



सत्यमेव जयते

**Government of India
Ministry of Environment, Forest and Climate Change**



Date: **04/01/2024**

ACKNOWLEDGEMENT

This is to acknowledge that AUROBINDO PHARMA LIMITED has provided the information on PARIVESH Portal in respect of Proposed Change in Product Mix without increase in pollution loads by Qule Pharma Pvt. Ltd. (formerly Auroactive Pharma Pvt. Ltd.) in the format attached herewith under the provisions of Para 7(ii) b of EIA Notification, 2006 and its subsequent amendment S.O.980 (E), dated 02nd March 2021.

To claim exemption from obtaining Prior Environment Clearance under the provisions of Para 7(ii) b of EIA Notification, 2006 and its subsequent amendment S.O 980 (E) dated 02nd March 2021 in respect of any increase in production capacity with or without any change in (i) raw material-mix or (ii) product-mix or (iii) quantities within products or (iv) number of products including new products falling in the same category or (v) configuration of the plant or process or (vi) operations in existing area or (vii) In areas contiguous to the existing area specified in the environmental clearance of the project, the project proponent / SPCB or UTPCC shall follow the following process:

1. The project proponent shall inform the SPCB or UTPCC, as the case may be, in specified format along with: (i) 'No increase in Pollution Load' certificate from the Environmental Auditor or reputed institutions empanelled by the SPCB or UTPCC or CPCB or Ministry; (ii) last Consent to Operate certificate for the project or activity; and (iii) online system generated acknowledgement of uploading of intimation and 'no increase in pollution load' certificate on PARIVESH Portal.
2. Based on the submission of above information, the project proponent may carry on the proposed activity as per the submitted details. However, if on verification the SPCB or UTPCC, as the case may be, holds that the change or expansion or modernization will result or has resulted in increase in pollution load, the exemption claimed under this clause shall not be valid and it shall be deemed that the project proponent was liable to obtain Prior Environmental Clearance before under taking such changes or increase, as per the clause (a) of sub-paragraph (ii) of paragraph 7 of EIA Notification, 2006 and the provisions of Environment (Protection) Act, 1986 shall apply accordingly.

Encl: Attached the Information provided by the project proponent

[CAFForm 10](#)

Application for No Increase in Pollution Load - Form-10

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Basic Details

1.	Whether Project /Activity accorded prior EC?		Yes
1.1.	SIA/AP/IND2/176872/2020		
1.2.	Proposed change in product mix without increase in pollution loads in existing site area of 172 acres 48 cents located at Sy.No. 349, 350, 351, 352 & 353, A.V. Nagaram village, Kakinada SEZ area, Tondangi mandal, Kakinada district (formerly East Godavari district), Andhra Pradesh by M/s. Qule Pharma Pvt. Ltd. (formerly Auroactive Pharma Pvt. Ltd.)		
1.3.	Whether the Project Activity attracts the provisions under 7(ii) (b)		
1.3.1.	Category		B2
1.3.2.	Whether Project/Activity falls in the category of Processing or Production or Manufacturing Sectors?		Yes
1.3.3.	Whether multiple items (Components) as per the notification involved in the proposal?		No
1.3.3.1.	Item No. as per schedule to EIA Notification, 2006 for Major Activity	5(f) Synthetic organic chemicals industry	Active Pharmaceuticals Ingredients (located outside the notified industrial area)
1.3.3.2.	Capacity	12400	TPA
1.3.3.3.	Whether Project/Activity falls in 'B2' Category		Yes
1.3.3.4.	Whether the instant proposal tantamount to change in Category?		No
2.	Whether the project proposed to be located in the Notified industrial area?		No

3. Details of Consent under Air (P&CP) Act, 1981 & Water (P&CP) Act, 1974

Consent No/Application No	Date	Valid Up to	Copy of Consent order
361/APPCB/CFE/RO- KKD /HO/2021	12/01/2022	12/01/2029	Qule Pharma Pvt Ltd CFE.pdf Preview

4. Details of Authorization under Hazardous & Other Waste Management Rules, 2016 and subsequent amendment

Authorization No./ Application No	Date	Valid Up to	Copy of Authorization order
361/APPCB/CFE/RO- KKD /HO/2021	12/01/2022	12/01/2029	Qule Pharma Pvt Ltd CFE.pdf Preview

