores 0.100% Exceeding Rs. 10 Crores but not exceeding Rs.50 Crores 0.080% Exceeding Rs. 50 Crores but not exceeding Rs.250 Crores 0.060% Exceeding Rs. 250 Crores but not exceeding Rs.500 Crores 0.040% Exceeding Rs. 500 Crores but not exceeding Rs.1000 Crores 0.030% Exceeding Rs. 1000 Crores 0.020% 0.010%

The Pollution Index Factor (PIF) are: Category

of Industry Green Factor (PIF) Orange 1.00 Red 1.50 2.00 Further, it is recommended to keep the maximum fee of the preceding slab as the basic fee of the next slab and the SF will be applicable on the difference amount. The same is shown below: Consent Fee (CF): Max. fees of the preceding slab + {( Diff. of CI ) \* SF\*PIF} Also recommended to keep a minimum consent fee on each slab of capital investment in the respective sector, as the Scale Factor reduces on higher investment. Accordingly, the minimum consent fee i.e. the basic fee as Rs. 5,000 per annum and the PIF factor will be applicable on above according to the category of industrial sector. (Green :1, Orange: 1.5 and Red: 2). d) Consent Fee for Local Bodies and Infrastructure projects (Residential and others): The CTE fee for Infrastructure Projects covered under EIA viz. Residential (Standalone Apartment / complexes), Layouts, Integrated projects, Commercial Complex, Office Complex, Education Institutions, Township and Local Body including Water Supply and Sewerage Board shall be charged on the basis of capital investment during the establishment phase as per the formula adopted for the industrial sector. Subsequently, the Consent fee for CTO shall be based on the quantity of sewage generated and treated by installing Sewage Treatment Plant (STP). Accordingly, the recommended fee for CTO is as follows: Consent Fee /Annum based on STP capacity S. No. Sewage generated & treated Other than Residential (Rs.) Local Bodies & Residential (Rs.)

S. No.	Sewage generated & treated	Other than Residential (Rs.)	Local Bodies & Residential (Rs.)
1	Up to 10 KLD	5,000	7,500
2	Above 10 - 50 KLD	15,000	22,500
3	Above 50 -100 KLD	25,000	37,500
4	Above 100 – 300 KLD	35,000	52,500
5	Above 300 – 500 KLD	55,000	82,500
6	Above 500 – 1 MLD	65,000	97,500
7	Above 1 to 5 MLD	75,000	1,12,500
8	Above 5 to 10 MLD	1,00,000	1,25,000
9	Above 10 MLD to 25 MLD	15,00,00	2,00,000
10	Above 25 MLD	30,00,00	4,00,000

e) Consent Fee for Mining Projects: 60,00,00 The Annual Consent Fee for Mining Activity is estimated based on the Consented Capacity of mineral to be mined, Type of Mineral, Mining Area, and Type of Mining. Accordingly, the formula to estimate the Annual Consent Fee (CF) is:  $CF = CC * MF * AF * TMF$  Where, S. No • CF: Annual Consent fee (in Rs. / Annum) • CC: Consented Capacity of Mineral (in Tonne / Annum) • MF: Mineral Factor (based on type of Mineral) • AF: Mineral Area Factor (in Rs. based on Mining area) • TMF: Type of Mining Factor (based on type of mining) Minerals MF (Rs) Lease hold area in Ha

Minerals	MF (Rs)	Lease hold area in Ha
1 Manganese, Chromite, Steatite, Barites, Mica, Gold, Uranium, Silver, Copper, Lead, Zinc	1	AF < 5
2 Iron, Bauxite, Coal	0.8	Open Cast 1.25 5 - 25 3 Dolomite, Limestone, Gypsum, Feldspar, Garnet, Quartz, Silica State Stone, Bentonite, Pyrophyllite, Graphite, Phosphorite, Clays – China, White, Fire and Ball 0.6 25 - 100 1.2 1.4 Under Ground 4 Other minerals such as stone quarry, Granite, Marble, River Sand / River bed material etc. 0.4 100 - 500 1 1.6 > 500 1.7

