



सत्यमेव जयते

File No: EC-09(97)/2024

Government of India

Ministry of Environment, Forest and Climate Change
(Issued by the State Environment Impact Assessment
Authority(SEIAA), UTTARAKHAND)



Dated 17/02/2024



To,

KAVITA PANDEY
KAVITA PANDEY
OXI PHARMA First Floor, 122/13 Min, Central Hope Town, Selaqui, Central Hope Town Selaqui ,
DEHRADUN, UTTARAKHAND, 248011
oxipharma9@gmail.com

Subject: Grant of EC under the provision of the EIA Notification 2006-regarding.

Sir/Madam,

This is in reference to your application for Grant of EC under the provision of the EIA Notification 2006-regarding in respect of project OXI PHARMA submitted to Ministry vide proposal number SIA/UK/IND3/458409/2024 dated 17/02/2024.

2. The particulars of the proposal are as below :

(i) EC Identification No.	EC24C2405UK5486244N
(ii) File No.	EC-09(97)/2024
(iii) Clearance Type	EC
(iv) Category	B2
(v) Project/Activity Included Schedule No.	5(f) Synthetic organic chemicals industry ,5(f) Synthetic organic chemicals industry
(vii) Name of Project	OXI PHARMA
(viii) Name of Company/Organization	KAVITA PANDEY
(ix) Location of Project (District, State)	DEHRADUN, UTTARAKHAND
(x) Issuing Authority	SEIAA
(xii) Applicability of General Conditions	no
(xiii) Applicability of Specific Conditions	no

3. In view of the particulars given in the Para 1 above, the project proposal interalia including Form-1(Part A and B) were submitted to the Ministry for an appraisal by the State Environment Impact Assessment Authority(SEIAA) Appraisal Committee (SEIAA) in the Ministry under the provision of EIA notification 2006 and its subsequent amendments.

4. The above-mentioned proposal has been considered by State Environment Impact Assessment Authority (SEIAA) Appraisal Committee of SEIAA in the meeting held on 22/01/2024. The minutes of the meeting and all the Application and documents submitted [(viz. Form-1 Part A, Part B, Part C EIA, EMP)] are available on PARIVESH portal which can be accessed by scanning the QR Code above.
5. The brief about configuration of plant/equipment, products and byproducts and salient features of the project along with environment settings, as submitted by the Project proponent in Form-1 (Part A, B and C)/EIA & EMP Reports/presented during SEIAA are annexed to this EC as Annexure (1).
6. The SEIAA, in its meeting held on 22/01/2024, based on information & clarifications provided by the project proponent and after detailed deliberations recommended the proposal for grant of EC under the provision of EIA Notification, 2006 and as amended thereof subject to stipulation of specific and general conditions as detailed in Annexure (2).
7. The SEIAA has examined the proposal in accordance with the Environment Impact Assessment (EIA) Notification, 2006 & further amendments thereto and after accepting the recommendations of the State Environment Impact Assessment Authority (SEIAA) Appraisal Committee hereby decided to grant EC for instant proposal of M/s. KAVITA PANDEY under the provisions of EIA Notification, 2006 and as amended thereof.
8. The Ministry reserves the right to stipulate additional conditions, if found necessary.
9. The EC to the aforementioned project is under provisions of EIA Notification, 2006. It does not tantamount to approvals/consent/permissions etc. required to be obtained under any other Act/Rule/regulation. The Project Proponent is under obligation to obtain approvals /clearances under any other Acts/ Regulations or Statutes, as applicable, to the project.
10. This issues with the approval of the Competent Authority.

Copy To

N/A

Annexure 1

Standard EC Conditions for (Synthetic organic chemicals industry)

1.

S. No	EC Conditions
1.1	The project proponent shall also upload/submit six monthly reports on Parivesh Portal on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data to the respective Integrated Regional Office of MoEF&CC, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.

Additional EC Conditions

Pre Operation- 1) The project proponent should advertise with basic details at least in two widely circulated local newspapers, within seven (7) days of the receipt of the clearance letter informing that the project has been accorded Environmental Clearance by SEIAA Uttarakhand and a copy of the same be sent to the Regional Office of Ministry of Environment, Forests and Climate Change, Govt of India located at 25 Subhash Road, Dehradun. 2) A copy of the Environmental Clearance letter shall be sent by the proponent to the concerned Panchayat/Town area. 3) Consent to Establish/Consent to Operate shall be obtained from Uttarakhand Pollution Control Board under relevant provisions of Air (Prevention and Control of Pollution) Act, 1981 and Water (Prevention and Control of Pollution) Act, 1974 before starting any construction activity at the site. 4) There shall be no felling of trees at the construction site and further no damage to