Product Details

1. Details of products & by-products including changes in product mix

List of products/by-products permitted under EC / CTO with CAS Number	Quantity permitted under EC / CTO	Unit	List of products/by- products proposed under clause 7(ii)(b) with CAS Number	Quantity proposed under clause 7(ii)(b)	Unit	Remarks if any
Ampicillin Trihydrate	0	TPA	Ampicillin Trihydrate	1200	TPA	New Product
Piperacillin Monohydrate	0	TPA	Piperacillin Monohydrate	480	TPA	New Product
Erythromycin Thiocyanate	1600	TPA	Erythromycin Thiocyanate	2080	TPA	Increase in Capacity
7-Phenylacetamido-3-Chloromethyl-Cephalosporanic acid para-methoxy benzylester (GCLE)	0	TPA	7-Phenylacetamido-3-Chloromethyl-Cephalosporanic acid para-methoxy benzylester (GCLE)	1800	TPA	New Product
Phenyl Acetic Acid (PAA)	0	TPA	Phenyl Acetic Acid (PAA)	1440	TPA	New Product
6-Amino Penicillanic Acid (6-APA)	0	TPA	6-Amino Penicillanic Acid (6-APA)	3600	TPA	New Product
Levetiracetam	3600	TPA	Levetiracetam	600	TPA	Decrease in Capacity
Ibuprofen	3600	TPA	Ibuprofen	1200	TPA	Decrease in Capacity
Cephalosporins	3600	TPA	Cephalosporins	1500	TPA	Decrease in Capacity

2. Details of Raw materials including water consumption and fuel consumption including changes in the raw material mix

List of raw materials envisaged under EC / CTO with CAS Number	Quantity permitted under EC/CTO	Unit	List of raw materials proposed under clause 7(ii)(b)	Quantity proposed under clause 7(ii)(b)	Unit	Remarks if any
Propylene	128	TPA	Propylene	384	TPA	Increase in consumption quantity
Phenyl Acetic Acid Crude	0	TPA	Phenyl Acetic Acid Crude	1704.1	TPA	New Raw Material
Penicillin G- Potassium	0	TPA	Penicillin G- Potassium	7260.8	TPA	New Raw Material
7-Aminocephalo Sporanic Acid (7-ACA)	471.1	TPA	7-Aminocephalo Sporanic Acid (7-ACA)	1130.6	TPA	Increase in consumption quantity
6-Aminp Penicillanic acid	0	TPA	6-Aminp Penicillanic	722.8	TPA	New Raw

List of raw materials envisaged under EC / CTO with CAS Number	Quantity permitted under EC/CTO	Unit	List of raw materials proposed under clause 7(ii)(b)	Quantity proposed under clause 7(ii)(b)	Unit	Remarks if any
			acid			Material
Penicillin G-Potassium	0	TPA	Penicillin G-Potassium	1706.4	TPA	New Raw Material
S-(2)-Amino butyramide HCl	91.8	TPA	S-(2)-Amino butyramide HCl	550.8	TPA	Increase in consumption quantity
1-Ethyl Piperazinedione	0	TPA	1-Ethyl Piperazinedione	896.7	TPA	New Raw Material
Starch	2703	TPA	Starch	2079.6	TPA	Decrease in consumption quantity

2.1. Approval for additional water consumption if applicable	No
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3.Details of Effluent Generation

3.1.Quantity

Propose	Quantity of existing effluent generati on in KLD (as per EC/CTO)	Quantity of effluent generation after the proposed change in product or raw material mix in KLD	Mode of Disposal Ultimate Receiving Body
Process + APCM	6204	6181.9	Sent to effluent treatment system and treated effluents are sent to marine outfall system
Boiler	300	300	Sent to effluent treatment system and treated effluents are sent to marine outfall system
Domestic	200	200	Sent to effluent treatment system and treated effluents are sent to marine outfall system
Other	10339	10339	Sent to effluent treatment system and treated effluents are sent to marine outfall system
Cooling	500	500	Sent to effluent treatment system and treated effluents are sent to marine outfall system

3.2.Quality

Composition as per the EC/CTO	Concentration as per EC/CTO in (mg/L)	Composition after proposed change in product or raw material mix	Concentration after proposed change in product or raw material mix in (mg/L)	Remarks, if any
Process Effluent TDS	41157	Process Effluent TDS	40385	Decrease in concentration of TDS