Also recommended to keep a minimum consent fee i.e. the basic fee as Rs. 5,000 per annum. f) Consent Fee for Coffee Pulping activities: The Annual Consent Fee for Coffee Pulping, it is suggested to keep only basic fee and Pulping Factor for Wet & Dry Pulping irrespective of capacity of operation, as it is a seasonal production. Accordingly, the formula to estimate the Annual Consent Fee (CF) for the Pulping Industry is:  $CF = BF * PF$  Where, • CF: Annual Consent fee (in Rs. / Annum) • BF: Basic Fee (in Rs.) • PF: Pulping Factor (based on type of pulping) Accordingly, the factors are as follows: • Basic Fee (BF): Rs. 2,500 per Annum

THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] • Pulping Factor (PF): S. No. Type of Pulping PF 1 Wet Pulping 1.25 2 Dry Pulping 1.00 g) Consent Fee for Aqua Culture activities:

The Annual Consent Fee for Aqua Culture based on Lease Hold Area and the consent fee per annum is: S. No. Lease Hold Area Consent Fee (Rs.) /Annum 1 Up to 5 Ha 2 Between 5 to 25 Ha Nil Rs. 5,000 3 Between 25 to 100 Ha Rs. 25,000 4 More than 100 Ha Rs. 1,00,000 h) Consent Fee for establishment having DG as the only source: The activity / establishment having Diesel Generator (DG) set as the only source of air pollution, the consent fee under Air Act is: S. No. Rating of D.G. Set Consent Fee (Rs) / D.G. Set / Annum 1  $\leq$  250 KVA Nil 2 250 KVA to  $\leq$  500 KVA Rs.1000 3 500 KVA to  $\leq$ 1MVA Rs.2000 4  $>$  1 MVA Rs.5000 i) Rebate and Late fee for Renewal of Consent: The industry shall be provided 5% rebate on consent fee for submitting consent renewal application within the stipulated time of 120 days under the Water & the Air Act. Further, it is recommended to impose late fee / closure directions respectively for late submission and expiry of consent. In view of this, it is recommended to impose the following late fee, to avoid last minute submission of a consent renewal application by Industries and also to be more watchful by the industry. Period of applying for Renewal Additional Fee as Late fee Before 120 days of expiry of consent Minus (-) 5% Between 120 – 45 days of expiry of consent 25% Between 45 days to till the date of expiry 50% After expiry date of consent Closure Notice for disconnection of power supply and subsequent application for renewal shall be treated as new application with 100% extra consent fee for one year. j) Incentives to the Industry: The industries adopting Environmental Conservative measures to reduce water, air and land pollutions, conservation of natural resources (resource consumption per unit production) and voluntary initiatives without SPCBs / PCCs directions / involvement to protect the environment using best technologies, cleaner technology, achieving below the National / Location specific standards shall be identified and incentives may be given in the form of a Green award, Cash award accordingly. [□□□ II—□□□ □ 3(i)] □□□□ □□ □□□□□□□ : □□□□□□□ 45 k) l) Revision of consent fee: Consent fees are not revised by the SPCBs / PCCs for many years resulting in revenue loss. In view of this, it is proposed to revise the consent fee based on an Annual Growth Rate arrived with reference to Wholesale Price Index (WPI) / Consumer Price Index (CPI) / RBI Target Inflation issued periodically by Government of India once in every five years by applying formula as below: Revised Consent Fee= Existing Consent Fee \* (1 + % increase in fee) Considering all above aspects, it is recommended to increase consent fee by 20% once in every five years by SPCB/PCC. Authorization under various Rules of EPA: The activities which are not covered under the Water & Air Acts, but required to obtain authorization under various Rules notified under Environment (Protection) Act, 1986, SPCBs/PCCs may consider to issue authorization for 5 years and recommend charging Rs. 10,000 as an “Administrative Charge” for issuing Authorization. The same may be notified by the State to collect the same as there is no provision under Rules notified under EPA. The SPCB/PCC may issue consolidated consents (Water & Air) along with Authorization as required under various Rules notified under the Environmental (Protection) Act, 1986. Also, recommends adding a factor of 1.1 to the estimated consent fee where authorization is required to be issued along with CTO.