the local vegetation shall be done. The installation of equipment/machineries shall be done within the vacant space available in the plant premises. During Operation Phase- 1) Project Proponent shall not produce Beta lactum, Ceflosporin, Anti-Cancer drugs, Narcotics. 2) Project Proponent shall install STP & ETP separately. 3) Project Proponent may install additional one DG set of 125 KVA capacity. 4) Project Proponent shall dispose off discarded medicines/raw materials to authorized TSDF/CBWTF as per applicable rules. 5) Project Proponent shall install ETP & VOC scrubbing system. 6) Project Proponent shall install Wet Scrubber, re-cycling pit as air pollution control device in his premises. 7) Project Proponent shall comply with the EPR authorization, if applicable. 8) Project Proponent shall ensure compliance of CER activity through any Govt. Organization. 9) Project Proponent shall dispose AHU filter dust and filters to TSDF. 10) The project proponent shall construct rainwater harvesting pits in such a manner to prevent the ingress of contaminated water from ETP & STP into rainwater harvesting pit. 11) The Project proponent shall install Ten Solar lights in Two adjoining villages in consultation with local Authorities/Forest officials. Detail shall be submitted within three months. 12) Project Proponent shall install solar lights on the periphery of its premises. 13) Regular health checkup of workers by recognized medical practitioners shall be ensured by the Project proponent and shall submit report to SEIAA along with six monthly compliance report. 14) The project proponent will submit reports pertaining to ambient air quality, report pertaining to ground water quality and noise. These reports should be monitored and generated by a NABL approved laboratory having scope of it. 15) The Project proponent will install advanced dust suppression system at the project site. 16) The Project proponent shall plant two rows fast growing species on both the sides of road connecting from the project premises to main road. 17) The project proponent shall submit the NoC from CGWB for utilization of ground water. 18) The project proponent shall undertake rain water harvesting activities in the two surrounding villages preferably in the schools, primary health centers in consultation with local authorities. 19) The building plan and structural design of the unit shall comply with requirements of Seismic Zone – IV as outlined in National Building Code. 20) No further expansion or modifications in the plan shall be carried out without the prior approval of competent authority. 21) The Project Authority shall strictly comply with provisions of Doon Valley Notification, 1989 & 2020. 22) During any type of construction in the existing land area, the topsoil excavated shall be used for backfilling/ landscape development/ green belt development. The same shall not be disposed of outside the boundaries of project site without approval of Competent Authority. 23) The groundwater samples shall be tested from accredited labs and it shall be ensured that test results comply with CPCB standards so as to ensure that there is no threat to groundwater quality by leaching of heavy metals and toxic contaminants. 24) All stacking and loading areas should be provided with proper garland drains equipped with baffles to prevent runoff from the site to enter any adjoining water body. Construction spoils including bituminous materials must not be allowed to contaminate watercourse and dumpsites as these may leach into ground water. 25) The manufacturing process shall be carried out in closed atmosphere without having any air emissions. However, air emissions from DG set should comply with CPCB norms by designing stack of adequate height. 26) No waste water shall be discharged outside the plant boundary and 'Zero Discharge' shall be strictly adhered to permissible standards. 27) All the hazardous residue and wastes arising from units shall be either sent to TSDF for land filling or for incineration. Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc. 28) The gaseous emissions (SO₂, NO_x, CO, VOC and HC) and particulate matter along with Respirable Suspended Particulate Matter (RSPM) levels from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency. 29) Fugitive emissions in the work zone environment, product and raw materials storage areas shall be regularly monitored. The emissions shall conform to the limits imposed by the UKPCB/Central Pollution Control Board. Dust / Powder from the formulation process shall be collected by dust extractor. 30) The project authorities shall strictly comply with the rules and guidelines under Manufacture, Storages and Import of Hazardous Chemicals Rules, 1989, (as amended from time to time). Authorization from the UEPPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes. 31) The DG sets shall use low sulphur diesel type fuel and should have stack height complying with CPCB norms. DG set should be operated only during power failure in emergency situation. 32) The ambient air quality and noise levels as per CPCB norms shall be ensured through a monitoring system. Dust Suppression during construction activity shall be ensured. Acoustic enclosures shall be provided with all machineries and DG sets on site complying with Noise Levels as per CPCB standards. 33) All liquid raw materials shall be stored in storage tanks and drums. Closed handling systems for chemicals and solvents shall be provided. Magnetic seals shall be provided for pumps/agitators for reactors for reductions of fugitive emissions. 34) The vehicles used at the factory site should comply with emission norms and noise level standards of CPCB and State Transport Department. They should be operated only during non-peak hours. 35) All necessary efforts shall be made to ensure safety and hygiene of workforce. First Aid facility shall be established and trained manpower be engaged to deal with emergency cases. The labour force engaged on site shall be screened for health from time to time. 36) Adequate drinking water and sanitation facility shall be provided on site for the workforce. 37) Separate toilets shall be

