Dr. JAYANTHI. M, I.F.S
MEMBER SECRETARY

STATE LEVEL ENVIRONMENT IMPACT
ASSESSMENT AUTHORITY – TAMIL NADU
3rd Floor, Panagal Maaligai,
No.1 Jeenis Road, Saidapet,
Chennai-15.
Phone No.044-24359973
Fax No. 044-24359975

ENVIRONMENTAL CLEARANCE (EC)

Letter No. SEIAA/TN/F. 5869/5(f)/EC - 67/2019 dated: 20.02.2019

To

The General Manager -Operations
M/s. Natco Pharma Limited,
Chemical Divison,Chennai,
No.74/7B, Vaikkadu,
TPP Salai,Manali
Chennai – 600 103

Sir,

Sub: SEIAA-TN– Environmental Clearance-Expansion project of Active Pharmaceuticals Ingredients (APIs) and its Intermediates with R & D facility by M/s. NATCO Pharma Limited at R.S.No. 73/1A, 73/2, 74/7B, 78/1B, 79/1, 79/2B, 79/3, 79/4B, 79/5, 79/6A, 79/6B, 79/7, 80/1, 80/2, 80/3, 80/4, 84/1, 84/2, 84/3A, 84/5A, 84/6, 84/7A, 85/1, 85/2B, 86/2B, 86/2C, 86/2D2, 86/3B, 86/4, 86/5, 86/6, 86/7, 86/8 & 86/9 of Manali Industrial area, Vaikkadu Village,Thiruvottiyur Taluk, Tiruvallur District, Tamil Nadu - Category - "B1" and Schedule 5(f)-Synthetic Organic Chemical Industry under the EIA Notification, 2006–Issued-Regarding.

Ref: 1. F.No.J-11011/119/2017-IA II (I) dated 30.05.2017 Terms of Reference issued by MoEF&CC

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2. Online proposal submitted for seeking EC to MoEF&CC vide IA/TN/IND2/63014/2017 dated 16.08.2017.
3. MoEF & CC transfer the file to SEIAA-TN vide F.No.J-11011/119/2017-IA II (I) dated 29.11.2017
4. Minutes of the 110th SEAC meeting held on 04.05.2018.
5. Minutes of the 115th SEAC meeting held on 28.06.2018.
6. The proponent reply dated 22.06.2018.
7. Minutes of the 117th SEAC meeting held on 28.07.2018.
8. The proponent reply dated 07.08.2018
9. Minutes of the 119th SEAC meeting held on 09.08.2018.
10. The proponent reply dated 11.01.2019.
11. Minutes of the 337th SEIAA meeting held on 07.02.2019.
12. The proponent reply dated 19.01.2019.
13. Minutes of the 338th SEIAA meeting held on 20.02.2019.

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This has reference to your application dated 16.08.2017 applied to MoEF&CC. MoEF & CC transferred the application to SEIAA-TN and subsequent communication on the above mentioned subject by M/s NATCO Pharma Limited for proposed Expansion project of Active Pharmaceuticals Ingredients (APIs) and Intermediates with R & D facility at R.S.No. 73/1A, 73/2, 74/7B, 78/1B, 79/1, 79/2B, 79/3, 79/4B, 79/5, 79/6A, 79/6B, 79/7, 80/1, 80/2, 80/3, 80/4, 84/1, 84/2, 84/3A, 84/5A, 84/6, 84/7A, 85/1, 85/2B, 86/2B, 86/2C, 86/2D2, 86/3B, 86/4, 86/5, 86/6, 86/7, 86/8 & 86/9 OF Manali Industrial area, Vaikkadu Village,Thiruvottiyur Taluk, Tiruvallur District, Tamil Nadu under Item No. 5(f)– ' Synthetic Organic chemicals Industry & Category 'B1'of the Schedule to the EIA Notification, 2006.

1. The Proponent, M/s NATCO Pharma Limited, has applied to MoEF& CC, GoI, for proposed Expansion project of Active Pharmaceuticals Ingredients (APIs) and

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Intermediates with R & D facility at R.S.No. 73/1A, 73/2, 74/7B, 78/1B, 79/1, 79/2B, 79/3, 79/4B, 79/5, 79/6A, 79/6B, 79/7, 80/1, 80/2, 80/3, 80/4, 84/1, 84/2, 84/3A, 84/5A, 84/6, 84/7A, 85/1, 85/2B, 86/2B, 86/2C, 86/2D2, 86/3B, 86/4, 86/5, 86/6, 86/7, 86/8 & 86/9 OF Manali Industrial area, Vaikkadu Village,Thiruvottiyur Taluk, Tiruvallur District, Tamil Nadu.

2. In response to the application, Terms of Reference (ToR) was issued by MoEF & CC vide F.No.J-11011/119/2017-IA II (I) dated 30.05.2017. Public hearing was exempted as per section 7(i), (iii) stage (3), Para (i)(b) of EIA Notification, 2006.
3. Based on the ToR issued by the MoEF& CC, the proponent prepared the EIA report and submitted the same to MOEF&CC on 16.08.2017. The Expert Appraisal Committee (EAC) of the MoEF & CC appraised the EIA report and decided to recommend the project for issue of EC. At this stage, moratorium imposed on the Manali industrial area was lifted and citing this reason the EAC decided to transfer the project proposal to SEIAA for appraisal.
4. MoEF & CC transferred the application to SEIAA-TN vide F.No.J-11011/119/2017-IA II (I) dated 29.11.2017
5. The proposal (EIA report) was placed in the 110th SEAC meeting held on 04.05.2018.. Accordingly, the SEAC decided to make an inspection and based on the outcome of the inspection, SEAC will take a decision regarding the grant of EC to the industry. The technical team inspected the site on 19.05.2018. The technical team, based on the site inspection and discussion with the proponent at the site has requested the proponent to furnish additional particulars/proposals. Accordingly, the proponent has submitted the additional particulars/proposals to the technical team on 22.06.2018. After the perusal of the additional particulars/proposals, the inspection report was placed in the 115th SEAC meeting held on 28.06.2018. Based on the recommendations of the technical team, the

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SEAC decided to recommend the proposal for the grant of Environmental Clearance to SEIAA – TN subject to certain conditions.

