

	<b>ANDHRA PRADESH POLLUTION CONTROL BOARD</b> <b><u>D.No. 33-26-14 D/2, Near Sunrise Hospital,</u></b> <b><u>Pushpa Hotel Centre, Chalamalavari Street,</u></b> <b><u>Kasturibaipet, Vijayawada – 520010</u></b>	Phone: 0866 - 2436217 Website: www.appcb.ap.nic.in
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**CONSENT ORDER FOR ESTABLISHMENT****Order No. 174 /APP CB/CFE/RO-NLR/HO/2011****17/09/2018**

Sub: APPCB – CFE - **M/s. Nutra Specialities Private Limited, Sy. No.69, Chandrapadiya (V), Vinjamur (M), SPSR Nellore District** - Consent for Establishment (CFE) of the Board for **Change of Product Mix** under Sec.25 of Water (P & C of P) Act, 1974 and Under Sec.21 of Air (P&C of P) Act, 1981 - Issued - Reg.

Ref:

1. EC order dt. 02.02.2009 issued by MoEF & CC, Gol, New Delhi.
2. Industry's CFE application received through APOCMMS on 16.08.2018.
3. R.O's inspection report dt. 20.08.2018.
4. Industry's Ir. dt. 05.09.2018.
5. CFE Committee meeting held on 06.09.2018.

1. In the reference 2<sup>nd</sup> cited, an application was submitted to the Board seeking Consent for Establishment (CFE) for **Change of Product Mix** to produce the products with installed capacities as mentioned below, with an additional project cost of Rs. 0.5 Crore.

**As per CFE order dt. 08.02.2018:**

Sl.NO.	Name of the Products	Quantity kg/day
1	Sitagliptin phosphate	3.33
2	Levetiracetam	8.33
3	Lacosamide	50.0
4	Risperidone	4.0
5	Diacerine	3.33
6	Vildagliptin	5.0
7	Policosanol	0.13
8	Warfarine sodium	4.0
9	Tetracaine hydrochloride	20.0
10	Olmisartan medoxomil	150.0
11	Boswellic acid	0.1
12	Moxifloxacin hydrochloride	3.33
13	Linagliptin	6.66
14	Voglibose	0.83
15	Teneligliptin	0.33
16	Sevelarner Carbonate	0.33
17	Pregabalin	0.33

18	Colistimide	0.33
19	Gabapantine	0.33
20	Methylcobalamin	0.16
21	L-Methylfolate Calsium	0.33
22	Ferric Citrate	0.15
23	Chlorozoxazone	0.15
24	Nitrofurantoin Monohydrate	0.15
25	Cinacalcet Hydrochloride	0.06
26	Sucroferric Oxyhydroxide	0.06
27	Dimethyl Fumarate	0.06
28.	Atovaquone	0.06
29.	Droxidopa	0.05
30.	Allyl Isopropyl Acetyl Urea	100
31.	Fexofenadine HCl	33.33
	<b>Total</b>	<b>395.25 kg/day</b> <b>(or) 142.32</b> <b>TPA)</b>

**By-Products**

S. No.	By- Products	Products from which Byproduct are generated	Quantity
1	NaBr	Olimesartan Medoximil	283 kg/ Month
2	NaBr	Teracaine Hydrochloride	68 kg/ Month

**After Change of Product Mix:**

S.N	Name of the Products	Quantity as per CFE (CPM) dt.08.02.2018 (kg/day)	Stating raw material	Qty. in kg/ day	Proposed qty. after change of product mix (kg/day)
1	Sitagliptin phosphate	3.33	2,4,5 tri fluoro pheny acetic acid	1.37	3.33
2	Levetiracetam	8.33	(s) – 2-amino butyramide HCl	9.99	166.67
3	Lacosamide	50.0	D-serine	25.44	16.67
4	Risperidone	4.0	3-(2-chloro ethyl)-2-methyl-6, 7, 8, 9-tetrahydro – 4H-pyrido (1.2-a)-pyrimidine-4-one-hydrochloride	7.13	4.0
5	Diacerine	3.33	Aloe emodine	2.59	3.33
6	Vildagliptin	5.0	L-proline	2.17	5.0
7	Policosanol	0.13	Extracted crude	0.29	0.13
8	Warfarine sodium	4.0	4-hydroxyl coumarin	1.96	4.0

