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File No.: IA-J-11011/445/2024-IA-II(I)
Government of India
Ministry of Environment, Forest and Climate Change
IA Division
****

Dated **09/12/2024**

To,

Dr G S S N Reddy
mole labs private limited
H. No.: 5-9-285/16/4, Plot No. 3, Ist Floor, Rajiv Gandhi Nagar, Near Prasanthi Nagar, Kukatpally, Hyderabad, Kukatpally, HYDERABAD, TELANGANA, 500072
molelabsprivatelimited@gmail.com

Subject: Grant of Standard Terms of Reference (ToR) to the proposed Project under the EIA Notification 2006-and as amended thereof-regarding.

Sir/Madam,

This is in reference to your application submitted to MoEF&CC vide proposal number IA/KA/IND3/510014/2024 dated 30/11/2024 for grant of Terms of Reference (ToR) to the project under the provision of the EIA Notification 2006-and as amended thereof.

2. The particulars of the proposal are as below :

(i) ToR Identification No.	TO24A2404KA5485943N
(ii) File No.	IA-J-11011/445/2024-IA-II(I)
(iii) Clearance Type	Fresh ToR
(iv) Category	A
(v) Project/Activity Included Schedule No.	5(f) Synthetic organic chemicals industry
(vi) Sector	Industrial Projects - 3
(vii) Name of Project	Proposed to establish Bulk Drugs & Drug Intermediates manufacturing unit by M/s. Mole Labs Private Limited with production capacity of 100.0 TPM in an area of 2.00 Acre (8080.00 Sqm)
(viii) Name of Company/Organization	mole labs private limited
(ix) Location of Project (District, State)	YADGIR, KARNATAKA
(x) Issuing Authority	MoEF&CC
(xii) Applicability of General Conditions	YES

3. The **MoEF&CC** has examined the proposal in accordance with the Environment Impact Assessment (EIA)

Notification, 2006 & further amendments thereto and after detailed examination hereby decided to grant Standard Terms of Reference to the instant proposal of **M/s.mole labs private limited** under the provisions of the aforementioned Notification.

4. The brief about products and by products as submitted by the Project proponent in Form-1 (Part A, B) and Standard Terms of Reference are annexed to this letter as Annexure (1).

5. The Ministry reserves the right to stipulate additional TORs, if found necessary.

6. The Standard Terms of Reference (ToR) to the aforementioned project is under provisions of EIA Notification, 2006 and as amended thereof. 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.

7. The granted letter, all the documents submitted as a part of application viz. Form-1 Part A and Part B are available on PARIVESH portal which can be accessed by scanning the QR Code above.

Copy To

1. The Secretary, Department of Forest, Environment & Ecology, Government of Karnataka, Room No. 708, Gate 2, Multi Storey Building, Dr. Ambedkar Veedhi, Bangalore - 1
2. The Regional Officer, Ministry of Env., Forest and Climate Change, Integrated Regional Office, Kendriya Sadan, 4th Floor, E&F Wings, 17th Main Road, Koramangala II Block, Bangalore - 34
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex East Arjun Nagar, Delhi - 32
4. The Member Secretary, Karnataka State Pollution Control Board, Parisara Bhavan, #49, 4th& 5th Floor, Church Street, Bangalore -1

Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi

Annexure 1

Standard Terms of Reference for conducting Environment Impact Assessment Study for Synthetic organic chemicals industry and information to be included in EIA/EMP report

1. Executive Summary

Sr. No.	Terms of Reference
1.1	Executive Summary

2. Introduction

Sr. No.	Terms of Reference
2.1	Details of the EIA Consultant including NABET accreditation
2.2	Information about the project proponent
2.3	Importance and benefits of the project