6. The subject was placed before 337th SEIAA Meeting held on 07.02.2019.The Authority called for certain additional details and the proponent has submitted the additional particulars/proposals to the SEIAA on 19.02.2019 and SEIAA after careful consideration decided to issue Environmental Clearance in its 338th meeting held on 20.02.2019 subject to terms and conditions stipulated under the provisions of Environment Impact Assessment Notification, 2006 as amended based on the Information submitted by you which are extracted below:

1	(i) Name of the Project:	i. Proposed Expansion project of Active Pharmaceuticals Ingredients (APIs) and Intermediates with R & D facility at R.S.No. 73/1A, 73/2, 74/7B, 78/1B, 79/1, 79/2B, 79/3, 79/4B, 79/5, 79/6A, 79/6B, 79/7, 80/1, 80/2, 80/3, 80/4, 84/1, 84/2, 84/3A, 84/5A, 84/6, 84/7A, 85/1, 85/2B, 86/2B, 86/2C, 86/2D2, 86/3B, 86/4, 86/5, 86/6, 86/7, 86/8 & 86/9 OF Manali Industrial area, Vaikkadu Village,Thiruvottiyur Taluk, Tiruvallur District, Tamil Nadu by M/s. NATCO Pharma Limited
	(ii) Date of Application:	ii. MoEF & CC transfer the file to SEIAA-TN vide F.No.J-11011/119/2017-IA II (I) dated 29.11.2017
2	Name of Sector:Schedule No(in the EIA Notification,2006)	Schedule S.No. 5(f) of Category "B1" – ' Synthetic Organic chemicals Industry (dyes & dyes intermediate; bulk drugs and intermediates excluding drug formulation; Synthetic rubbers; basic Organic Chemicals, other synthetic organic chemicals and chemical intermediates (located in a notified industrial

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<table>
<tr><td></td><td></td><td>area/estate).</td></tr>
<tr><td>3.</td><td>New Project/ Expansion</td><td>Expansion</td></tr>
<tr><td>4</td><td>Name of the Applicant/Project Proponent</td><td>M/s. NATCO Pharma Limited, Chemical Division- Chennai</td></tr>
<tr><td rowspan="3">5</td><td>(i) Project</td><td>No.74/7B, Vaikkadu, TPP Salai, Manali, Chennai, Tamil Nadu</td></tr>
<tr><td>(ii) Co-ordinates (lat-long) of all four corners of the site</td><td>
<table>
<tr><td>S.No</td><td>Latitude</td><td>Longtitude</td></tr>
<tr><td>1.</td><td>13°11'26.65"N</td><td>80°16'3.21"E</td></tr>
<tr><td>2.</td><td>13°11'11.57"N</td><td>80°16'1.28"E</td></tr>
<tr><td>3.</td><td>13°11'12.53"N</td><td>80°15'54.45"E</td></tr>
<tr><td></td><td>13°11'32.61"N</td><td>80°15'58.14"E</td></tr>
</table>
</td></tr>
<tr><td>(iii) Whether any GO attracted</td><td>No.</td></tr>
<tr><td>6</td><td>(i)Area of the Site(in Hectares)</td><td>10.57 Ha (No Additional land is required for the proposed expansion)</td></tr>
<tr><td></td><td>(ii)Land use are(in Ha)</td><td>
<table>
<tr><td>S. No</td><td>Description</td><td>Existing Land (Sq.m)</td><td>Proposed Land use for Expansion (Sq.m)</td><td>Total Land after Expansion (Sq.m)</td></tr>
<tr><td>1</td><td>Ground Coverage Area</td><td>16361.21</td><td>10788.48</td><td>27149.69</td></tr>
<tr><td>2</td><td>Green Belt Area</td><td>35129</td><td>-</td><td>35129</td></tr>
<tr><td>3</td><td>Lawn Area</td><td>3911</td><td>-</td><td>3911</td></tr>
<tr><td>4</td><td>OSR Land</td><td>10285</td><td>-</td><td>10285</td></tr>
<tr><td>3</td><td>Road Area</td><td>19870</td><td>-</td><td>19870</td></tr>
<tr><td>4</td><td>Vacant Area for Future Expansion</td><td>20147.8</td><td>Reduced by10.20%</td><td>9359.32</td></tr>
</table>
</td></tr>
</table>

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		Total	105704		105704
8	Land use Classification as per Record	Special and Hazardous Use zone as per Chennai Metropolitan Development Authority			
9	TOR issued? (If yes then specify the details)	Yes. Terms of Reference (ToR) was issued vide File. No. J-11011/119/2017-IA-II (I) dated: 30.05.2017 by MoEF& CC. Public hearing was exempted as per section 7(i), (iii) stage (3), Para (i)(b) of EIA Notification, 2006. The Expert Appraisal Committee (EAC) of the MoEF & CC appraised the EIA report and decided to recommend the project for issue of EC. At this stage, moratorium imposed on the Manali industrial area was lifted and citing this reason the EAC decided to transfer the project proposal to SEIAA for appraisal.			
10	Project Cost (after expansion)	Rs. 186.82 Crores			
11	Distance from Protected areas /Critically Polluted areas/Eco-Sensitive areas/Inter-State Boundaries.	Moratorium imposed on the Manali industrial area was lifted vide O.M.No.J-11013/5/2010-IA.II(I) dated 17.09.2013 and citing this reason the EAC decided to transfer the project proposal to SEIAA for appraisal.			
12.	Production Details	Annexure -I			
13	Manufacturing Process	➢ Most pharmaceutical substances are manufactured utilizing batch process. ➢ The manufacture of pharmaceuticals products can be divided into three main stages: Research and development			