provided for ladies staff. 38) A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions. 39) Energy consumption measures like installation of LED/TFL for the external lighting area shall be ensured. The used LED/TFL shall be properly collected and disposed off as per the prevailing guidelines/rules of the regulatory authority to avoid mercury contamination. 40) The Project Proponent shall develop multi layered green belt around the periphery of the plant. The green belt thus developed should be on 25 sqm. 41) Action plan for establishment of solar energy shall be submitted to this office within three months. 42) The project proponent shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment. 43) The project proponent shall ensure compliance to provisions of all the Acts, Rules, Regulations and Guidelines, for the time being in force, as applicable to the project. 44) The vehicles used at the factory site should comply with emission norms and noise level standards of CPCB. 45) The project authority shall also comply with the entire environment protection measures and safeguards proposed in the EMP. All the recommendations made in respect of environmental management and risk mitigation measures relating to the project shall be implemented. 46) The fire safety arrangements and emergency exit plan should be as per the norms of the concerned regulatory authority/agency. 47) Rainwater harvesting for surface run off shall be ensured. Before recharging the surface run off, pretreatment must be done to remove suspended matter, oil and other particles. 48) Emergency preparedness plan based on risk assessment shall be made and shall be submitted to this office within three months. 49) The project proponent shall submit within the next 3 months the details on quantification of yearwise CER activities along with cost and other details. 50) STP shall be connected with separate electric meter and photocopy of electric consumption bill shall be submitted with compliance report to this office. 51) The project proponent shall provide Personal Protection Equipment (PPE) as per the norms of factory act. 52) Agreement with TSDF vendors shall be submitted. 53) The grant of this EC is issued from the environmental angle only, and does not absolve the project proponent from the other statutory obligations prescribed under any other law or any other instrument as force the sole and complete responsibility to comply with the conditions laid down in all other laws for the time being inforce, rests with the project proponent. 54) The provisions of the Solid Waste (Management) Rules, 2016 and the plastic waste (management) Rules 2016 shall be followed. 55) The project proponent shall abide by all commitments and recommendation made in the form- I, Pre-feasibility report/Environment Management Plan (EMP) and also during their presentation to the expert appraisal committee. 56) Any change in planning of the approved plan/site plan will leads to environment clearance void-ab initio and project proponent will have to seek fresh Environmental Clearance. 57) Concealing factual data or submission of false/fabricated data may result in revocation of this environmental clearance and attract action under the provision of Environment Protection Act 1986. 58) The ministry or any other competent authority may alter/modify the above conditions or stipulate any further condition in the interest of Environment Protection. 59) The ministry/SEIAA reserves the right to stipulate additional condition if necessary the project proponent/company in time bound manner shall implement these conditions. 60) The Ministry/SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory. 61) The Regional office of the Ministry shall monitor compliance of the stipulated conditions. The project authorities should extent full cooperation to the officers (s) of the Regional office by furnishing the requisite data/information/monitoring reports. 62) The above conditions shall be enforced, inter-alia under the provisions of water Prevention & Control of Pollution) Act 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment Protection) Act, 1986, Hazardous and other wastes Rules,2016, and the Public Insurance Act 1991, along with their amendments and rules and any other orders passed by the Hon'ble Supreme court of India/High court of law relating to the subject matter. 63) The project proponent shall submit half yearly compliance report of stipulated conditions of Environment Clearance in soft copy through PARIVESH PORTAL given link: <https://parivesh.nic.in>.The compliance report shall also be e mailed to the Regional Office in Dehradun in moef.ddn@gov.in 64) The project proponent shall ensure compliance to provisions of all the Acts, Rules, Regulations and Guidelines, for the time being in force, as applicable to the project. 65) The above environmental safeguards shall be implemented in letter and spirit. The project proponent shall establish Environment Monitoring Cell, and also submit six monthly compliance reports to this Authority and regional office of Ministry of Environment, Forests and Climate Change, Govt of India at Dehradun. The contact details of the incharge of Environment Monitoring Cell will also be intimated in the compliance reports. 66) The SEIAA reserves the right to include additional safeguard measures, if found necessary and also to take action including revoking of the EC granted under provisions of EIA Notification 2006. This EC is being granted subject to compliance of Hon'ble Court Orders issued from time to time. 67) The SEIAA Uttarakhand reserves the right to withdraw the Environmental Clearance or add additional conditions. 68) If ownership is transferred then fresh Environment Clearance is to be obtained under EIA notification dated 14.09.2006. However, no activity shall be undertaken till the Environment Clearance is transferred in his name and he is lawfully bound to comply with the conditions of the Environmental Clearance. 69) This Environmental Clearance (E.C.) is subject to obtaining clearance under the Wildlife (Protection) Act, 1972 from the competent Authority as may be applicable to this project. 70) The Project Proponent shall follow all relevant

directions/orders issued by Hon'ble High Court/NGT/ Supreme Court. 71) The project proponent shall ensure compliance to provisions of all the Acts, Rules, Regulations Guidelines and directions of Hon'ble Courts for the time being in force, as applicable to the project. 72) Any appeal against this EC shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under section 16 of the National Green Tribunal Act, 2010.

Pre Operation-

- 1) The project proponent should advertise with basic details at least in two widely circulated local newspapers, within seven (7) days of the receipt of the clearance letter informing that the project has been accorded Environmental Clearance by SEIAA Uttarakhand and a copy of the same be sent to the Regional Office of Ministry of Environment, Forests and Climate Change, Govt of India located at 25 Subhash Road, Dehradun.
- 2) A copy of the Environmental Clearance letter shall be sent by the proponent to the concerned Panchayat/Town area.
- 3) Consent to Establish/Consent to Operate shall be obtained from Uttarakhand Pollution Control Board under relevant provisions of Air (Prevention and Control of Pollution) Act, 1981 and Water (Prevention and Control of Pollution) Act, 1974 before starting any construction activity at the site.
- 4) There shall be no felling of trees at the construction site and further no damage to the local vegetation shall be done. The installation of equipment/machineries shall be done within the vacant space available in the plant premises.