3. Project Description

Sr. No.	Terms of Reference
3.1	Cost of project and time of completion.
3.2	Products with capacities for the proposed project.
3.3	If expansion project, details of existing products with capacities and whether adequate land is available for expansion, reference of earlier EC if any.
3.4	Details of existing products and production, if any, along with present product/production details in tabular format, to verify the compliance of the EIA Notifications.
3.5	List of raw materials required and their source along with mode of transportation.
3.6	Other chemicals and materials required with quantities and storage capacities
3.7	Details of Emission, effluents, hazardous waste generation and their management.
3.8	Requirement of water, power, with source of supply, status of approval, water balance diagram, man-power requirement (regular and contract)
3.9	Details of boiler/gensets (including stacks/exhausts) and fuels to be used
3.10	Process description along with major equipment's and machineries, process flow sheet (quantitative) from raw materials to products to be provided
3.11	Hazard identification and details of proposed safety systems.
3.12	Expansion/modernization proposals: a. Copy of all the Environmental Clearance(s) including Amendments thereto obtained for the project from MOEF/SEIAA shall be attached as an Annexure. A certified copy of the latest Monitoring Report of the Integrated Regional Office of the Ministry of Environment, Forest and Climate Change as per circular dated 30th May, 2012 on the status of compliance of conditions stipulated in all the existing environmental clearances including Amendments shall be provided. In addition, copy of the latest CTO and status of compliance of Consent to Operate for the ongoing/existing operation of the project from SPCB shall be attached with the EIA-EMP report. b. In case the existing project has not obtained environmental clearance, reasons for not taking EC under the provisions of the EIA Notification 1994 and/or EIA Notification 2006 shall be provided. Copies of Consent to Establish/No Objection Certificate and Consent to Operate (in case of units operating prior to EIA Notification 2006, CTE and CTO of FY 2005-2006) obtained from the SPCB shall be submitted. Further, compliance report to the conditions of consents from the SPCB shall be submitted.

4. Site Details

Sr. No.	Terms of Reference
4.1	Location of the project site covering village, Taluka/Tehsil, District and State, Justification for selecting the site, whether other sites were considered.

Sr. No.	Terms of Reference
4.2	A topo-sheet of the study area of radius of 10km and site location on 1:50,000/1:25,000 scale on an A3/A2 sheet. (including all eco-sensitive areas and environmentally sensitive places)
4.3	Details w.r.t. option analysis for selection of site
4.4	Co-ordinates (lat-long) of all four corners of the site.
4.5	Google map-Earth download of the project site.
4.6	Layout maps indicating existing unit as well as proposed unit indicating storage area, plant area, greenbelt area, utilities etc. If located within an Industrial area/Estate/Complex, layout of Industrial Area indicating location of unit within the Industrial area/Estate.
4.7	Photographs of the proposed and existing (if applicable) plant site. If existing, show photographs of plantation/greenbelt, in particular.
4.8	Land-use break-up of total land of the project site (identified and acquired), government/private - agricultural, forest, wasteland, water bodies, settlements, etc shall be included. (not required for industrial area)
4.9	A list of major industries with name and type within study area (10km radius) shall be incorporated. Land use details of the study area
4.10	Geological features and Geo-hydrological status of the study area shall be included.
4.11	Details of Drainage of the project upto 5km radius of study area. If the site is within 1 km radius of any major river, peak and lean season river discharge as well as flood occurrence frequency based on peak rainfall data of the past 30 years. Details of Flood Level of the project site and maximum Flood Level of the river shall also be provided. (mega green field projects)
4.12	Status of acquisition of land. If acquisition is not complete, stage of the acquisition process and expected time of complete possession of the land. Documents related to conversion of land for Industrial purpose.
4.13	R&R details in respect of land in line with state Government policy.

5. Forest, wildlife and CRZ related issues (if applicable):

Sr. No.	Terms of Reference
5.1	Permission and approval for the use of forest land (forestry clearance), if any, and recommendations of the State Forest Department. (if applicable)
5.2	Land-use map based on High resolution satellite imagery of the proposed site delineating the forestland (in case of projects involving forest land more than 40 ha)
5.3	Status of Application submitted for obtaining the stage I forestry clearance along with latest status shall be submitted.
5.4	The projects to be located within 10 km of the National Parks, Sanctuaries, Biosphere Reserves, Migratory