9	Tetracaine hydrochloride	20.0	4-amino benzoic acid	10.49	20.0
10	<b>Olmisartan medoxomil</b>	<b>150.0</b>	<b>Imidazole ester</b>	<b>48.12</b>	<b>83.34</b>
11	Boswellic acid	0.1	Boswellia serata gum	0.21	0.1
12	Moxifloxacin hydrochloride	3.33	Gati Acid	2.66	3.33
13	Linagliptin	6.66	Xanthan moiety	5.27	6.66
14	Voglibose	0.83	Voglibose Crude	0.87	0.83
15	Teneligliptin	0.33	4-oxopyrrolidine carboxylic acid	0.10	0.33
16	Sevelamer Carbonate	0.33	Allyamine	0.12	0.33
17	Pregabalin	0.33	Ter-butyl-3-(hydroxyl methyl) – 5-methyl hexanoate	0.51	0.33
18	Colistimide	0.33	2-methyl imidazole	0.16	0.33
19	Gabapentine	0.33	Gabapentine tech	0.34	0.33
20	Methylcobalamin	0.16	Cyanocobaltamin	0.19	0.16
21	L-Methylfolate Calcium	0.33	Folic acid	0.38	0.33
22	Ferric Citrate	0.15	Ferric chloride	0.14	0.15
23	Chlorzoxazone	0.15	4-chloro-2-aminophanol	0.09	0.15
24	Nitrofurantoin Monohydrate	0.15	Urea	0.04	0.15
25	Cinacalcet Hydrochloride	0.06	3-(3-Trifluoromethyl-phenyl)-propionaldehyde	0.05	0.06
26	Sucroferric Oxyhydroxide	0.06	Ferric chloride	0.02	0.06
27	Dimethyl Fumarate	0.06	Fumaric acid	0.05	0.06
28.	Atovaquone	0.06	Intermediate-1	0.03	0.06
29.	<b>Droxidopa</b>	<b>0.05</b>	<b>Intermediate-1</b>	<b>0.09</b>	<b>0.06</b>
30.	<b>Allyl Isopropyl Acetyl Urea</b>	<b>100</b>	<b>Dimethyl malonate</b>	<b>90.90</b>	<b>33.34</b>
31.	<b>Fexofenadine HCl</b>	<b>33.33</b>	<b>Fexofenadine HCl Crude</b>	<b>35.32</b>	<b>16.67</b>
32.	<b>Loxoprofen</b>	<b>--</b>	<b>2-Phenyl propanoic acid</b>	<b>9.52</b>	<b>13.33</b>
33.	<b>Loratadine</b>	<b>--</b>	<b>Loratadine crude</b>	<b>8.5</b>	<b>8.33</b>
34.	<b>Bepotastin</b>	<b>--</b>	<b>Bepotastin crude</b>	<b>1.70</b>	<b>1.67</b>
35.	<b>Azilsartan Medoxomil</b>	<b>--</b>	<b>Benzo carboxylate</b>	<b>1.34</b>	<b>1.67</b>
	<b>Total</b>	<b>395.25 kg/day (or) 142.32 TPA)</b>			<b>395.29 kg/day (or) 142.32 TPA)</b>

S. No.	By-Product	Products from which by-products are generated	After change of product mix
1	NaBr	Olimesartan Medoximil	157.23 kg/ Month
2	NaBr	Teracaine hydrochloride	68 kg/ Month

2. As per the application, the above activity is to be located at Sy. No.69, Chandrapadiya (V), Vinjamur (M), SPSR Nellore District in an area of 33.0 Acres.
3. The above site was inspected by the Environmental Engineer, Regional Office, Nellore, A.P Pollution Control Board on 17.08.2018 and observed that the site is surrounded by

**North** : Agriculture lands  
**East** : Forest area  
**South** : Vinjamur - Atmakur road  
**West** : Forest area

4. The Board, after careful scrutiny of the application, verification report of Regional Officer and recommendations of the CFE Committee, hereby issues **CONSENT FOR ESTABLISHMENT FOR CHANGE OF PRODUCT MIX** to the project under Section 25 of Water (Prevention & Control of Pollution) Act 1974 and Section 21 of Air (Prevention & Control of Pollution) Act, 1981 and the rules made there under. **This order is issued to manufacture the products as mentioned at para (1) only.**
5. This Consent order issued is subject to the conditions mentioned in the Annexure.
6. This order is issued from pollution control point of view only. Zoning and other regulations are not considered.
7. **This order is valid for a period of 7 years from the date of issue.**

Encl: Annexure

**VIVEK YADAV IAS**  
**MEMBER SECRETARY**

To

**M/s. Nutra Specialities Private Limited,**  
**No. - 4, 1<sup>st</sup> floor,**  
**Bharati Nagar, T Nagar,**  
**Chennai – 600 017.**  
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Copy to: 1. The JCEE, Z.O: Vijayawada for information and necessary action.  
2. The EE, R.O: Nellore for information and necessary action.

**Annexure**

1. The proponent shall obtain Consent for Operation (CFO) from APPCB, as required Under Sec.25/26 of the Water (P&C of P) Act, 1974 and under sec. 21/22 of the Air (P&C of P) Act, 1981, before commencement of the trial runs.
2. The applicant shall provide separate energy meters for Effluent Treatment Plant (ETP) and Air pollution Control equipments to record energy consumed. An alternative electric power source sufficient to operate all pollution control systems shall be provided.
3. The industry shall construct separate storm water drains and provide rain water harvesting structures. No effluents shall be discharged in to the storm water drains.