During Operation Phase-

- 19) The building plan and structural design of the unit shall comply with requirements of Seismic Zone – IV as outlined in National Building Code.
- 20) No further expansion or modifications in the plan shall be carried out without the prior approval of competent authority.
- 21) The Project Authority shall strictly comply with provisions of Doon Valley Notification, 1989 & 2020.
- 22) During any type of construction in the existing land area, the topsoil excavated shall be used for backfilling/ landscape development/ green belt development. The same shall not be disposed of outside the boundaries of project site without approval of Competent Authority.
- 23) The groundwater samples shall be tested from accredited labs and it shall be ensured that test results comply with CPCB standards so as to ensure that there is no threat to groundwater quality by leaching of heavy metals and toxic contaminants.
- 24) All stacking and loading areas should be provided with proper garland drains equipped with baffles to prevent runoff from the site to enter any adjoining water body. Construction spoils including bituminous materials must not be allowed to contaminate watercourse and dumpsites as these may leach into ground water.
- 25) The manufacturing process shall be carried out in closed atmosphere without having any air emissions. However, air emissions from DG set should comply with CPCB norms by designing stack of adequate height.
- 26) No waste water shall be discharged outside the plant boundary and 'Zero Discharge' shall be strictly adhered to permissible standards.
- 27) All the hazardous residue and wastes arising from units shall be either sent to TSDF for land filling or for incineration. Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc.
- 28) The gaseous emissions (SO₂, NO_x, CO, VOC and HC) and particulate matter along with Respirable Suspended Particulate Matter (RSPM) levels from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency.
- 29) Fugitive emissions in the work zone environment, product and raw materials storage areas shall be regularly monitored. The emissions shall conform to the limits imposed by the UKPCB/Central Pollution Control Board. Dust / Powder from the formulation process shall be collected by dust extractor.
- 30) The project authorities shall strictly comply with the rules and guidelines under Manufacture, Storages and Import of Hazardous Chemicals Rules, 1989, (as amended from time to time). Authorization from the UEPPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.
- 31) The DG sets shall use low sulphur diesel type fuel and should have stack height complying with CPCB norms. DG set should be operated only during power failure in emergency situation.
- 32) The ambient air quality and noise levels as per CPCB norms shall be ensured through a monitoring system. Dust Suppression during construction activity shall be ensured. Acoustic enclosures shall be provided with all machineries and DG sets on site complying with Noise Levels as per CPCB standards.
- 33) All liquid raw materials shall be stored in storage tanks and drums. Closed handling systems for chemicals and solvents shall be provided. Magnetic seals shall be provided for pumps/agitators for reactors for reductions of fugitive emissions.
- 34) The vehicles used at the factory site should comply with emission norms and noise level standards of CPCB and State Transport Department. They should be operated only during non-peak hours.
- 35) All necessary efforts shall be made to ensure safety and hygiene of workforce. First Aid facility shall be established and trained manpower be engaged to deal with emergency cases. The labour force engaged on site shall be screened for health from time to time.

- 36) Adequate drinking water and sanitation facility shall be provided on site for the workforce.
- 37) Separate toilets shall be provided for ladies staff.
- 38) A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- 39) Energy consumption measures like installation of LED/TFL for the external lighting area shall be ensured. The used LED/TFL shall be properly collected and disposed off as per the prevailing guidelines/rules of the regulatory authority to avoid mercury contamination.
- 41) Action plan for establishment of solar energy shall be submitted to this office within three months.
- 42) The project proponent shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- 43) The project proponent shall ensure compliance to provisions of all the Acts, Rules, Regulations and Guidelines, for the time being in force, as applicable to the project.
- 44) The vehicles used at the factory site should comply with emission norms and noise level standards of CPCB.
- 45) The project authority shall also comply with the entire environment protection measures and safeguards proposed in the EMP. All the recommendations made in respect of environmental management and risk mitigation measures relating to the project shall be implemented.
- 46) The fire safety arrangements and emergency exit plan should be as per the norms of the concerned regulatory authority/agency.
- 47) Rainwater harvesting for surface run off shall be ensured. Before recharging the surface run off, pretreatment must be done to remove suspended matter, oil and other particles.
- 48) Emergency preparedness plan based on risk assessment shall be made and shall be submitted to this office within three months.
- 49) **The project proponent shall submit within the next 3 months the details on quantification of yearwise CER activities along with cost and other details.**
- 50) STP shall be connected with separate electric meter and photocopy of electric consumption bill shall be submitted with compliance report to this office.
- 51) The project proponent shall provide Personal Protection Equipment (PPE) as per the norms of factory act.
- 52) Agreement with TSDF vendors shall be submitted.
- 53) The grant of this EC is issued from the environmental angle only, and does not absolve the project proponent from the other statutory obligations prescribed under any other law or any other instrument as force the sole and complete responsibility to comply with the conditions laid down in all other laws for the time being in force, rests with the project proponent.
- 54) The provisions of the Solid Waste (Management) Rules, 2016 and the plastic waste (management) Rules 2016 shall be followed.
- 55) The project proponent shall abide by all commitments and recommendation made in the form- I, Pre-feasibility report/Environment Management Plan (EMP) and also during their presentation to the expert appraisal committee.
- 56) Any change in planning of the approved plan/site plan will leads to environment clearance void-ab initio and project proponent will have to seek fresh Environmental Clearance.
- 57) Concealing factual data or submission of false/fabricated data may result in revocation of this environmental clearance and attract action under the provision of Environment Protection Act 1986.
- 58) The ministry or any other competent authority may alter/modify the above conditions or stipulate any further condition in the interest of Environment Protection.
- 59) The ministry/SEIAA reserves the right to stipulate additional condition if necessary the project proponent/company in time bound manner shall implement these conditions.
- 60) The Ministry/SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
- 61) The Regional office of the Ministry shall monitor compliance of the stipulated conditions. The project authorities should extent full cooperation to the officers (s) of the Regional office by furnishing the requisite data/information/monitoring reports.
- 62) The above conditions shall be enforced, inter-alia under the provisions of water Prevention & Control of Pollution) Act 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment Protection) Act, 1986, Hazardous and other wastes Rules,2016, and the Public Insurance Act 1991, along with their amendments and rules and any other orders passed by the Hon'ble Supreme court of India/High court of law relating to the subject matter.
- 63) The project proponent shall submit half yearly compliance report of stipulated conditions of Environment Clearance in soft copy through PARIVESH PORTAL given link: <https://parivesh.nic.in>.The compliance report shall also be e mailed to the Regional Office in Dehradun in moef.ddn@gov.in
- 64) The project proponent shall ensure compliance to provisions of all the Acts, Rules, Regulations and Guidelines, for the time being in force, as applicable to the project.
- 65) The above environmental safeguards shall be implemented in letter and spirit. The project proponent shall establish Environment Monitoring Cell, and also submit six monthly compliance reports to this Authority and regional office of Ministry

of Environment, Forests and Climate Change, Govt of India at Dehradun. The contact details of the incharge of Environment Monitoring Cell will also be intimated in the compliance reports.