Sr. No.	Terms of Reference
	Corridors of Wild Animals, the project proponent shall submit the map duly authenticated by Chief Wildlife Warden showing these features vis-à-vis the project location and the recommendations or comments of the Chief Wildlife Wardenthereon
5.5	Wildlife Conservation Plan duly authenticated by the Chief Wildlife Warden of the State Government for conservation of Schedule I fauna, if any exists in the study area
5.6	Copy of application submitted for clearance under the Wildlife (Protection) Act, 1972, to the Standing Committee of the National Board for Wildlife
5.7	Recommendations and NOC from the concerned State/UT Coastal Zone Management Authority on CRZ angle

6. Environmental Status

Sr. No.	Terms of Reference
6.1	Determination of atmospheric inversion level at the project site and site-specific micrometeorological data using temperature, relative humidity, hourly wind speed and direction and rainfall.P • AAQ data (except monsoon) at 8 locations for PM10, PM2.5, SO2, NOX, CO and other parameters relevant to the project shall be collected. The monitoring stations shall be based CPCB guidelines and take into account the pre-dominant wind direction, population zone and sensitive receptors including reserved forests. Study should indicate minimum, maximum value of different parameters for the period (3 months) collected. Collected data should be supported by the reference data of either CPCB or SPCB. AAQ data & GLC of pollutants from stack emissions should suggest technology/ measures- Best Practiced Technology (BPT) indicating best achieved results.
6.2	Raw data of all AAQ measurement for 12 weeks of all stations as per frequency given in the NAQQM Notification of Nov. 2009 along with – min., max., average and 98% values for each of the AAQ parameters from data of all AAQ stations should be provided as an annexure to the EIA Report.
6.3	Surface water quality of nearby River (100m upstream and downstream of discharge point) and other surface drains at eight locations as per CPCB/MoEF&CC guidelines.
6.4	Whether the site falls near to polluted stretch of river identified by the CPCB/MoEF&CC, if yes give details.
6.5	Ground water monitoring at minimum at 8 locations shall be included.
6.6	Noise levels monitoring at 8 locations within the study area.
6.7	Soil Characteristic as per CPCB guidelines.
6.8	Traffic study of the area, type of vehicles, frequency of vehicles for transportation of materials, additional traffic due to proposed project, parking arrangement etc.
6.9	Detailed description of flora and fauna (terrestrial and aquatic) existing in the study area shall be given with special reference to rare, endemic and endangered species. If Schedule-I fauna are found within the study area, a Wildlife Conservation Plan shall be prepared and furnished.

Sr. No.	Terms of Reference
6.10	Socio-economic status of the study area.

7. Environment Impact and Environment Management Plan

Sr. No.	Terms of Reference
7.1	Assessment of ground level concentration of pollutants from the stack emission based on site-specific meteorological features. In case the project is located on a hilly terrain, the AQIP Modelling shall be done using inputs of the specific terrain characteristics for determining the potential impacts of the project on the AAQ. Cumulative impact of all sources of emissions (including transportation) on the AAQ of the area shall be assessed. Details of the model used and the input data used for modelling shall also be provided. The air quality contours shall be plotted on a location map showing the location of project site, habitation nearby, sensitive receptors, if any.
7.2	Water Quality Modelling – in case of discharge in water body
7.3	Impact of the transport of the raw materials and end products on the surrounding environment shall be assessed and provided. In this regard, options for transport of raw materials and finished products and wastes (large quantities) by rail or rail-cum road transport or conveyor-cum-rail transport shall be examined.
7.4	A note on treatment of wastewater from different plant operations, extent recycled and reused for different purposes shall be included. Complete scheme of effluent treatment. Characteristics of untreated and treated effluent to meet the prescribed standards of discharge under E(P) Rules 1986.
7.5	Details of stack emission and action plan for control of emissions to meet standards
7.6	Measures for fugitive emission control
7.7	Details of hazardous waste generation and their storage, utilization and management. Copies of MOU regarding utilization of solid and hazardous waste in cement plant shall also be included. EMP shall include the concept of waste-minimization, recycle/reuse/recover techniques, Energy conservation, and natural resource conservation.
7.8	Proper utilization of fly ash shall be ensured as per Fly Ash Notification, 2009. A detailed plan of action shall be provided.
7.9	Action plan for the green belt development plan in 33 % area i.e. land with not less than 2,500 trees per ha. Giving details of species, width of plantation, planning schedule etc. shall be included. The green belt shall be around the project boundary and a scheme for greening of the roads used for the project shall also be incorporated.
7.10	Action plan for rainwater harvesting measures at plant site shall be submitted to harvest rainwater from the roof tops and storm water drains to recharge the ground water and also to use for the various activities at the project site to conserve fresh water and reduce the water requirement from other sources.
7.11	Total capital cost and recurring cost/annum for environmental pollution control measures shall be included.