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<table>
<tr><td></td><td></td><td>Conversion of organic and natural substances into bulk pharmaceutical substances or ingredients through fermentation, extraction and/or chemical synthesis and
Formulation of the final pharmaceutical.
➢ Bulk pharmaceuticals substances typically consist of structurally complex organic chemical under precise condition.
➢ These substances are used in the manufacture of the dosage form of a formulated pharmaceutical product and are manufactured by :
Chemical synthesis
Isolation/recovery from natural sources and/or
Combination of above.</td></tr>
<tr><td>14</td><td>Man-power Requirement(after expansion)</td><td>350 Nos direct and 100 Nos indirect</td></tr>
<tr><td>15</td><td>Total Water Requirement - 576 KLD</td><td>
<table>
<tr><th>S. No</th><th>Activity</th><th>Quantity (KLD)</th></tr>
<tr><td>1.</td><td>Process</td><td>30</td></tr>
<tr><td>2.</td><td>Washings</td><td>50</td></tr>
<tr><td>3.</td><td>Cooling Towers</td><td>67</td></tr>
<tr><td>4.</td><td>Boiler</td><td>39</td></tr>
<tr><td>5.</td><td>Domestic</td><td>25</td></tr>
<tr><td>6.</td><td>DM regeneration</td><td>10</td></tr>
<tr><td>7.</td><td>Scrubber</td><td>12</td></tr>
<tr><td>8.</td><td>QC and R&D</td><td>10</td></tr>
<tr><td>9.</td><td>Utility Rejects</td><td>25</td></tr>
</table>
</td></tr>
</table>

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<table>
<tr><td></td><td></td><td>
<table>
<tr><td>10.</td><td>Fire hydrant make up</td><td>5</td></tr>
<tr><td>11.</td><td>Gardening</td><td>30</td></tr>
<tr><td colspan="2">Fresh water Requirement</td><td>303</td></tr>
<tr><td colspan="2">Reused treated effluent</td><td>182</td></tr>
<tr><td colspan="2">Steam condensate from Boiler</td><td>91</td></tr>
<tr><td colspan="2"></td><td>273</td></tr>
<tr><td colspan="2">Total water requirement</td><td>576</td></tr>
</table>
Source of water – CMWSSB
</td></tr>
<tr><td>16</td><td>Sewage generation and treatment</td><td>Sewage Generation –21 KLD which is treated in the STP of 30 KLD capacity and the treated water is used for greenbelt.

STP design of 30 KLD capacity

1. Bar screen chamber - 1 Unit – 0.6m x 1.3m
2. Aeration Tank - 1 Unit – 1.7m x 1.2m x 3.0m
3. Sewage collection sump – 1 unit – 2.4m x 2.4m x 2.4m
4. Secondary settling tank - 1 unit – 1.8m x 1.2m x 2.9m
5. Clarified water Tank – 1 Unit – 0.5m X 1.2m x2.8m
6. Pressure sand filter - 1 Unit – 0.35m(Dia) x 1.65m (H)
7. Activated carbon filter – 1 Unit – 0.33m(Dia) x 1.37m(H)
8. UV system – 1 Unit – 75mm (Dia) x 900 mm(long)
9. Treated water tank – 1unit – 1.5m x 1.5m x 3.0m
10. Sludge drying beds - 2 units – 1.0m x 1.0m x 1.0m</td></tr>
<tr><td>17</td><td>ETP Details</td><td>• ETP Capacity 250 KLD.
• Total Effluent generation – 174 KLD. From that water loss in sludge, salts, stripper and evaporation losses will be 12 KLD</td></tr>
</table>

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		and 162 KLD will be recovered from and reused for cooling towers. ETP - existing 1. Oil and grease trap - 1 Unit – 1.8m x 1.8m x 2.5m 2. Equilization tank -1 - 1 Unit – 10m x 3m x 10m 3. Flocculent dosing tank - 1 Unit – 0.9m(H) x 1.2m Dia. 4. Coagulant Dosing Tank – 1 Unit - 0.9m(H) x 1.2m Dia. 5. Flash mixer - 1 Unit -1.2m dia x 1.8m(H). 6. Clariflocculator – 1 Unit – 4.5m(Dia) x 3.35m(H) 7. Utility Effluent Collection tank – 50 KL 8. Aeration tank – 1 Unit – 20m x 12m x 5m 9. Clarifier – 1 – 4.5m(dia) x 3.35m(H) 10. Aeration tank – 2 – 1 Unit – 12m x 12m x 3.70m 11. Secondary clarifier – 1 Unit – 4.5m(dia) x 3.35m(H) 12. Decanter feed tank – 1Unit – 1.8m(dia) x 2m(H) 13. Decanter centrifuge – 1 unit 14. Primary RO feed tank – 1 unit 15. Primary RO plant (existing) – 125 KLD upgraded to 250KLD 16. Secondary RO feed tank – 1 unit 17. Secondary RO plant (existing) – 100 KLD upgraded to 250 KLD 18. Permeate storage tank – 1 unit 19. HPRO feed tank – 1 unit 20. MEE feed tank– 1 unit

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<table>
<tr><td></td><td></td><td>21. MEE -3 KL/Hr
22. ATFD feed tank – 1 unit
23. ATFD - 600 Kg/hr