66) The SEIAA reserves the right to include additional safeguard measures, if found necessary and also to take action including revoking of the EC granted under provisions of EIA Notification 2006. This EC is being granted subject to compliance of Hon'ble Court Orders issued from time to time.

67) The SEIAA Uttarakhand reserves the right to withdraw the Environmental Clearance or add additional conditions.

68) If ownership is transferred then fresh Environment Clearance is to be obtained under EIA notification dated 14.09.2006. However, no activity shall be undertaken till the Environment Clearance is transferred in his name and he is lawfully bound to comply with the conditions of the Environmental Clearance.

71) The project proponent shall ensure compliance to provisions of all the Acts, Rules, Regulations Guidelines and directions of Hon'ble Courts for the time being in force, as applicable to the project.

72) Any appeal against this EC shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under section 16 of the National Green Tribunal Act, 2010.

Annexure 2

Details of Products & By-products

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (eg. CAS number)
Tablet, Capsule, Oral Liquid & Sachet	Tablet, Capsule, Oral Liquid & Sachet	60	Tons per Annum (TPA)	Road	

राज्य स्तर पर्यावरण समाघात निर्धारण प्राधिकरण, उत्तराखण्ड, "गौरादेवी पर्यावरण भवन, तृतीय तल, 46-बी, आई.टी. पार्क, सहस्रधारा रोड, देहरादून"
(पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय, भारत सरकार, नई दिल्ली द्वारा गठित)
दूरभाष: 0135-2976159
ईमेल: seiaa.seac.uk@gmail.com



State Level Environment Impact Assessment Authority, "Gauradevi Paryavaran Bhawan, Third Floor, 46-B I.T. Park, Sahasradhara Road, Dehradun"
(Constituted by Ministry of Environment, Forests and Climate Change Government of India.)
Phone No-0135-2976159
Email- seiaa.seac.uk@gmail.com

E.C.No- 171 -09(97)/2024

Dated- 14 -02-2024

To,

M/s Oxi Pharma by Smt Kavita Pandey (Proprietor).
Khata No- 711, Khasra No- 122/13 Min, Central Hope Town,
Tehsil- Vikasnagar, District- Dehradun.

Sub: Regarding Environmental Clearance for Proposed Manufacturing of Pharmaceutical Products at Khata No- 711, Khasra No- 122/13 Min, Central Hope Town, Tehsil- Vikasnagar, District- Dehradun.

Kindly refer to your online proposal No SIA/UK/IND3/458409/2024 submitted to SEIAA Uttarakhand regarding aforementioned subject. The details about the project site and proposal for EC as per the documents submitted by the project proponent is as under:

S.No	Parameters	Description			
		S.no	Products	Qtyper Annum	
1.	Products and quantity	1	Tablet, Capsules, Oral Liquid & Sachet	60 TPA	
2.	Estimated Project Cost	1.50Crore			
3.	Total Plot Area	112sqm			
4.	Proposed Green Area	25sqm			
5.	Proposed Green Area	25sqm			
6.	Fresh Water Consumption	7KLD			
7.	Fresh Water Source	Uttarakhand JalSansthan			
8.	Power Demand	125KVA			
9.	Power back up	DG Set of 125K.V.A. x 1no			
10.	Wastewater Management	Use of Water	Water requirement	Waste water generation	Mode of Disposal
		Process	4.75KLD	3.80KLD	ETP
		Domestic	2.25KLD	1.80KLD	Septic tank and soak pit
11.	Steam and heating system	Boiler 500kg/hrHSDfire			
12.	Fuel Consumption	HSD15ltr/hr for DG Set& Boiler LSD fuel – 25ltr/hr			

Land use details:

S.No	Parameters	Description
1.	Ground Coverage	112sqm
2.	Road and Paved area	50sqm
3.	Parking area	50sqm
4.	Green Area	25sqm
5.	Switchyard [OTS]	N.A.
6.	Future Expansion Area	N.A.
	Total Plot Area	112sqm

Raw material details:

S.No	Major Raw Material	Avg. consumption Annually	Source	Mode of Transport
1.	Sorbitol	20.0 MTA	Open	By Road
2.	Glycien	1.0 MTA	Open	By Road
3.	Propylegluconate	0.5 MTA	Open	By Road
4.	Xanthangum	0.4 MTA	Open	By Road