Sr. No.	Terms of Reference
7.12	Action plan for post-project environmental monitoring shall be submitted.
7.13	Onsite and Offsite Disaster (natural and Man-made) Preparedness and Emergency Management Plan including Risk Assessment and damage control. Disaster management plan should be linked with District Disaster Management Plan.

8. Occupational health

Sr. No.	Terms of Reference
8.1	Plan and fund allocation to ensure the occupational health & safety of all contract and casual workers
8.2	Details of exposure specific health status evaluation of worker. If the workers' health is being evaluated by pre designed format, chest x rays, Audiometry, Spirometry, Vision testing (Far & Near vision, colour vision and any other ocular defect) ECG, during preplacement and periodical examinations give the details of the same. Details regarding last month analyzed data of above mentioned parameters as per age, sex, duration of exposure and department wise.
8.3	Details of existing Occupational & Safety Hazards. What are the exposure levels of hazards and whether they are within Permissible Exposure level (PEL). If these are not within PEL, what measures the company has adopted to keep them within PEL so that health of the workers can be preserved,
8.4	Annual report of health status of workers with special reference to Occupational Health and Safety.

9. Corporate Environment Policy

Sr. No.	Terms of Reference
9.1	Does the company have a well laid down Environment Policy approved by its Board of Directors? If so, it may be detailed in the EIA report.
9.2	Does the Environment Policy prescribe for standard operating process / procedures to bring into focus any infringement / deviation / violation of the environmental or forest norms / conditions? If so, it may be detailed in the EIA.
9.3	What is the hierarchical system or Administrative order of the company to deal with the environmental issues and for ensuring compliance with the environmental clearance conditions? Details of this system may be given.
9.4	Does the company have system of reporting of non-compliances / violations of environmental norms to the Board of Directors of the company and / or shareholders or stakeholders at large? This reporting mechanism shall be detailed in the EIA report
9.5	Details regarding infrastructure facilities such as sanitation, fuel, restroom etc. to be provided to the labour force during construction as well as to the casual workers including truck drivers during operation phase.

10. Corporate Environmental Responsibility (CER)

Sr. No.	Terms of Reference
10.1	Adequate funds, as per the Ministry's OM/Guidelines, shall be earmarked towards the Corporate Environmental Responsibility based on Public Hearing issues/socioeconomic issues and item-wise details along with time bound action plan shall be included (CER activities shall be related to environment). Socio-economic development activities need to be elaborated upon. For the projects where public hearing is not conducted, CER plan shall be provided based on socio-economic study of the area.

11. Additional studies/Measures to be considered

Sr. No.	Terms of Reference
11.1	Provide latest and ecofriendly technology for product manufacturing.
11.2	Emphasize on Green chemistry/Clean Manufacturing
11.3	Provide CAS No. of products along with product list.
11.4	Provide details of amount of carbon sequestered in their unit through greenbelt/other modes, in case of expansion project.
11.5	Life structure and sustainability for carbon and water foot print.
11.6	Detailed pollution Load estimation.
11.7	Transportation of Hazardous substance, effluents etc shall be carriedout through authorized and GPS enable vehicles/Trucks only.
11.8	Category of Hazardous Wastes shall be mentioned in the EIA/EMP report and in presentation.
11.9	Details of greenhouse gases and emissions shall be provided.
11.10	Greenbelt shall be developed in the first year of the project and wind breaks shall be erected.
11.11	Study area map shall be overlapped with all the associated features.
11.12	Emphasize on green fuels.
11.13	The project from NCR shall not use Coal as fuel. Further, PP shall avoid use of Coal in the CPAs and elsewhere also if alternatives are available.
11.14	Provide the Cost-Benefit analysis with respect to the environment due to the project.
11.15	Details of carbon foot prints and carbon sequestration study w.r.t. proposed project needs to spelled out. Proposed mitigation measures also needs to be analyzed and submitted for further appraisal of the EAC
11.16	Any litigation pending against the project and/or any direction/order passed by any Court of Law against the project, if so, details thereof shall also be included. Has the unit received any notice under the Section 5 of Environment (Protection) Act, 1986 or relevant Sections of Air and Water Acts? If so, details thereof and compliance/ATR to the notice(s) and present status of the case.