3.3.Total load in respect of Effluent

Total load in respect of Effluent as per the EC/CTO	Treatment facility existing (with capacity in KLD)	Total load in respect of Effluent after proposed change in product or raw material mix in KLD	Treatment facility proposed with capacity after proposed change in product or raw material mix in KLD	Remarks if any
26193	41157	24980.2	40385	Decrease in Process Effluent TDS load and concentration of

3.4.Details of effluent management

3.4.1. Whether Segregation of Concentrated stream and its disposal is proposed?	Yes
3.4.1.1. Brief report on Segregation of Concentrated stream and its disposal	Effluent Segregation.pdf Preview
7.4.2. Whether Reduction / Recycle / Reuse of effluent are proposed?	No
7.4.3. Whether any additional Effluent Treatment Facilities Provided?	No
7.4.4. Whether is there any proposal for up-gradation of ETP?	No
7.4.5. Whether the unit is having Membership of Common Effluent Conveyance / Disposal Facility?	No
7.4.6. Whether it is Proposed to achieve zero discharge?	No
7.4.7. Whether Project has Membership of CETP?	No

Emission Generation

1.Details of Emission Generation

1.1.

Quantity

(i) From Stacks

Point Source (s)	Height of stack (m)	As per EC / CTO			After the proposed change in product or raw material mix				
		Emission rate	Unit	Total emission	Unit	Emission rate	Unit	Total emission	Unit
150 TPH Coal Fired Boiler	70	6.8	g/s	6.8	g/s	6.8	g/s	6.8	g/s

(ii) From Fugitive sources

Fugitive Sources	Height of discharge in m	As per EC / CTO			After the proposed change in product or raw material mix				
		Emission rate	Unit	Total emission	Unit	Emission rate	Unit	Total emission	Unit
Process Scrubber	30	2500	Kg Per Day	2500	Kg Per Day	2302.2	Kg Per Day	2302.2	Kg Per Day

(iii) From other sources

Other Source(s)	Height of discharge in m	As per EC / CTO			After proposed change in product or raw material mix				
		Emission rate	Unit	Total emission	Unit	Emission rate	Unit	Total emission	Unit
4 x 4 Lakh Kcal Thermic Fluid Heaters	30	0.16		0.16	g/s	0.16	g/s	0.16	g/s

1.2.

Quality

Stack attached to	Stack Height in Meter	APCM	Parameter	Concentration			
				As per EC / CTO	Unit	After the proposed change in product or raw material mix	Unit
150 TPH Coal Fired Boiler	70	Electro Static Precipitator	Particulate Matter	50	Miligram per Normal cubic meter (mg/Nm ³)	50	Miligram per Normal cubic meter (mg/Nm ³)

2.

Total load in respect of Emission

Total load in respect of emission as per the EC / CTO	Unit	APCM existing with capacity	Unit	Total load in respect of emission after proposed change in product or raw material mix	Unit	APCM proposed with capacity after proposed change in product or raw material mix	Unit	Remarks if any
50	Miligram per Normal cubic meter (mg/Nm3)	150	Cu.M/Hr	50	Miligram per Normal cubic meter (mg/Nm3)	150	Cu.M/Hr	No Change in emission rate from combustion of coal used in 150 TPH boiler for steam generation

3.Details of emission management

3.1. Whether there is any Proposal for switching over to cleaner fuel?	No
3.2. Whether there is any Proposal for the up gradation of existing APCM? (with the time-bound program)	No
3.3. Whether there is Proposal for the installation of new APCM? (with time-bound program)	No

1.Hazardous Waste Generation

1.1.