ETP - Proposed
1. High TDS collection tank – 2 units – 25 KL
2. Lamella Clarifier - 1 Unit – 1.5 KL/hr(36 KLD)
3. High TDS stripper feed tank - 1 Unit – 10 KL
4. Stripper – 1 Unit – 30 KLD
5. Stripper solvents collection tank - 1 Unit – 2 KL
6. Static Mixer – 1 unit – 120 KLD
7. Feed tank – 1unit – 20 KL
8. ECOT system – 1 unit – 120 KLD
9. Paddle dryer – 1 unit – 200 kg/hr
10. HPRO plant – 50 KLD
11. Flash mixer – 1 unit – 3KL
12. Lamella clarifier – 1 unit – 70 KLD</td></tr>
<tr><td>18</td><td>Solid waste Management</td><td>
<table>
<tr><th rowspan="2">Sl. No.</th><th rowspan="2">Description</th><th colspan="2">*Proposed Quantity</th><th rowspan="2">Disposal</th></tr>
<tr><th>TPD</th><th>TPA</th></tr>
<tr><td>1.</td><td>Process Organic residue</td><td>1.31</td><td>471.6</td><td rowspan="3">Sent to Authorized Cement Industries (or) TNWML for incineration (or) disposed in in-house incineration in the plant premises</td></tr>
<tr><td>2.</td><td>Distillation residue</td><td>0.22</td><td>79.2</td></tr>
<tr><td>3.</td><td>Spent carbon</td><td>0.1</td><td>36</td></tr>
<tr><td>4.</td><td>(a) Inorganic salt (Process)</td><td>1.08</td><td>388.8</td><td>Sent to Tamil Nadu Waste Management</td></tr>
</table>
</td></tr>
</table>

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			(b)Evaporation salt (Process)	2.35	846	Limited (TNWML)
		5.	Evaporation salt (Non-Process)	1	360	
		6.	ETP Sludge	0.45	180	
		7.	Incinerator ash	0.1	36	
		8.	STP sludge	0.117	42.12	Used as manure for Greenbelt development.
		9.	Spent Catalyst	0.06	21.6	Sold to Authorized Recyclers (or) Sent to TNWML
		10.	Detoxified Container / Liners drums, HDPE Carboys, Fiber Drums, PP Bags	--	100 Nos./ month	After Detoxification sent to outside agencies or recyclers
		11.	Spent solvents with moisture (22 KLD)	22 KLD	7920 KL/A	Recovered within the premises duly sending the residue to TNWML
		12.	Recovered solvents from spent solvents	20 KLD	7200 KL/A	Reuse in process (or) sold to authorized recyclers
		13.	Spent Mixed solvents	2.4 KLD	864 KL/A	Sent to Cement industries for Co-Processing (or) Sent to TNWML for incineration (or) On-site Incineration (Existing)
		14.	Waste oils & Grease	--	4 KL/A	Senttoauthorized re-processors (or)TNWML

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		15.	Used Lead acid Batteries	--	24 Nos/A	Sent to suppliers on buy-back basis.
		16.	Dateexpiredproducts/ chemicals	0.0009	0.33	SenttoTNWML (or) Cement Industriesfor processing (or) On-site Incineration (existing Incinerator)
		17.	Offspecification products/ chemicals	0.0009	0.33	
		18.	Spillcontrol Wastes/ Residues containingOil	0.001	0.36	SenttoTNWML

19 Stack emission Details: (All the stacks attached to process units, Boilers, D.G. Sets, (kg/hr)

S. No	Process Emission	Treatment	Type of Scrubber
1	HCl	Scrubbed by caustic Soda(CS)lye solution	Proposed additional 4 nos of wet scrubbers will be installed to the existing 8 nos of wet scrubber with Stack **Height2 Meter aboveroofLevel) x dia 10"**
2	SO_2	Scrubbed by using CS lye solution	
3	CO_2	Scrubbed by using CS lye solution	
4	Methyl Bromide	Scrubbed by using CS lye solution or Sodium thiosulfate	
5	Cl_2	Scrubbed by using CS lye solution	
6	Chloroethane	Scrubbed by using Dilute sulphuric acid	
7	Dimethylamine	Scrubbed by using chilled water	
8	NH_3	Scrubbed by using chilled water	

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		S.No	Source	Stack Height (m)	Diameter (m)
		1	Boiler- 6TPH (proposed)	40	0.6
		2	Boiler- 3TPH (Existing-Standby)		
		3	Incinerator -100kg/hr	40	0.6
		4	DG- 1010KVA	11	0.2
		5	DG- 1010KVA	11	0.2
		6	DG- 1010KVA	11	0.2
		7	DG- 100KVA	7	0.1
20	Details of Fuel to be used:	S. No	Name of Fuel	Point of use	Fuel Consumption Quantity: Expansion / Natural Gas (Optional)
		1	High Speed Diesel	Diesel Generator	630 LPH / 375 m^3/hr
		2	Furnace Oil	Boiler	400 LPH / 460 m^3/hr
21	Steam Generation	6 TPH			
22	Storm Water Management	The storm water in the project area will be collected through existing storm water ponds.			
23	Rain Water Harvesting	Rainwater harvesting storage capacity is 80 cu.m.			
24	Green Belt Development	35129 Sq.m (3.51 Ha)			
25	CER details	Rs. 100 lakhs			

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26	EMP Cost(O&M)	Capital Investment: 500 Lakhs O & M (Recurring): 1200 Lakhs

The proponent has furnished the sword of affidavit in Rs. 100 stamp paper:

1. we commit we are replacing the MDC & Chloroform with the alternate solvents for the existing and the proposed products and thus will not use MDC & Chloroform in the existing and proposed products further and other following undertaking.
2. In case if the yield, Quality and Stability of the final Product is not as per the limits and regulatory specifications, we shall approach MOEF (Ministry of Environment & Forest) for the relaxation of Specific Condition v. as accorded in the Environmental Clearance F.No. J-11011/456/2006/IA-II (I) dated 15th June 2007 which will be done prior to obtaining CTO Expansion from TNPCB.
3. We hereby commit that total fresh water requirement is 303 KLD will be meet through CMWSSB.
4. We hereby undertake that treated sewage water of (20 KLD) will be reused for Gardening (Greenbelt) and shall not pollute the soil/ground water/adjacent canals /lakes/ponds/etc due to usage of treated sewage for above purpose.
5. We hereby undertake that treated trade effluent of 162 KLD will be reused in cooling tower as makeup and 91 KLD of steam condensate will be recovered & reused in boiler and total trade effluent of 174KLD will be treated through Effluent Treatment Plant followed by RO system, Multi effect Evaporator, Agitated Thin Film Drier.
6. We also hereby undertake that all the Hazardous waste generated during operation of our plant will be transported to TNWML for incineration and Landfill purpose as the case
7. As committed we shall maintain total green belt area with plantation of local native species.

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8. We shall commit to spend the detailed CER proposal for Rs.100 Lakhs (1% of the project Cost Rs.100 crores) towards nearby government schools & Health centers as follow as:

   a.) Government High school-Manali New town,

   b.) Government middle school -andarkuppam,

   C.) Government Primary School – Kanniyamman pettai.

   D.) Government Primary health center-Manali New town.

   e.) Urban primary health center-Manali in Chennai, Tamil Nadu before issue of CTO as recommended by SEAC.

I am aware that I can be prosecuted under relevant Acts & Rules, if I am not ensuring the adherence of the above commitment.

The Authority after consideration all the requisite documents with status and data and based on SEAC appraisal and recommendations for issue of Environmental Clearance in its 119th meeting held on 09.08.2018, the recommendation of SEAC along with the proposal was placed in the 338th SEIAA meeting held on 20.02.2019 hereby conveyed Environmental Clearance along with the conditions.

Specific Conditions

General Conditions

Validity:

The SEIAA hereby accords Environmental Clearance to the above project under the provisions of EIA Notification dated 14th September, 2006 as amended, with validity for Seven years from the date of issue of EC, subject to the compliance of the terms and conditions stipulated below:

(A) Statutory compliance

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i. The project proponent shall obtain forest clearance under the provisions of Forest (Conservation) Act, 1986, in case of the diversion of forest land for non-forest purpose involved in the project.

ii. The project proponent shall obtain clearance from the National Board for Wildlife, if applicable.

iii. The project proponent shall prepare a Site-Specific Conservation Plan & Wildlife Management Plan and approved by the Chief Wildlife Warden. The recommendations of the approved Site-Specific Conservation Plan / Wildlife Management Plan shall be implemented in consultation with the State Forest Department. The implementation report shall be furnished along with the six-monthly compliance report. (incase of the presence of schedule-I species in the study area)

iv. The project proponent shall obtain Consent to Establish / Operate under the provisions of Air (Prevention & Control of Pollution) Act, 1981 and the Water (Prevention & Control of Pollution) Act, 1974 from the concerned State pollution Control Board/ Committee.

v. The project proponent shall obtain authorization under the Hazardous and other Waste Management Rules, 2016 as amended from time to time.

vi. The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989

(B) Air quality monitoring and preservation:

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i. The project proponent shall install 24x7 continuous emission monitoring system at process stacks to monitor stack emission with respect to standards prescribed in Environment (Protection) Rules 1986 and connected to SPCB and CPCB online servers and calibrate these system from time to time according to equipment supplier specification through labs recognised under Environment (Protection) Act, 1986 or NABL accredited laboratories.

ii. The project proponent shall monitor fugitive emissions in the plant premises at least once in every quarter through labs recognised under Environment (Protection) Act, 1986.

iii. The project proponent shall install system to carryout Ambient Air Quality monitoring for common/criterion parameters relevant to the main pollutants released (e.g. PM10and PM25 in reference to PM emission, and SO2and NOx in reference to SO2 and NOx emissions) within and outside the plant area at least at four locations (one within and three outside the plant area at an angle of 120 each), covering upwind and downwind directions.

iv. To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. Sulphur content should not exceed 0.5% in the coal for use in coal fired boilers to control particulate emissions within permissible limits (as applicable). The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.

v. Storage of raw materials, coal etc shall be either stored in silos or in covered areas to prevent dust pollution and other fugitive emissions.

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vi. National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended from time to time shall be followed.

vii. The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16thNovember, 2009 shall be complied with

(C) Water quality monitoring and preservation:

i. The project proponent shall provide online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises (applicable in case of the projects achieving ZLD)

ii. As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises (applicable in case of the projects achieving the ZLD).

iii. The effluent discharge shall conform to the standards prescribed under the Environment (Protection) Rules, 1986, or as specified by the State Pollution Control Board while granting Consent under the Air/Water Act, whichever is more stringent.

iv. Total fresh water requirement shall not exceed the proposed quantity or as specified by the Committee. Prior permission shall be obtained from the concerned regulatory authority/CGWA in this regard.

v. Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system.

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vi. The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial operations within the plant.

vii. The DG sets shall be equipped with suitable pollution control devices and the adequate stack height so that the emissions are in conformity with the extant regulations and the guidelines in this regard.