Sr. No.	Terms of Reference
11.17	A tabular chart with index for point wise compliance of above TORs and its details needs to be submitted in the EIA/EMP Report.

12. Specific Condition

Sr. No.	Terms of Reference
12.1	Details on solvents to be used, measures for solvent recovery and for emissions control.
12.2	Details of process emissions from the proposed unit and its arrangement to control.
12.3	Ambient air quality data should include VOC, other process-specific pollutants* like NH3*,chlorine*,HCl*,HBr*,H2S*,HF*,etc.,(*-as applicable)
12.4	Work zone monitoring arrangements for hazardous chemicals.
12.5	Detailed effluent treatment scheme including segregation of effluent streams for units adopting 'Zero' liquid discharge.
12.6	Action plan for odour control to be submitted.
12.7	A copy of the Memorandum of Understanding signed with cement manufacturers indicating clearly that they co-process organic solid/hazardous waste generated.
12.8	Authorization/Membership for the disposal of liquid effluent in CETP and solid/hazardous waste in TSDF, if any.
12.9	Action plan for utilization of MEE/dryers salts.
12.10	Material Safety Data Sheet for all the Chemicals are being used/will be used.
12.11	Authorization/Membership for the disposal of solid/hazardous waste in TSDF.
12.12	Details of incinerator if to be installed.
12.13	Risk assessment for storage and handling of hazardous chemicals/solvents. Action plan for handling & safety system to be incorporated.
12.14	Arrangements for ensuring health and safety of workers engaged in handling of toxic materials.
12.15	Details of carbon foot prints and carbon sequestration study w.r.t. proposed project needs to spelled out. Proposed mitigation measures also needs to be analysed and submitted for further appraisal of the EAC.

Additional Terms of Reference

(i) PP to submit NOC issued by KIADB regarding project site is not located in the flood plain.

Annexure 2

Details of Products & By-products

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
Apixaban	Product	0.5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Capecitabine	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Carisoprodol	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Dibenzoyl-L-Tartaric Acid	Product	20	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Hydralazine Hydrochloride	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Linagliptin	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Pirfenidone	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
Azacitidine	Product	0.5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Bempedoic Acid	Product	0.52	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Celecoxib	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Duloxetine Hydrochloride	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Fexofenadine Hydrochloride	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Pregabalin	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Brivaracetam	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Bupropion Hydrochloride	Product	2	Tons per	Road	Any 12 prod be manufact

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
			Month		any point of with product capacity of 1 TPM
Clopidogrel Bisulfate	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Dapagliflozin propandiol monohydrate	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Empagliflozin	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Enzalutamide	Product	0.5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Imatinib.Mesylate	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Itraconazole	Product	3	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Nilotinib hydrochloride	Product	0.5	Tons per Month	Road	Any 12 prod be manufact any point of with product

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
					capacity of 1 TPM
Quetiapine Fumarate	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Dexlansoprazole	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Edoxaban	Product	0.2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Mebeverine Hydrochloride	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Tolvaptan	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Cariprazine Hydrochloride	Product	0.2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Gemcitabine hydrochloride	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
Sodium Picosulfate	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Vildagliptin	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
3-Dimethylamino-1-thiophen-2-yl-propan-1-ol(DuloxetineHydrochloride intermediate)	Product	3	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
1-(4-Aminophenyl)-3-morpholino-5,6-dihydropyridin-2(1H)-one(Apixaban intermediate)	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
2-Methyl-2-Propyl-1,3-Propane diol(Carisoprodol intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
3α-Hydroxy-7-Oxo-5β-cholan-24-oic Acid (Ursodeoxy Cholic Acid intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
4-(3,4-Dichlororphenyl)-1-Tetralone(Sertraline Hydrochloride intermediate)	Product	15	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Ethyl trans-2-(4-Amino Cyclohexyl)acetate.Hydrochloride(Cariprazine Hydrochloride	Product	1	Tons per	Road	Any 12 prod be manufact