5.	Bronopol	0.5 MTA	Open	By Road
6.	Citric Acid	0.3 MTA	Open	By Road
7.	Edta	2.0 MTA	Open	By Road
8.	Methyleparaben	2.0 MTA	Open	By Road
9.	Propyleparaben	2.0 MTA	Open	By Road
10.	Aspartam	0.1 MTA	Open	By Road
11.	Sugar	8.0 MTA	Open	By Road
12.	BromhexinHcl	0.2 MTA	Open	By Road
13.	Dextromethorphan	0.2 MTA	Open	By Road
14.	Ambroxol	0.2 MTA	Open	By Road
15.	Guaiphenasin	0.4 MTA	Open	By Road
16.	TurbutalineSulphate	0.3 MTA	Open	By Road
17.	SulbutamolSulphate	0.3 MTA	Open	By Road
18.	Vitamin B1	0.1 MTA	Open	By Road
19.	Vitamin B2	0.1 MTA	Open	By Road
20.	Vitamin B6	0.1 MTA	Open	By Road
21.	Niaicinamide	1.0 MTA	Open	By Road
22.	Vitamin E	0.5 MTA	Open	By Road
23.	Lycopiene	0.4 MTA	Open	By Road
24.	Silymarine	0.5 MTA	Open	By Road
25.	Montelukast	0.6 MTA	Open	By Road
26.	Levocetirizine	0.5 MTA	Open	By Road
27.	FungalDiastage	0.5 MTA	Open	By Road
28.	Pepsin	0.5 MTA	Open	By Road
29.	Lactoluse	4.0 MTA	Open	By Road
30.	Azithromycine	1.0 MTA	Open	By Road
31.	Paracetamol	5.0 MTA	Open	By Road
32.	Cyproheptadine	0.4 MTA	Open	By Road
33.	Tricolin Citrate	0.3 MTA	Open	By Road
34.	Mefenamic Acid	1.0 MTA	Open	By Road
35.	Metronidazole	0.5 MTA	Open	By Road
36.	Folic Acid	0.3 MTA	Open	By Road
37.	Vitamin B 12	0.4 MTA	Open	By Road
38.	Ornidazol	1.0 MTA	Open	By Road
39.	Tinidazole	0.5 MTA	Open	By Road
40.	Sodium Benzoate	0.4 MTA	Open	By Road
41.	Ofloxacin	2.0 MTA	Open	By Road
42.	Ferrous Ascorbate	1.0 MTA	Open	By Road

Domestic Water Demand and Effluent Generation:

S.No.	Uses	Population/ area	Consumption rate	Water requirement [KLD]	Domestic Effluent [KLD]
1	Domestic uses [drinking, sanitation]	50 nos	45	2.25	1.80
2	Flushing water	50 nos	L.S.	1.00	0.00
3	Canteen Facility	--	--	--	--
4	Housekeeping (Floor Washing)	L.S.	L.S.	0.25	--
5	Gardening	25sqm	L.S.	0.50	--

Industrial Water Demand and Effluent Generation:

S.No.	Uses	Water requirement [KLD]	Effluent Generation [KLD]
1	Process - Boiler Chiller	1.00	0.4
2	Cooling Tower make up	--	--
3	Laboratory	--	--
4	APC devices [Fume scrubber]	--	--
5	Rejects from Water Treatment	3.75	3.40
	Total	4.75	3.80

Solid waste details:

S.No.	Waste Detail	Quantity	Utilization/Disposal
-------	--------------	----------	----------------------

		Generation	
1	Used Oil – 5.1	0.25 MTA	Authorized TSDF
2	Process Residue & Waste – 28.1	0.15 MTA	Authorized TSDF
3	Off Specification Products – 28.4	0.35 MTA	Authorized TSDF
4	Date-expired Products – 28.5	0.50 MTA	Authorized TSDF
5	Chemical sludge from waste water treatment – 35.3	0.35 MTA	Authorized TSDF

Products Details

S.no.	Product	Salt
1.	Oxi Para Tablet	Paracetamol
2.	Oxi Para – A Tablet	Paracetamol + Aceclofenac
3.	Oxi Para – SP Tablet	Paracetamol + Aceclofenac + Serratio
4.	Kerof – 200 Tablet	Ofloxacin
5.	Kerof – Oz Tablet	Ofloxacin + Ornidazole
6.	Kerof – Tz Tablet	Ofloxacin + Tinidazole
7.	Oxirabe Tablet	Rabeprazole
8.	OxirabeDSR Capsule	Rabeprazole + Domperidone
9.	OxipaneDSR Capsule	Pentoprazole + Domperidone
10.	Oxi Suspension	Paracetamol
11.	Oxi MF	Paracetamol + Mefenamic acid
12.	OxiZyme	Fungal Pepsin
13.	Oxi Cough	Dextromethorphan + Guaiphenesin + Terbutaline
14.	Oxi Powder	Sodium Chloride + Sugar

The SEAC during its meeting held on 22nd January, 2024 had undertaken appraisal of the project. It has been found that the proposal is not classified under any schedule of EIA Notification 2006 requiring EC. But the project site being located within the territorial limits of Doon Valley, hence provisions of Doon Valley Notification, 1989 & 2020 (as amended from time to time) are applicable and the proposal is placed under **Orange category** (B2) requiring prior EC. After due examination of the relevant documents submitted by the project proponent and additional clarification furnished in response to its observations earlier, SEAC has recommended the grant of Environmental Clearance for the above project subject to compliance of the EMP and other stipulated conditions. SEIAA during its meeting dated 7th February, 2024 considered the above proposal based on the recommendation of SEAC. After due examination and deliberation, the SEIAA Uttarakhand hereby accords Environmental Clearance for the above project under category B-2 of EIA notification 2006 (as amended from time to time) subject to the strict compliance of the conditions mentioned below:-

Pre Operation-

- 1) The project proponent should advertise with basic details at least in two widely circulated local newspapers, within seven (7) days of the receipt of the clearance letter informing that the project has been accorded Environmental Clearance by SEIAA Uttarakhand and a copy of the same be sent to the Regional Office of Ministry of Environment, Forests and Climate Change, Govt of India located at 25 Subhash Road, Dehradun.
- 2) A copy of the Environmental Clearance letter shall be sent by the proponent to the concerned Panchayat/Town area.
- 3) Consent to Establish/Consent to Operate shall be obtained from Uttarakhand Pollution Control Board under relevant provisions of Air (Prevention and Control of Pollution) Act, 1981 and Water (Prevention and Control of Pollution) Act, 1974 before starting any construction activity at the site.
- 4) There shall be no felling of trees at the construction site and further no damage to the local vegetation shall be done. The installation of equipment/machineries shall be done within the vacant space available in the plant premises.