(D) Noise monitoring and prevention:

i. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.

ii. The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation.

iii. The ambient noise levels should conform to the standards prescribed under E(P)A Rules, 1986 viz. 75 dB(A) during day time and 70 dB(A) during night time

(E) **Safety, Public hearing and Human health issues**:

i. Emergency preparedness plan based on the Hazard identification and Risk Assessment (HIRA) and Disaster Management Plan shall be implemented.

ii. The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire fighting system shall be as per the norms.

iii. The PP shall provide Personal Protection Equipment (PPE) as per the norms of Factory Act.

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iv. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.

v. Provision shall be made for the housing of construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile STP, safe drinking water, medical health care, creche etc. The housing may be in the form of temporary structures to be removed after the completion of the project.

vi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

vii. There shall be adequate space inside the plant premises earmarked for parking of vehicles for raw materials and finished products, and no parking to be allowed outside on public places

(F) Corporate Environment Responsibility:

i. The project proponent shall comply with the provisions contained in this Ministry's OM vide F.No. 22-65/2017-IA.III dated 1stMay 2018, as applicable, regarding Corporate Environment Responsibility.

ii. The company shall have a well laid down environmental policy duly approve by the Board of Directors. The environmental policy should prescribe for standard operating procedures to have proper checks and balances and to bring into focus any infringements/deviation/violation of the environmental / forest /wildlife norms/ conditions. The company shall have defined system of reporting infringements / deviation / violation of the environmental / forest / wildlife

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norms / conditions and / or shareholders / stake holders. The copy of the board resolution in this regard shall be submitted to the MoEF&CC as a part of six-monthly report.

iii. A separate Environmental Cell both at the project and company head quarter level, with qualified personnel shall be set up under the control of senior Executive, who will directly to the head of the organization.

iv. Action plan for implementing EMP and environmental conditions along with responsibility matrix of the company shall be prepared and shall be duly approved by competent authority. The year wise funds earmarked for environmental protection measures shall be kept in separate account and not to be diverted for any other 5 purpose. Year wise progress of implementation of action plan shall be reported to the Ministry/Regional Office along with the Six Monthly Compliance Report.

v. Self environmental audit shall be conducted annually. Every three years third party environmental audit shall be carried out.

(G) Waste management:

i. Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm and the solvent transfer through pumps.

ii. Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.

iii. The company shall undertake waste minimization measures as below:-

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a. Metering and control of quantities of active ingredients to minimize waste.

b. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.

c. Use of automated filling to minimize spillage.

d. Use of Close Feed system into batch reactors.

e. Venting equipment through vapour recovery system.

f. Use of high pressure hoses for equipment clearing to reduce wastewater generation

(H) SPECIFIC CONDITIONS:

(i) It is mandatory for the project proponent to furnish to the SEIAA, Half yearly compliance report in hard and soft copies on 1st June and 1st December of each calendar year in respect of the conditions stipulated in the prior Environmental clearance issued.

(ii) "Consent for Establishment" shall be obtained from Tamil Nadu Pollution Control Board and a copy of the same shall be furnished to the SEIAA, Tamil Nadu before start of project construction activity at the site.

(iii) "Consent to Operate" should be obtained from the Tamil Nadu pollution Control Board before the start of the operation of the project and copy shall be submitted to the SEIAA-TN.

(iv) The implementation of Environmental Management Plan in regard to treatment and disposal of sewage & Effluent, Solid waste Management, Hazardous - Waste Management, and CSR Activities should be carried out, as proposed and committed. Regular monitoring should be carried out during operation phases.

(v) The residue collected from the evaporator shall be documented by maintaining proper register and it should be made available at the time of inspection.

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(vi) Adequate dust extraction system such as Ducting with dust extracting arrangement wherever required shall be established to achieve Occupational –health standards and ambient air quality standards.

(vii) The proponent shall carryout best housekeeping practices as spillage management for handling and maintenance of raw materials and products inside the unit premises.

(viii) Nature of chemicals Handled, the Do and Don'ts shall be displayed at all vital locations as laid down in MSDS.

(ix) The proponent shall ensure that the quantity of Hazardous Waste handed over to the TSDF shall match with the quantity generated.

(x) The proponent shall provide a separate closed area earmarked for storing solid waste including Hazardous Waste as proposed.

(xi) The proponent shall dispose Hazardous Waste generated as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016. Spent oil from D.G sets should be stored in HDPE drums in an isolated covered facility and disposed off through TNPCB registered recyclers.

(xii) The Plastic wastes shall be segregated and disposed as per the provisions of Plastic Waste (Management & Handling) Rules 2016.

(xiii) The e - waste generated should be collected and disposed to a nearby authorized e-waste centre as per e waste (Management & Handling), Rules 2016 as amended.

(xiv) The Municipal solid waste generated shall be collected, segregated and disposed as per Solid Waste Management Rules, 2016.

(xv) The industry shall conduct air sampling at least once in six months for the general core parameters (PM_{10}, $PM_{2.5}$,SO_x, NO_X) through TNPCB/NABL Accredited Laboratory and maintain records of the same and it should be made available at the time of inspection.

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(xvi) Regular monitoring on the air quality, water quality and noise on the selected locations in and around the project site as mentioned in the EMP report for creating base line data shall be continued and records shall be maintained.

(xvii) A separate environment and safety management cell with qualified staff shall be set up before establishment of the facility and shall be retained throughout the lifetime of the industry, for implementation of the stipulated environmental safeguards.

(xviii) The Green belt area already developed within the project area shall be properly maintained.

(xix) The green belt of 5-10 m width shall be developed in more than 33% of the total project area, mainly along the plant periphery, in downward wind direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.

(xx) The industry shall promote tree plantation to neutralize their carbon foot print. The industry shall engage regularly in afforestation programme.

(xxi) The proponent shall ensure effective risk management strategy regarding confined space management to avoid risk while handling raw materials, products in the process area and storage.