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
intermediate)			Month		any point of with product capacity of 1 TPM
L(+) Diethyl Tartarate(Dex-(Lansoprazole intermediate)	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Cyclophospanamide Monohydrate	Product	0.5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Dabigatran Etexilate Mesylate	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Losartan Potassium	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Esomeprazole Magnesium Trihydrate	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Rifaximin	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
2-Hydroxy-5-methyl pyridine(Pirfenidone intermediate)	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
					capacity of 1 TPM
Cis-N-methyl-4-(3,4-Dichlorophenyl)-1,2,3,4-tetrahydro-1-Napthalene amine. HCl or Racemic SertralineHydrochloride(Sertraline Hydrochloride intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Rabeprazole Sodium	Product	3	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Rivaroxaban	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Ursodeoxy Cholic Acid	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Sertraline Hydrochloride	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
5-Methoxy-2-(4-methoxy-3,5-dimethyl-pyridin-2-ylmethylthio)-1H-benzo[d]Imidazole (Es-Omeprazole Magnessium intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
2-Butyl-4-chloro-5-formylimidazole(Losartan Potassium intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
Dibenzo [b, f][1, 4] thiazepine 11-(10H one) dihydrochloride (Quetiapine intermediate)	Product	10	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Methyl-2-[4-(4-chlorobutanoyl) phenyl]-2-methylpropanoate (Fexofenadine Hydrochloride intermediate)	Product	10	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Sunitinib Malate	Product	0.5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Temozolomide	Product	0.5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Tenefovir Alafenamide Hemifumarate	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
3'-Chloro Propiophenone(Bupropion Hydrochloride intermediate)	Product	10	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Phosphorous trichloride	By-Product	12.4	Kg per Day	Road	By-product Apixaban
p-Toluene sulfonic acid	By-Product	84.4	Kg per Day	Road	By-product Clopidogrel
Potassium chloride	By-Product	99.3	Kg per	Road	By-product Fexofenadin

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
			Day		Hydrochlori
Succinimide	By-Product	54.4	Kg per Day	Road	By-product Losartan Pot
Tapentadol Hydrochloride	Product	1	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
11-Piperazinyl dibenzo[b,f][1,4]Thiazepine Hydrochloride(Quetiapine Fumarate intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
2-[4-(3-methoxy-propoxy)-3-methyl-pyridin-2-ylmethylsulfanyl]-1h-benzoimidazole(rabeprazole sodium intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
1-[2-(2,4-Dichloro-phenyl)-4-ethyl-[1,3]dioxolan-2-ylmethyl]-1H-[1,2,4]triazole(Itraconazole intermediate)	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Potassium bromide	By-Product	12.5	Kg per Day	Road	By-product Apixaban
Tartaric acid	By-Product	18.7	Kg per Day	Road	By-product Dexlansopra
Potassium chloride	By-Product	11.2	Kg per Day	Road	By-product Mebeverine hydrochlorid
(4-(4-(5-Aminomethyl)-2-Oxo oxazolidin-3-yl)phenyl)morpholine-3-one.(Rivaroxaban intermediate)	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
4-Bromomethyl-2-cyanobiphenyl(Losartan Potassium	Product	5	Tons	Road	Any 12 prod