## **BULK DRUG MANUFACTURERS ASSOCIATION (INDIA) SKILL DEVELOPMENT AND TRAINING INSTITUTE**

**Dear member,**

We are happy to inform you that BDMAI has been mandated for conducting free UpSkilling Training Program under PMKVY 4.0 RPL Scheme to BDMAI Members in association with LSSSDC(Life Sciences Sector Skill Development Council) , NSDC and MSDE(GoI).

### **Courses Offered**

<b>S.No</b>	<b>Job Role</b>	<b>Total Training Hours</b>	<b>#Training Hours Per Day</b>	<b>No.of Candidates Target Available</b>
<b>1</b>	<b>Analyst/Chemist-Quality Control: High-Performance Liquid Chromatography (HPLC)</b>	<b>30</b>	<b>4</b>	<b>150</b>
<b>2</b>	<b>Assistant- Maintenance (Pharma, Biologics and Medical Device Facility): Mechanical and Fitting</b>	<b>30</b>	<b>4</b>	<b>150</b>
<b>3</b>	<b>Chemist – Production (Pharma, Cosmetics &amp; Biologics): API Manufacturing</b>	<b>30</b>	<b>4</b>	<b>200</b>
<b>4</b>	<b>Effluent Treatment Plant Operator – Life Sciences (Pharma, Bio-Pharma &amp; Research)</b>	<b>30</b>	<b>4</b>	<b>375</b>
<b>5</b>	<b>Specialist- Quality Assurance (Pharma, Biological Products and Medical Devices) : Equipment Validation</b>	<b>30</b>	<b>4</b>	<b>500</b>

### **Project Details**

- Training Modules: Customize training modules relevant to job roles and potentially aligned to offer an opportunity to meet industrial needs using government funding.

- Training Mode: Physical training

- Training Venue: BDMAI Training and Technology Center, Jeedimetla, Hyderabad.

- Training Duration: Mandatory 30 hours (including 4 hours for program orientation and mock assessment practice) + 2-3 hours for mandatory assessments.

- Daily Training Hours: 4 hours.
- Training Timings :
  - Batch-1: 9AM-1PM ,
  - Batch-2: 2PM-6PM
- Batch Size - Maximum 45 Candidates

### **Program Benefits to Industry**

- Govt. Certification to the employee (Approved by MSDE, Govt. of India)
- Ensure that existing manpower is up-to-date on the newest information and abilities to keep them abreast of changing technologies and innovations.
- Cost Effective as complete scheme will be funded by Govt. of India.
- Under the scheme, manpower will receive proper hazard recognition and adequate protection from the harmful products.
- Compliant to the entire mandatory reporting requirement of Govt. Administration and avoiding warning letters.

#### **Program Benefits to Employees**

- Govt. Certification to the employee (Approved by MSDE, Govt. of India)
- Dual Advantage to industry
  - a) Formally recognized skill levels mapped with NSQF
  - b) Open up different paths for workers to upskill and grow through higher NSQF level training and bridge courses.
- Job Stability & Respected Profession
- Employee can progress to other training programs and education that they could not do without a certification
- Boosts employee morale and self esteem by rewarding them for their accomplishment as learners.
- Learning is a lifelong process and you can learn new things irrespective of your current job.
- Every passed & certifies candidate shall be provided a 1 year accidental and permanent disability insurance which covers up to Rs. 2 Lacs amount. Operationally, the insurance premium will be paid directly to the Insurance Company by the Ministry.