(xxii) The energy sources for lighting purposes shall preferably be LED based.

(xxiii) The industry shall conduct air sampling at least twice in a week (104 times in a year), as stipulated under EP Act 1986.

(xxiv) Risk cum disaster management plan should be in placed in the industry premises at all time.

(xxv) Water conservation scheme including rain water harvesting measures to augment ground water resources shall be implemented so as to collect and reuse the entire rainwater harvested as a supplement to fresh water.

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(xxvi) The natural drainage pattern in the project area shall be maintained and storm water drain along the boundary and appropriate places shall be provided considering the Catchment area and maximum intensity of rainfall to collect runoff water/rain water for proper disposal to avoid flooding around the premises.

(xxvii) The Environmental Clearance is issued without prejudice to any order that may be passed by the Hon'ble NGT/ Honb'le High Court of Madras.

(xxviii) All the assurances given in EIA and EMP shall be adhered strictly.

(xxix) Detail study shall be carried out by engaging accredited agencies / reputed institutions for Risk management and detailed Disaster management plan prepared for compliance.

(xxx) Sufficient funds should be provided for Disaster management.

(xxxi) The Project Proponent shall provide disinfection by UV system for the sewage treatment plant for treating the sewage before applying on land for gardening.

(xxxii) The project proponent shall provide sufficient ventilation (air circulation) in the hazardous waste storage yard where the hazardous waste like spent carbon, Chemical sludge, used or spent oil are being kept.

(xxxiii) The Project Proponent shall carry out safety audit in the different operating zones of the plant at least once in a year and the same shall be considered as base for reviewing the unsafe conditions during the plant safety meeting.

(xxxiv) The Project Proponent shall prepare a code of practice for safe operation for educating the safety standards to the work force deployed in the plant through appropriate training by the concerned experts.

(xxxv) As the plant operation involves the sensitive processing, the medical officer and the supporting staff involved in the health centre activities shall be trained in occupational health surveillance (OHS) aspects through the outsourced training from the experts available in the field of OHS for ensuring the health standard of persons employed.

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(xxxvi) The Activity of the industry should not impact on agricultural, irrigation system and mangroves surrounding the area.

(xxxvii) The EMP cost of Rs.500 lakhs and operation and maintenance cost Rs. 1200 lakhs shall be deposited in a nationalized bank by opening separate account and the head wise expenses statement shall be submitted to TNPCB with a copy to SEIAA annually.

(xxxviii) There should be no threat to Bio diversity due to the operation of the industry.

(xxxix) The flora & fauna present in and around the project site should be get affected due to the activity as reported.

(xl) The Project Proponent has to provide rain water harvesting collection tank to the capacity of 80 cu.m in order to recover and reuse the rain water during normal rains.

(xli) The operation of the activity should not impact on the soil, micro flora & Fauna present in and around the project site.

(xlii) The project proponent shall carry out risk assessment process for all the operations involved in the plant and a suitable risk management plan showing the contours of sensitive zones should be prepared.

(xliii) The project proponent shall take up better housekeeping measures including scraps disposal and up keeping the machineries, pipes, etc.

(xliv) The proponent should continuously monitor the VOC and ensure that VOC levels are within permissible limits.

(I) GENERAL CONDITIONS:-

i. This Environmental Clearance shall not be cited to relax any other rules applicable to this project.

ii. The Project Proponent should advertise at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality concerned, within 7 days of the issue of the Environmental Clearance informing that the project has

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been accorded environmental clearance and a copy of the clearance letter is available with TNPCB.

iii. A copy of the Environmental Clearance shall be sent by the project proponent to concerned local body and local NGO, if any from whom suggestions/representatives, if any were received while processing the proposal.

iv. The project proponent shall monitor the criteria pollutants level namely; PMio, SO2, NOx (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the projects and display the same at a convenient location for disclosure to the public and put on the website of the company.

v. The Environmental Clearance shall also be put on the website of the company.

vi. No expansion or modernization in the project shall be carried out without prior approval of the SEIAA-TN. In case of any deviations or alterations in the project proposal from those submitted to this Authority for clearance, a fresh reference shall be made to the SEIAA-TN to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

vii. All the environmental protection measures and safeguards as recommended in the EIA report shall be complied with.

viii. The project proponent shall submit the environmental statement for each financial year in Form-V to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently and put on the website of the company.

ix. The implementation of the project vis-à-vis environmental action plans shall be monitored by the Regional office of MoEF& CC at Chennai, TNPCB and CPCB. A six monthly compliance status report shall be submitted to monitoring agencies regularly.

x. Data on ambient air, stack and fugitive emissions shall be regularly submitted online to the Regional office of MoEF&CC,GOI, at Chennai, TNPCB and Central Pollution

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Control Board as well as hard copy once in six months and display data on RSPM, SO_2 and NOx outside the premises at the appropriate place for the general public.

xi. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

xii. Proper house-keeping and cleanliness must be maintained within and outside the plant.

xiii. Occupational health surveillance programme shall be undertaken as regular exercise for all the employees, especially for those engaged in handling hazardous substances. The first aid facilities in the occupational health centre shall be strengthened and the medical records of each employee should be maintained separately.

xiv. The overall noise levels in and around the plant area shall be kept well within the standards prescribed for by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels should conform to the standards prescribed under EPA Rules, 1989 viz. 75dBA (day time) and 70 dBA (night time).

xv. A separate Environmental Management Cell equipped with full fledged laboratory facilities to carry out the various Environmental Management and Monitoring functions shall be set up under the control of a Senior Executive.

xvi. The requisite amount earmarked towards capital cost and recurring cost/annum for implementing pollution control measures shall be used judiciously to implement the Environment Management Plan as furnished in the EIA report. The funds so provided shall not be diverted for any other purposes.