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
intermediate)			per Month		be manufact any point of with product capacity of 1 TPM
Methyl 3α,7α-diacetoxy-12-oxo-5β-cholan-24-oate (Ursodeoxy Cholic Acid intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Tert-Butyl [(1r,2s,5s)-2-Amino-5[(Dimethylamino)Carbony]Cyclohexy]Carbamate(Edoxaban Intermediate)	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Aluminium hydroxide	By-Product	180.9	Kg per Day	Road	By-product Fexofenadin Hydrochlori
Ammonium chloride	By-Product	25.4	Kg per Day	Road	By-product Rabeprazole
2-(4-Cyanophenylamino) Acetic Acid (Dabigatran intermediate)	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Manganese dioxide	By-Product	66.7	Kg per Day	Road	By-product Fexofenadin Hydrochlori
Manganese oxide	By-Product	13.1	Kg per Day	Road	By-product Mebeverine hydrochlorid
Sodium nitrite	By-Product	59.5	Kg per Day	Road	By-product Rabeprazole
2-{4-[4-(4-Hydroxy-phenyl)-piperazin-1-yl]-phenyl}-4-isobutyl-2,4-dihydro-[1,2,4]triazol-3-one(Itraconazole intermediate)	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
Ethyl (5-chloropyridin-2-ylcarbamoyl)formate (Edoxaban intermediate)	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Ethyl 3-(3-amino-4-(methyl amino)-N-(pyridin-2-yl) benzamido) propanoate(Dabigatran intermediate)	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Potassium chloride	By-Product	7.8	Kg per Day	Road	By-product Apixaban
1,1,1,3,3,3-Hexamethyl –disilazane	By-Product	60.9	Kg per Day	Road	By-product Brivaracetan
Trityl alcohol	By-Product	124.4	Kg per Day	Road	By-product Losartan Pot
Sodium bromide	By-Product	19.6	Kg per Day	Road	By-product Mebeverine hydrochlorid
Ammonium chloride	By-Product	429.2	Kg per Day	Road	By-product Pregabalin
2[[[3-methyl-4-(2, 2, 2-trifluoro ethoxy)2-pyridinyl] methyl] sulfanyl]-1H-Benzimadzole(Lansoprazole intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
5-Methyl-4,5,6,7-tetrahydro-thiazolo[5,4-c]pyridine-2-carboxylicacidhydrochloride(Edoxaban intermediate).	Product	2	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Ethyl-[2-(4-methoxy-phenyl)-1-methyl-ethyl]-amine(Mebeverine Hydrochloride intermediate)	Product	3	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
					TPM
Chloro pentyl formate	By-Product	41.6	Kg per Day	Road	By-product Capecitabin
Triethylamine Hydrochloride	By-Product	74.9	Kg per Day	Road	By-product Clopidogrel
Cumin hydroxide	By-Product	17.5	Kg per Day	Road	By-product Dexlansopra
Manganese dioxide	By-Product	6.6	Kg per Day	Road	By-product Enzalutamid
Sodium bromide	By-Product	49.2	Kg per Day	Road	By-product Losartan Pot
Acetic acid	By-Product	42.4	Kg per Day	Road	By-product Rabeprazole
4-Nitro-2,3-Dimethylpyridine-1-Oxide(Rabeprazole Sodium intermediate)	Product	5	Tons per Month	Road	Any 12 prod be manufact any point of with product capacity of 1 TPM
Triethylamine Hydrochloride	By-Product	38.5	Kg per Day	Road	By-product Cyclophospl Monohydrat
Tri ethyl amine hydrochloride	By-Product	9	Kg per Day	Road	By-product Enzalutamid
Carbonic acid	By-Product	5.3	Kg per Day	Road	By-product Mebeverine hydrochlorid
Sodium acetate	By-Product	58	Kg per Day	Road	By-product Rabeprazole
Triethylamine Hydrochloride	By-Product	67	Kg per Day	Road	By-product Rivaroxaban
Potassium chloride	By-Product	24.6	Kg per Day	Road	By-product Rivaroxaban

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
Sodium bromide	By-Product	25.58	Kg per Day	Road	By-product Bempedoic
Sodium bromide	By-Product	4.93	Kg per Day	Road	By-product Enzalutamid
Potassium chloride	By-Product	12.6	Kg per Day	Road	By-product Sunitinib Ma
Magnesium hydroxide	By-Product	49.5	Kg per Day	Road	By-product Bromomethy cyanobipher (Losartan Po intermediate
Tri ethylamine hydrochloride	By-Product	279.5	Kg per Day	Road	By-product Dibenzo (b,f thiazepine-1 one (Quetipi fumarate intermediate
Phosphoric acid	By-Product	169.1	Kg per Day	Road	By-product Dibenzo (b,f thiazepine-1 one (Quetipi fumarate intermediate
Sodium bromide	By-Product	87.25	Kg per Day	Road	By-product Bromomethy cyanobipher (Losartan Po intermediate
Diisopropyl ethyl amine hydrochloride salt	By-Product	35.7	Kg per Day	Road	By-product Tolvaptan
Imidazole	By-Product	7.3	Kg per Day	Road	By-product Ursodeoxy acid
Aluminum Hydroxide	By-Product	103.1	Kg per Day	Road	By-product methyl-4-(3, Dichlorophe 1,2,3,4- tetra Napthalene hydrochloric (Sertaline