#### **Support Required from BDMAI Members**

- Nomination of employees for free Upskilling Training in respective Job Roles
- Declaration Letter from the Industry announcing the Designation of Industry Association Premises as a Training Center for Conducting Upskilling Programs.
- Consent to Send Candidates to the Industry Association Training Center for attending Upskilling Programs
  - Consent to conduct training as per the project details .
  - Facilitation of enrolled trainees' documents (Aadhaar, educational documents).

We are looking forward to **BDMAI Members'** active participation and request you to send Nomination details as per the below forma:

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#### **Nomination Details**



**Member Name** :

**Member Address** :

**Contact Person Name** :

**Contact Person Phone Number** :

**Contact Person Email Id** :

Employee Name	Course Name	Batch No ( 1 or 2)	Employee			Education Details
			Contact No.	Email Id	Aadhar No	

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**Declaration Letter**

**To whom so ever it may concern**

We hereby designate Bulk Drug Manufacturers Association(India) Training and Technology Centre premises for conducting free Up Skilling Training Program under PMKVY 4.0 RPL as per the project details. We also give consent to send our employees to Bulk Drug Manufacturers Association(India) Training and Technology Centre for training.

For

Company Name:

Address:

Signature:

Designation:

Company Seal:

Date:

Request all the members desiring to nominate their employees for training to send the details and consent letters as per the above format latest by 5<sup>th</sup> October 2024 so that the training batches can be started after Dussera festival.

Schedule of batches is attached for your reference.

Requesting members to take full advantage of this scheme by nominating the maximum number of employees as BDMA has an approval for training 1200 candidates.



FEW RECENT PHOTOGRAPHS OF THE BDMA TECHNOLOGY AND TRAINING INSTITUTE, JEEDIMETLA



**MEETING WITH HR TEAM OF VASUDHA PHARMA**



HYDERABAD, SEP 12  
(UNI):- Dr.B.Partha Saradhi Reddy, Chairman, Hetero Group Dr.A. Ramkishan, Dy.Drugs Controller (India) as Guest of Honour along with P Eshwar Reddy, Executive Director-BDMA at the Passing Out Ceremony of 1st Batch Students of BDMA Technology and Training Centre at BDMA Technology and Training Centre, Jeedimetla Industrial Estate, in Hyderabad on Thursday.  
UNI PHOTO-23U

#### UNI Photo



HYDERABAD, SEP 12 (UNI):- Dr.B.Partha Saradhi Reddy, Chairman, Hetero Group Dr.A. Ramkishan, Dy.Drug Controller (India) as Guest of Honour along with P I Reddy, Executive Director-BDMA at the Passing Out Ceremony of 1st Batch Students of BDMA Technology and Training Centre at BDMA Technology and Training (Jeedimetla Industrial Estate, in Hyderabad on Thursday.  
UNI PHOTO-23U



## పార్థా విద్యార్థులకు ధ్రువపత్రాల ప్రదానం

జీడిమెట్ట, న్యూస్టుడే: జీడిమెట్ట పారిశ్రామిక వాడలో బిల్డింగ్ మాన్యుఫాక్చరర్స్ అసోసియేషన్ ఆఫ్ ఇండియా ఆధ్వర్యంలో కొనసాగుతున్న ది పార్థా పాఠశాలలో శిక్షణ పూర్తి చేసుకున్న విద్యార్థులకు ధ్రువపత్రాలను ప్రదానం చేశారు. ఈ కార్యక్రమానికి రాజ్యసభ సభ్యులు బండి పార్లమెంటు రెడ్డి, డిప్యూటీ డ్రగ్ కంట్రోలర్ (ఇండియా) డాక్టర్ రాంకిషన్ లు హాజరై ధ్రువపత్రాలను ప్రదానం చేశారు. ఇది మొదటి బ్యాచ్ అని ఎండి సత్యనారాయణ చెప్పారు.



విద్యార్థునికి ధ్రువపత్రాల అందజేత

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