During Operation Phase-

- 1) Project Proponent shall not produce Beta lactum, Ceflosporin, Anti-Cancer drugs, Narcotics.
- 2) Project Proponent shall install STP & ETP separately.
- 3) Project Proponent may install additional one DG set of 125 KVA capacity.
- 4) Project Proponent shall dispose off discarded medicines/raw materials to authorized TSDF/CBWTF as per applicable rules.
- 5) Project Proponent shall install ETP & VOC scrubbing system.
- 6) Project Proponent shall install Wet Scrubber, re-cycling pit as air pollution control device in his premises.
- 7) Project Proponent shall comply with the EPR authorization, if applicable.
- 8) Project Proponent shall ensure compliance of CER activity through any Govt. Organization.
- 9) Project Proponent shall dispose AHU filter dust and filters to TSDF.
- 10) The project proponent shall construct rainwater harvesting pits in such a manner to prevent the ingress of contaminated water from ETP & STP into rainwater harvesting pit.

- 11) The Project proponent shall install Ten Solar lights in Two adjoining villages in consultation with local Authorities/Forest officials. Detail shall be submitted within three months.
- 12) Project Proponent shall install solar lights on the periphery of its premises.
- 13) Regular health checkup of workers by recognized medical practitioners shall be ensured by the Project proponent and shall submit report to SEIAA along with six monthly compliance report.
- 14) The project proponent will submit reports pertaining to ambient air quality, report pertaining to ground water quality and noise. These reports should be monitored and generated by a NABL approved laboratory having scope of it.
- 15) The Project proponent will install advanced dust suppression system at the project site.
- 16) The Project proponent shall plant two rows fast growing species on both the sides of road connecting from the project premises to main road.
- 17) The project proponent shall submit the NoC from CGWB for utilization of ground water.
- 18) **The project proponent shall undertake rain water harvesting activities in the two surrounding villages preferably in the schools, primary health centers in consultation with local authorities.**
- 19) The building plan and structural design of the unit shall comply with requirements of Seismic Zone – IV as outlined in National Building Code.
- 20) No further expansion or modifications in the plan shall be carried out without the prior approval of competent authority.
- 21) The Project Authority shall strictly comply with provisions of Doon Valley Notification, 1989 & 2020.
- 22) During any type of construction in the existing land area, the topsoil excavated shall be used for backfilling/ landscape development/ green belt development. The same shall not be disposed of outside the boundaries of project site without approval of Competent Authority.
- 23) The groundwater samples shall be tested from accredited labs and it shall be ensured that test results comply with CPCB standards so as to ensure that there is no threat to groundwater quality by leaching of heavy metals and toxic contaminants.
- 24) All stacking and loading areas should be provided with proper garland drains equipped with baffles to prevent runoff from the site to enter any adjoining water body. Construction spoils including bituminous materials must not be allowed to contaminate watercourse and dumpsites as these may leach into ground water.
- 25) The manufacturing process shall be carried out in closed atmosphere without having any air emissions. However, air emissions from DG set should comply with CPCB norms by designing stack of adequate height.
- 26) No waste water shall be discharged outside the plant boundary and 'Zero Discharge' shall be strictly adhered to permissible standards.
- 27) All the hazardous residue and wastes arising from units shall be either sent to TSDF for land filling or for incineration. Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc.
- 28) The gaseous emissions (SO₂, NO_x, CO, VOC and HC) and particulate matter along with Respirable Suspended Particulate Matter (RSPM) levels from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency.
- 29) Fugitive emissions in the work zone environment, product and raw materials storage areas shall be regularly monitored. The emissions shall conform to the limits imposed by the UKPCB/Central Pollution Control Board. Dust / Powder from the formulation process shall be collected by dust extractor.
- 30) The project authorities shall strictly comply with the rules and guidelines under Manufacture, Storages and Import of Hazardous Chemicals Rules, 1989, (as amended from time to time). Authorization from the UEPPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.
- 31) The DG sets shall use low sulphur diesel type fuel and should have stack height complying with CPCB norms. DG set should be operated only during power failure in emergency situation.
- 32) The ambient air quality and noise levels as per CPCB norms shall be ensured through a monitoring system. Dust Suppression during construction activity shall be ensured. Acoustic enclosures shall be provided with all machineries and DG sets on site complying with Noise Levels as per CPCB standards.
- 33) All liquid raw materials shall be stored in storage tanks and drums. Closed handling systems for chemicals and solvents shall be provided. Magnetic seals shall be provided for pumps/agitators for reactors for reductions of fugitive emissions.