**Water:**

4. The source of water is Ground water and the maximum permitted water consumption is as following:

S. No.	Purpose	Consented qty. as per CFE (CPM) dt. 08.02.2018.	Total after Change of product mix
1.	Industrial cooling, boiler feed.	142.00	142.00
2.	Domestic and gardening purposes.	18.00	18.00
3.	Processing, whereby water gets polluted and pollutants are easily bio- degradable.	---	---
4.	Processing, whereby water gets polluted and the pollutants are not easily bio-degradable.	13.80	13.80
	<b>Total</b>	<b>173.80</b>	<b>173.80</b>

Separate meters with necessary pipe-line shall be provided for assessing the quantity of water used for each of the purposes mentioned above.

5. The maximum waste water generation shall not exceed the following:

S. No.	Source	Consented qty. as per CFE (CPM) dt. 08.02.2018 (KLD)	Total qty. after Change of product mix (KLD)
1.	Process & Washings	14.23	14.23
2.	Boiler Blow Down	11.8	11.8
3.	Cooling Tower Blow Down	35.0	35.0
4.	Domestic	6.0	6.0
	<b>Total</b>	<b>67.03</b>	<b>67.03</b>

**Treatment & disposal:**

Effluent source	Treatment	Treatment & Mode of final disposal
Process effluents: HTDS 14.23 KLD	Stripper (1 KL/hr-2 Nos.), MEE (3 KL/hr), ATFD (500 L/hr),	<ul style="list-style-type: none"> <li>• Shall be stripped off for organics recovery.</li> <li>• Stripper condensate to distillate for separation of organic compounds followed by disposal to cement plants for co-processing &amp; distilled effluents shall be recycled.</li> <li>• Stripped effluents to forced evaporation in MEE followed by ATFD.</li> <li>• Condensate from MEE &amp; ATFD shall be recycled after treatment in ETP along with other LTDS effluents.</li> <li>• ATFD salts to TSDF.</li> </ul>
LTDS effluents: 46.8 KLD	ETP of 100 KLD capacity consisting of collection tank cum equalization tank, flash mixer, aeration tank, secondary settling tank, sand filter, UV purifier, sludge tank, filter press, RO Plant etc.	<ul style="list-style-type: none"> <li>• Treated effluents shall be filtered in the RO Plant.</li> <li>• RO permeate to be recycled.</li> <li>• RO rejects to MEE</li> </ul>

6. All the units of ZLD system consisting of stripper, MEE, ATFD system with condenser, Biological ETP and RO plant shall operated properly. All the units of the ZLD system shall be impervious to prevent ground water pollution.

Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.

7. The industry shall provide magnetic digital flow meters with totalisers at the inlet and outlet of Stripper, MEE, ETP and RO.
8. The industry shall install online real time monitoring system along with web camera facilities as per the directions of CPCB. The industry shall connect them to APPCB / CPCB websites as per CPCB directions.
9. Floor washing shall be admitted into the effluent collection system only and shall not be allowed to find their way in storm drains or open areas. All pipe valves, sewers, drains shall be leak proof.

**Air:**

10. The Air pollution Control equipment shall be installed along with the commissioning of the activity and shall comply with the following for controlling air pollution.

S. No.	Details of Stack	Consented as per CFE (CPM) order dt. 08.02.2018	Proposed for product mix	Existing	Existing
		Stack 1*	Stack 2	Stack 3	Stack 4
a)	Attached to	Boiler	<b>New Boiler</b>	D.G. Set	D.G. Set
b)	Capacity	3.0 TPH*	<b>4.0 TPH</b>	500 KVA	725 KVA
c)	Name of the Fuel	Coal/ Briquettes	<b>Bio Briquettes</b>	Diesel	Diesel
d)	Stack height above ground	30 m	<b>30 m</b>	4 m	4 m
e)	Air Pollution Control Equipment	Multi-cyclones followed by Bag filter	<b>Multi-cyclones following bag filter</b>	Acoustic enclosures	

\* The existing 3 TPH boiler shall be kept as stand by after installation of new 4 TPH boiler as committed vide Ir. dt. 05.09.2018.

11. A sampling port with removable dummy of not less than 15 cm diameter shall be provided in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc. A platform with suitable ladder shall be provided below 1 meter of sampling port to accommodate three persons with instruments. A 15 AMP 250 V plug point shall be provided on the platform.
12. The industry shall properly maintain & operate the monitoring system to all the stacks / vents in the plant. Regular monitoring shall be carried out and report shall be submitted to the Regional officer.
13. The industry shall properly maintain & operate multi-stage scrubbers to the process vents to control the process emissions. The industry shall provide online pH measuring facility with auto recording system to the scrubbers provided to treat the process emissions.
14. The industry shall properly maintain & operate VOC monitoring system with auto recording facility.
15. The industry shall implement adequate measures to control all fugitive emissions from the plant.