xvii. The project proponent shall upload the status of compliance of the stipulated environmental clearance conditions, including results of monitored data on their website and shall update the same periodically. It shall simultaneously be sent to the Regional Office of the MOEF&CC,GOI at Chennai, the respective Zonal Office of CPCB and the SPCB. The criteria pollutant levels namely; RSPM, SO_2, NOx (ambient levels as well as

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stack emissions) or critical sector parameters, indicated for the projects shall be monitored and displayed at a convenient location near the main gate of the company in the public domain.

xviii. The environmental statement for each financial year ending 31st March in Form-V as is mandated to be submitted by the project proponent to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental conditions and shall also be sent to the respective Regional Offices of the MOEF by e-mail.

xix. Environmental Clearance is being issued without prejudice to the action initiated under Environment (Protection) Act, 1986 or any court case pending or any other court order shall prevail.

xx. The SEIAA, TN may alter/modify the above conditions or stipulate any further condition in the interest of environment protection.

xxi. The SEIAA/SEAC or any Competent Authority may suitably add any further condition(s) on receiving reports from the project authority. The above condition shall be monitored by the Regional Office of MoEF located at Chennai.

xxii. The SEIAA, TN may revoke or suspend the Environmental clearance, if implementation of any of the above conditions is not satisfactory.

xxiii. The SEIAA, TN may cancel the environmental clearance granted to this project under the provisions of EIA Notification, 2006, if, at any stage of the validity of this environmental clearance, if it is found or if it comes to the knowledge of this SEIAA, TN that the project proponent has deliberately concealed and/or submitted false or misleading information or inadequate data for obtaining the environmental clearance.

xxiv. Failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of the Environment (Protection)

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Act, 1986.

xxv. The SEIAA-TN reserves the right to stipulate additional conditions if found necessary. The industry in a time bound manner shall implement these conditions.

xxvi. The above conditions will be enforced inter-alia, under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, the Public Liability Insurance Act, 1991, along with their amendments ,draft Minor Mineral Conservation & Development Rules , 2010 framed under MMDR Act 1957,National Commission for protection of Child Right Rules ,2006 and rules made there under and also any other orders passed by the Hon'ble Supreme Court of India/Hon'ble High Court of Madras and any other Courts of Law relating to the subject matter.

xxvii. Any appeal against this environmental clearance shall lie with the Hon'ble National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.

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Copy to:-

1. The Principal Secretary to Government,
   Environment & Forests Department,
   Govt. of Tamil Nadu, Fort St. George,
   Chennai – 600 009.

2. The Chairman,
   Central Pollution Control Board, PariveshBhavan,
   CBD Cum-Office Complex, East Arjun Nagar,
   New Delhi 110032.

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3. The Member Secretary,
   Tamil Nadu Pollution Control Board,
   76, Mount Salai, Guindy,
   Chennai - 600 032.

4. The ACCF(C), Regional Office of MoEF,
   34, HEPC Building, I & 2 nd Floors, Cathedral Garden Road, Nungampakkam,
   Chennai - 600 034.

5. Monitoring Cell, I A Division.
   Ministry of Environment & Forests.
   Paryavaran Bhavan, CGO Complex,
   New Delhi 110003.

6. The District Collector, Tiruvallur District.

7. Stock File.

STATE LEVEL ENVIRONMENT IMPACT ASSESSMENT AUTHORITY * TAMIL NADU *
20 FEB 2019


STATE LEVEL ENVIRONMENT
20 FEB 2019

Annexure-01

List of Proposed Products and their Quantities

SI.No	Product	Quantity(TPA)
1.	Bendamustine HCl	0.30
2.	Bortezomib	0.01
3.	Decetabine	0.12
4.	Everolimus	0.03
5.	Temsilrolimus	0.01
6.	Trabectedine	0.01
7.	Busulfan	0.05
8.	Lenalidomide	0.36
9.	Nelarabine	0.01
10.	Thiotepa	0.01
11.	Azacitidine	0.30
12.	Chlorambucil	0.01
13.	Doxorubicin Hydrochloride	0.05
14.	EpothilineB	0.05
15.	Fulvestrant	0.05
16.	Pomolidomide	0.30
17.	Sirolimus	0.12
18.	Carmustine	0.05
19.	Melphalan	0.01
20.	Cabozantinib-S-Malate	1.02
21.	Dasatinib Monohydrate	1.20
22.	Erlotinib Hydrochloride	4.20
23.	Geftinib	4.20
24.	Imatinib Mesylate	8.40
25.	Lapatinib Ditosylate Monohydrate	2.04
26.	Nilotinib Hydrochloride	1.80
27.	Palbociclib	1.80
28.	Pazopanib Hydrochloride	1.80
29.	SorafenibTosylate	4.80
30.	Sunitinib Malate	1.80

STATE LEVEL ENVIRONMENT IMPACT ASSESSMENT AUTHORITY TAMIL NADU
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20/02/19

31.	Dabigatran Etexilate	4.50
32.	Deferasirox	1.02
33.	Lansoprazole	4.50
34.	Lanthanum Carbonate Dihydrate	6.00
35.	Ledipasvir	3.00
36.	Ondansetron Hydochloride Dihydrate	3.60
37.	Pirfenidone	2.04
38.	Rizatriptan Benzoate	1.02
39.	Sacubitril	5.04
40.	Sertaline Hydrochloride	6.00
41.	Sumatriptan Succinate	3.00
42.	Ticagrelor	3.00
Total Production Capacity(Maximum 16 products at a time).		**66.12**
R&D activity		**0.2**
Total Production Capacity (Maximum 16 products at a time) and R&D activity		**66.32**

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