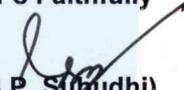


- 34) The vehicles used at the factory site should comply with emission norms and noise level standards of CPCB and State Transport Department. They should be operated only during non-peak hours.
- 35) All necessary efforts shall be made to ensure safety and hygiene of workforce. First Aid facility shall be established and trained manpower be engaged to deal with emergency cases. The labour force engaged on site shall be screened for health from time to time.
- 36) Adequate drinking water and sanitation facility shall be provided on site for the workforce.
- 37) Separate toilets shall be provided for ladies staff.
- 38) A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- 39) Energy consumption measures like installation of LED/TFL for the external lighting area shall be ensured. The used LED/TFL shall be properly collected and disposed off as per the prevailing guidelines/rules of the regulatory authority to avoid mercury contamination.
- 40) **The Project Proponent shall develop multi layered green belt around the periphery of the plant. The green belt thus developed should be on 25 sqm.**
- 41) Action plan for establishment of solar energy shall be submitted to this office within three months.
- 42) The project proponent shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- 43) The project proponent shall ensure compliance to provisions of all the Acts, Rules, Regulations and Guidelines, for the time being in force, as applicable to the project.
- 44) The vehicles used at the factory site should comply with emission norms and noise level standards of CPCB.
- 45) The project authority shall also comply with the entire environment protection measures and safeguards proposed in the EMP. All the recommendations made in respect of environmental management and risk mitigation measures relating to the project shall be implemented.
- 46) The fire safety arrangements and emergency exit plan should be as per the norms of the concerned regulatory authority/agency.
- 47) Rainwater harvesting for surface run off shall be ensured. Before recharging the surface run off, pretreatment must be done to remove suspended matter, oil and other particles.
- 48) Emergency preparedness plan based on risk assessment shall be made and shall be submitted to this office within three months.
- 49) **The project proponent shall submit within the next 3 months the details on quantification of yearwise CER activities along with cost and other details.**
- 50) STP shall be connected with separate electric meter and photocopy of electric consumption bill shall be submitted with compliance report to this office.
- 51) The project proponent shall provide Personal Protection Equipment (PPE) as per the norms of factory act.
- 52) Agreement with TSDF vendors shall be submitted.
- 53) The grant of this EC is issued from the environmental angle only, and does not absolve the project proponent from the other statutory obligations prescribed under any other law or any other instrument as force the sole and complete responsibility to comply with the conditions laid down in all other laws for the time being inforce, rests with the project proponent.
- 54) The provisions of the Solid Waste (Management) Rules, 2016 and the plastic waste (management) Rules 2016 shall be followed.
- 55) The project proponent shall abide by all commitments and recommendation made in the form- I, Pre-feasibility report/Environment Management Plan (EMP) and also during their presentation to the expert appraisal committee.
- 56) Any change in planning of the approved plan/site plan will leads to environment clearance void-ab initio and project proponent will have to seek fresh Environmental Clearance.
- 57) Concealing factual data or submission of false/fabricated data may result in revocation of this environmental clearance and attract action under the provision of Environment Protection Act 1986.
- 58) The ministry or any other competent authority may alter/modify the above conditions or stipulate any further condition in the interest of Environment Protection.
- 59) The ministry/SEIAA reserves the right to stipulate additional condition if necessary the project proponent/company in time bound manner shall implement these conditions.
- 60) The Ministry/SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
- 61) The Regional office of the Ministry shall monitor compliance of the stipulated conditions. The project authorities should extent full cooperation to the officers (s) of the Regional office by furnishing the requisite data/information/monitoring reports.
- 62) The above conditions shall be enforced, inter-alia under the provisions of water Prevention & Control of Pollution) Act 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment Protection) Act, 1986, Hazardous and other wastes Rules,2016, and the Public

Insurance Act 1991, along with their amendments and rules and any other orders passed by the Hon'ble Supreme court of India/High court of law relating to the subject matter.

- 63) The project proponent shall submit half yearly compliance report of stipulated conditions of Environment Clearance in soft copy through PARIVESH PORTAL given link: <https://parivesh.nic.in>. The compliance report shall also be e mailed to the Regional Office in Dehradun in moef.ddn@gov.in
- 64) The project proponent shall ensure compliance to provisions of all the Acts, Rules, Regulations and Guidelines, for the time being in force, as applicable to the project.
- 65) The above environmental safeguards shall be implemented in letter and spirit. The project proponent shall establish Environment Monitoring Cell, and also submit six monthly compliance reports to this Authority and regional office of Ministry of Environment, Forests and Climate Change, Govt of India at Dehradun. The contact details of the incharge of Environment Monitoring Cell will also be intimated in the compliance reports.
- 66) The SEIAA reserves the right to include additional safeguard measures, if found necessary and also to take action including revoking of the EC granted under provisions of EIA Notification 2006. This EC is being granted subject to compliance of Hon'ble Court Orders issued from time to time.
- 67) The SEIAA Uttarakhand reserves the right to withdraw the Environmental Clearance or add additional conditions.
- 68) If ownership is transferred then fresh Environment Clearance is to be obtained under EIA notification dated 14.09.2006. However, no activity shall be undertaken till the Environment Clearance is transferred in his name and he is lawfully bound to comply with the conditions of the Environmental Clearance.
- 69) This Environmental Clearance (E.C.) is subject to obtaining clearance under the Wildlife (Protection) Act, 1972 from the competent Authority as may be applicable to this project.
- 70) The Project Proponent shall follow all relevant directions/orders issued by Hon'ble High Court/NGT/ Supreme Court.
- 71) The project proponent shall ensure compliance to provisions of all the Acts, Rules, Regulations Guidelines and directions of Hon'ble Courts for the time being in force, as applicable to the project.
- 72) Any appeal against this EC shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under section 16 of the National Green Tribunal Act, 2010.

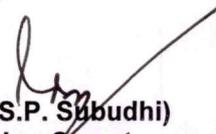
Your's Faithfully


(Dr. S.P. Subudhi)
Member Secretary,
SEIAA, Uttarakhand

No.- 171-09(97)/2024 dated- as above

Copy to following for information and necessary action:

1. APCCF, Regional office (Central) MoEFCC Govt of India, 25 Subhash Road, Dehradun.
2. Principal Secretary, Forests & Environment, Government of Uttarakhand, Dehradun.
3. Directorate of Industries, Dehradun.
4. District Magistrate, Dehradun.
5. Member Secretary, UKPCB, IT Park Dehradun.
6. D.F.O. Dehradun, Forest Division, Dehradun.
7. Guard File for uploading in Parivesh Website.


(Dr. S.P. Subudhi)
Member Secretary,
SEIAA, Uttarakhand