Quantity and type of waste

Type of Waste	Category (As per Schedule under Hazardous & Other Waste Management Rules, 2016)	Generation per Year						
		Existing as per the EC / CTO	Unit	After Change in Product Mix	Unit	Source of Generation	Mode of Storage	Mode of Treatment & Disposal method
Off specification raw materials/products		24	Tons per Annum (TPA)	24	Tons per Annum (TPA)	Process	Drums	Sent to Cement Plants for Co-incineration
Mixed Spent Solvents	28.6	2.66	Kilo liters per Day (KLD)	2.66	Kilo liters per Day (KLD)	Process	Drums	Sent to authorized recovery units or Cement

Type of Waste	Category (As per Schedule under Hazardous & Other Waste Management Rules, 2016)	Generation per Year						
		Existing as per the EC / CTO	Unit	After Change in Product Mix	Unit	Source of Generation	Mode of Storage	Mode of Treatment & Disposal method
								Plants for Co-incineration
Process Liquid Organic Waste, Solvents from QC and R&D Laboratory	28	1.5	Kilo liters per Day (KLD)	1.5	Kilo liters per Day (KLD)	Process, QC and R&D Laboratory	Drums	Sent to Cement Plants for Co-incineration
Process Inorganic Waste/ Salts	28	1	Tons per Day (TPD)	0.95	Tons per Day (TPD)	Process	HDPE Bags	Sent to TSDF
Spent Carbon and Hyflow	28.2	13.16	Tons per Day (TPD)	2.75	Tons per Day (TPD)	Process	HDPE Bags Or Drums	Sent to TSDF/ Cement Plants for Co-incineration
Forced Evaporation Salts	34.3	25	Tons per Day (TPD)	24.98	Tons per Day (TPD)	From Effluent treatment	HDPE Bags	Sent to TSDF
Date Expired Products		24	Tons per Annum (TPA)	24	Tons per Annum (TPA)	Process	Bags	Sent to Cement Plants for Co-incineration
Distillation Bottom Residue and Process Organic Wastes	28.1	41.1	Tons per Day (TPD)	40.9	Tons per Day (TPD)	Process and Distillation Bottom Residue	Drums	Sent to Cement Plants for Co-incineration

1.2.

Details of Waste management

1.2.1. Whether Proposal for reduction / recovery / reuse / recycle / sale of waste (with technical details) is proposed?	No
1.2.2. Whether Project has Membership of Common Secured Landfill Site?	No
1.2.3. Whether Project has Membership of Common hazardous waste incineration facility	No

2.

No Increase in Pollution Load certificates from the authorized environmental auditor and countersigned by Project Proponent

<p>2.1. Authorized environmental auditor/Reputed Institution Empaneled by the SPCB/CPCB/MoEFCC</p>	<p>Authorized Environmental Auditors</p>
<p>2.2. Upload the Certificate of 'No Increase in Pollution' Load.</p>	<p>Qule Pharma NIPL Auditor Certificate.pdf Preview</p>

3.

Online Continuous effluent/emission Monitoring System

Quantity

							Date of connection to the servers of	
Attribute	Constituents	Date of installation	Details calibration of OCEMS	No. of time data exceeds the limit	Value Exceeded	Status of OCEMS functioning	CPCB	SPCB
Emissions	Particulate Matter	07/12/2023	No yet installed	0	0	No	No	No

1.Additional Information

S. No.	Document Name	Remark	Document
1	Auroactive EC Transfer Online Filed Form 7	Auroactive EC Transfer Online Filed Form 7 10.11.2023	Auroactive EC Transfer Online Filed Form 7 10.11.2023.pdf Preview
2	Qule Pharma Pvt Ltd CFE 12.01.2022	Qule Pharma Pvt Ltd CFE 12.01.2022	Qule Pharma Pvt Ltd CFE 12.01.2022.pdf Preview
3	Auroactive (Qule) Pharma EC 29.07.2021	Auroactive (Qule) Pharma EC 29.07.2021	Auroactive (Qule) Pharma EC 29.07.2021.pdf Preview
4	Qule Pharma CPM EMP Report	Qule Pharma CPM EMP Report	Qule Pharma CPM EMP Report.pdf Preview

1.Undertaking

I hereby give undertaking that the data and information given in the application and enclosures are true to be best of my knowledge and belief and I am aware that if any part of the data and information is found to be false or misleading at any stage, the project will be rejected and clearance given if any to the project will be revoked at our risk and cost. In addition to the above, I hereby give undertaking that no activity/construction/expansion has been taken up

<p>1.1. Name</p>	<p>JVN Reddy</p>
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1.2. Designation	Advisor EHSS
1.3. Company	AUROBINDO PHARMA LIMITED
1.4. Address	Aurobindo Pharma Ltd Galaxy, Floors: 22-24, Plot No. 1, Sy. No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Rangareddy District, Hyderabad– 500 032
1.5. Date	04-01-2024