16. The proponent shall ensure compliance of the National Ambient Air quality standards notified by MoEF, GoI vide notification No. GSR. 826 (E), dated. 16.11.2009 during construction and regular operational phase of the project at the periphery.

The generator shall be installed in a closed area with a silencer and suitable noise absorption systems. The ambient noise level shall not exceed 75 dB(A) during day time and 70 dB(A) during night time.

17. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.
18. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.
19. The evaporation losses in solvents shall be controlled by taking the following measures:
- Chilled brine circulation shall be carried out to effectively reduce the solvent losses into the atmosphere.
  - Transfer of solvents shall be done by using pumps instead of manual handling.
  - Closed centrifuges shall be used to reduce solvent losses.
  - All the solvent storage tanks shall be connected with vent condensers to prevent solvent vapours.
  - The reactor vents shall be connected with primary & secondary condensers to prevent escaping of solvent vapour emissions into atmosphere.

#### **Solid Waste:**

20. The industry shall comply with the following for disposal of Solid wastes:

S.N	Description of Waste	Consented as per CFE (CPM) dt. 08.02.2018.	Qty. after change of product mix	Mode of final disposal
1.	Solid Waste from process	781.34 kg/day	740.82 kg/day	To TSDF for secured land fill
2.	ETP Sludge	11.94 kg/day	10.32 kg/day	
3.	Salts from Forced Evaporation system	162.41 kg/day	135.48 kg/day	
4.	Carbon Waste	38.45 kg/day	21.85 kg/day	To TSDF for incineration/ cement industries for processing
5.	Solvent residue & Organic residue	254.0 kg/day	218.7 kg/day	
6.	Spent Oil	120 LPA	120 LPA	Authorised reprocessors
7.	Stripper waste	289 kg/day	238.9 kg/day	To cement units for co-processing
8.	Mixed Solvents	50 TPM	45 TPM	To authorized recyclers / cement plants



9.	Container and container liners of hazardous chemicals (after detoxification)	30 Nos./Month	30 Nos./Month	To Recyclers after complete detoxification
10.	Boiler ash	3.0 TPD	3.0 TPD	To Brick Manufacturers

21. The proponent shall place the chemical drums and / or any drums in a shed provided with concrete platform only. The Platform shall be provided with sufficient dyke wall and effluent collection system. The industry shall provide containers detoxification facility. Container & Container liners shall be detoxified at the specified covered platform with dyke walls and the wash wastewater shall be routed to low TDS collection tank.
22. The following rules and regulations notified by the MoEF&CC, GoI shall be implemented.
- Hazardous waste and other wastes (Management and Transboundary Movement) Rules, 2016.
  - Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989
  - Fly Ash Notification, 2016.
  - Batteries (Management & Handling) Rules, 2010.
  - E-Waste (Management) Rules, 2016.
  - Construction and Demolition waste Management Rules, 2016.

**Other Conditions:**

23. **Separate Bag filters shall be installed for each boiler as committed vide Ir. dt. 05.09.2018.**
24. Green belt shall be developed in remaining area of 5 acres with tall growing trees with good canopy so that it shall not be less than 33% of the total area, as committed vide Ir. dt. 05.09.2018.
25. The industry shall submit the information regarding usage of Ozone Depleting Substance once in six months to the Regional Office and Zonal Office of the Board.
26. Concealing the factual data or submission of false information / fabricated data and failure to comply with any of the conditions mentioned in this order attracts action under the provisions of relevant pollution control Acts.

27. Notwithstanding anything contained in this conditional letter or consent, the Board hereby reserves its right and power Under Sec. 27(2) of Water (Prevention and Control of Pollution) Act, 1974 and Under Sec.21(4) of Air (Prevention and Control of Pollution) Act, 1981 to revoke the order, to review any or all the conditions imposed herein and to make such modifications as deemed fit and stipulate any additional conditions.
28. Any person aggrieved by an order made by the State Board under Section 25, Section 26, Section 27 of Water Act, 1974 or Section 21 of Air Act, 1981 may within thirty days from the date on which the order is communicated to him, prefer an appeal as per Andhra Pradesh Water Rules, 1976 and Air Rules, 1982, to such authority (hereinafter referred to as the Appellate Authority) constituted under Section 28 of Water (Prevention and Control of Pollution) Act, 1974 and Section 31 of the Air (Prevention and Control of Pollution) Act, 1981.

**VIVEK YADAV IAS**  
**MEMBER SECRETARY**

**To**

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