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
					hydrochloric intermediate
Manganese Dioxide	By-Product	164.1	Kg per Day	Road	By-product Methyl-2-[4 chlorobutan phenyl]-2- methylpropa (Fexofenadi Hydrochlori intermediate
Diisopropyl ethyl amine oxalate salt	By-Product	18.8	Kg per Day	Road	By-product Tolvaptan
Sodium dihydrogen phosphate	By-Product	14.5	Kg per Day	Road	By-product Ursodeoxy acid
Sodium bromide	By-Product	56.35	Kg per Day	Road	By-product Bupropion Hydrochlori
Sodium bromide	By-Product	13.96	Kg per Day	Road	By-product Empagliflo
Sodium bromide	By-Product	10.64	Kg per Day	Road	By-product Linagliptin
Sodium acetate	By-Product	60.8	Kg per Day	Road	By-product Methyl-4-(2 trifluoro-eth pyridin-2-yl methylthio]- benzo[d]Imi (Lansoprazo intermediate
Acetic acid	By-Product	44.5	Kg per Day	Road	By-product Methyl-4-(2 trifluoro-eth pyridin-2-yl methylthio]- benzo[d]Imi (Lansoprazo intermediate
Phenol	By-Product	162.4	Kg per Day	Road	By-product Dibenzo (b,f thiazepine-1

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
					one (Quetipi fumarate intermediate
Sodium bromide	By-Product	74.87	Kg per Day	Road	By-product (2,4-Dichlor phenyl)-4-et [1,3]dioxola ylmethyl]-1H triazole (Itra intermediate
Potassium Nitrite	By-Product	63.1	Kg per Day	Road	By-product (Methyl-4-(2 trifluoro-eth pyridin-2-yl methylthio]- benzo[d]Imi (Lansoprazo intermediate
Sodium bromide	By-Product	27.89	Kg per Day	Road	By-product (Pirfenidone
Aluminium hydroxide	By-Product	208.7	Kg per Day	Road	By-product (Chloropropi (Bupropion hydrochloric
Phosphoric acid	By-Product	62.8	Kg per Day	Road	By-product (piperazin-1- yldibenzo[b, [1,4]thiazepi hydrochloric (Quetiapine intermediate
Aluminium hydroxide	By-Product	443.7	Kg per Day	Road	By-product (Methyl-2-[4 chlorobutano phenyl]-2- methylpropa (Fexofenadi Hydrochlori intermediate
Potassium chloride	By-Product	140.7	Kg per Day	Road	By-product (Methyl-2-[4 chlorobutano phenyl]-2-

Name of the product /By-product	Product / By-product	Quantity	Unit	Mode of Transport / Transmission	Remarks (numb
					methylpropa (Fexofenadi Hydrochlori intermediate
Sodium bromide	By-Product	68.24	Kg per Day	Road	By-product Itraconazole
Sodium bromide	By-Product	49.92	Kg per Day	Road	By-product [4-(4-Hydro phenyl)-pipe yl]-phenyl}- isobutyl-2,4- [1,2,4]triazo (Itraconazol intermediate
Acetic acid	By-Product	134.4	Kg per Day	Road	By-product Methyl-2-[4 chlorobutan phenyl]-2- methylpropa (Fexofenadi Hydrochlori intermediate
Sodium bromide	By-Product	5.09	Kg per Day	Road	By-product Apixaban

Signature Not Verified

Digitally Signed by : Mr A N Singh
Member Secretary, MoEFCC (EC)

Date: 13/12/2024