



CONSENT ORDER FOR ESTABLISHMENT AND OPERATION

Order No. 135 /APPCB/CFE/RO-VSP/HO/2014

Dt: 26.04.2018

Sub: APPCB – CFE - **M/s. Torrent Pharmaceuticals Ltd., (Formerly M/s. Glochem Industries Ltd.) Plot No: 77, JN Pharmacy, Thanam (V), Parawada (M), Visakhapatnam District** – Consent for Establishment (CFE) and Consent for Operation (CFO) for **Change of Product Mix** under Sec. 25 / 26 of Water (P & C of P) Act, 1974 and Under Sec. 21 of Air (P&C of P) Act, 1981 - Issued - Reg.

Ref: 1) CFE expansion order dt. 10.06.2016.
2) Industry's application received through A.P. Single Desk Portal on 27.03.2018.
3) R.O's inspection report dt. 10.04.2018.
4) CFE Committee meeting held on 24.04.2018.
5) Industry's lr. dt. 25.04.2018.

1. In the reference 2nd cited, an application was submitted to the Board seeking Consent for Establishment (CFE) and Consent for Operation order (CFO) for **Change of Product Mix** within the existing premises to produce the products with installed capacities as mentioned below, with an additional investment of Rs. 0.34 Crore.

As per CFE (expansion) order dt. 10.06.2016:

S. No	Name of the Product	Quantity (kg/day)
1	RALOXIFINE HYDROCHLORIDE	16.66
2	AMLODIPINE BESILATE	27.77
3	CETIRIZINE DIHYDROCHLORIDE	1.389
4	CLOPIDOGREL BESILATE	2.22
5	RABEPRAZOLE SODIUM	4.166
6	OLANZAPINE	3.333
7	TRIENTINE DI HYDROCHLORIDE	0.277
8	ALFUZOSIN HYDROCHLORIDE	2.777
9	AMISULPRIDE	1.389
10	LEVOCETIRIZINE DIHYDROCHLORIDE	8.333
11	TERBINAFINE HYDROCHLORIDE	1.389
12	TELMISARTAN	13.889
13	6-CHLORO-2-CHLORO ETHYL OXYINDOLE	6.944
14	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	6.944
15	TOLCAPONE	1.389
16	CLOPIDOGREL BISULPHATE FORM-II	4.166
17	CLOPIDOGREL BISULPHATE FORM-I	1.389
18	OLMESARTAN MEDOXOMIL	1.389
19	ILOPERIDONE	0.111
20	TOPIRAMATE	8.333
21	RUFINAMIDE INTERMEDIATE	2.777
22	LUBIPROSTONE INTERMEDIATE	0.041
23	CIPROFIBRATE	13.889
24	METHENAMINE HIPPURATE	1.389
25	AMLODIPINE MESILATE MONOHYDRATE	2.777
26	LEVODOPA	5.55
27	LERCANIDIPINE	1.66
28	PHTHALIMIDO AMLODIPINE	138.889
29	RALOXIFINE HYDROCHLORIDE STAGE-II	22.22
30	RALOXIFINE HYDROCHLORIDE STAGE-III	13.888
31	THTP HYDROCHLORIDE (CPG-IA)	5.555
32	ESOMEPRAZOLE INTERMEDIATE (STAGE-III)	100
33	RIVASTIGMINE HYDROGEN TARTARATE	0.833
34	OLANZAPINE PAMOATE	0.555
35	AMLODIPINE BASE	2.777
36	CLOPIDOGREL LCS	5.555
37	RIVAROXABAN INTERMEDIATE	1.389
38	VENLAFAXINE HYDROCHLORIDE	1.389
39	OSELTAMIVIR EPOXIDE	1.389

40	PHTHALIMIDO AMLODIPINE CRUDE	222.22
41	IPRONIAZID PHOSPHATE	2.777
42	ARMODAFINIL INTERMEDIATE	13.889
43	HALOPERIDOL	4.166
44	LIMECYCLINE	8.333
45	DIPYRIDAMOLE	1.389
46	NIRCORANDIL	4.166
47	CINACALCET HCL	6.944
48	TOLVAPTON	6.944
49	DULOXETINE HCL	6.944
50	LAMOTRIGINE	6.944
51	PRAMIPEXOLE	6.944
52	SILDENAFIL CITRATE	6.944
53	TRC041266	6.944
54	CANDESARTAN CILEXETINE	6.944
55	DONEPEZILE HCl	6.944
56	ATORVASTATIN CALCIUM	6.944
57	QUETIAPINE FUMARATE	6.944
58	SERTRALINE HCL	6.944
59	CLOPIDOGREL CSA	13.889
60	RESEARCH AND DEVELOPMENT	8.333
Total quantity of any 49 products on worst combination		789.166

After Change of Product Mix:

S. No	Name of product	Quantity kg/day	No. of stages	Starting key Raw material	Quantity kg/day
1	Esomeprazolemagnesium amorphous (or) Esomeprazolemagnesium trihydrate	16.44	5	2-Chloromethyl-3,5-Dimethyl-4-Methoxy Pyridine Hydrochloride	56.6
2	TRC 150094	19.73	7	5-Methyl-indan-4-ol*	34.5
3	Duloxetine HCL	16.44	3	S-(-)-N,N-dimethyl-3-hydroxy-3-(2-thienyl)-1-propanamine	15.5
4	TRC041266	19.99	3	MSNH	45.1
5	Febuxostat API	9.86	3	Ethyl 2-(3-formyl-4-hydroxy phenyl)-4-methyl-1,3-thiazole-5-carboxylate	17.9
6	TRC 160334	9.86	2	m-Chloro per benzoic acid	49.2
7	Esomeprazole Intermediate (Stage-III)	96.99	3	2-Chloromethyl-3,5-Dimethyl-4-Methoxy Pyridine Hydrochloride	65.6
8	TRC 240138	2.99	12	3-chloro-4-methoxyaniline	5.5
9	Rivastigmine hydrogen tartarate	8.22	5	3-(1-(dimethyl amine) ethyl) Phenol HCL	55.4
10	Candesartan Cilexetine	23.01	5	3-Nitro thalic acid	39.8
11	Olanzapine	9.99	4	2-Amino-5-Methylthiophene-3-Carbonitrile	12.3
12	Sildenafil Citrate	19.73	4	4-[2-Ethoxy benzamido]-1-Methyl-3-N-Propyl prazole-5-2-Caboximade	46.4
13	Sildenafil	5.00	4	(3-{5-[(2R)-2-aminopropyl]-7-cyano-2,3-dihydro-1H-indol-1-yl}propyl benzoate (2R,3R-monotartarate)	15.7
14	Oltmesartan Medoxomil	9.99	3	N,N-Dimethyl acetamide	8.5
15	Pramipexole	2.01	4	(±) 2,6 - diamino -4,5,6,7-Tetrahydro-benzothiazole	11.1
16	Lamotrigine	82.19	2	2,3 Dichloro BenzoylChloride	147.1
17	Rasaqiline Fumarate	2.99	3	1-Amino indane	19.0
18	Sitagliptin Tartrate	9.99	2	(3R)-3-[(tert-Butoxycarbonyl)amino]-4-(2,4,5-trifluoro phenyl)butanoic acid	10.1
19	Rabeprazole Sodium	16.44	3	2-(Chloromethoxy)-4-(3-Methoxy Propoxy)-3-Methyl pyridine Hydrochloride	23.6

S. No	Name of product	Quantity kg/day	No. of stages	Starting key Raw material	Quantity kg/day
20	Venlafaxine Hydrochloride	45.01	2	1-(2-amino-1-(4-methoxy phenyl)ethyl)cyclohexanol HCL	52.1
21	Perampanel	5.00	2	3-Bromo-5-(2-pyridyl)-1,2-dihydropyridin-2-One	7.3
22	Lercanidipine	16.44	2	2,N-Dimethyl-N-(3,3diphenylpropyl)-1-amino-2-propanol	19.9
23	Quetiapine Fumarate	9.99	2	Dibenzo(1,4)thiazepin-1,1(10H)-one	9.2
24	Topiramate	9.99	2	D-Fructose	13.1
25	Famotidine	32.88	2	N-[4-[(Aminoiminomethyl)thio] methyl]-2-thiazolyl]-guanidine dihydrochloride	52.2
26	Donepezile HCL	9.99	3	5,6-dimethoxy 1-indanone	0.9
27	Nircorandil	13.15	3	Nicotinic Acid	33.0
28	Alfuzosin Hydrochloride	2.01	3	4-amino-2-chloro-6,7-dimethoxy quinazoline	2.0
29	Raloxifine Hydrochloride	3.29	6	3-Methoxy thiophenol(Thiol)	1.7
30	Vilazodone Hydrochloride	9.99	2	5-(piperazin-1-yl) benzofuran-2-carboxamide	10.1
31	Olanzapine Pamoate	2.99	1	Olanzapine (IP)	1.4
32	Sacubitril-valsartan	2.99	5	N-(R)-4-t-butoxycarbonyl-(p-phenylphenyl)-alanine carboxaldehyde	9.1
33	Safinamide	2.99	3	4-Hydroxy benzaldehyde	2.8
34	Roflumilast	0.99	2	3-Cyclopropylmethoxy-4-difluoro methoxy benzoic acid	1.1
35	Sertraline HCL	9.86	4	Tetralone	51.8
36	Ferric citrate Hydrate	14.99	2	Ferric chloride hexahydrate (KSM-1)	19.0
37	Telmisartan	2.99	5	Methyl-4-n-Butryl Amino 3—Methyl-5-NitroBenzoate	3.8
38	Clopidogrel Bisulphate form-II *	2.99	6	Thiophene-2-Ethyl amine	1.7
39	Apixaban	2.99	3	3-Morpholin-4-yl-1-[4-(2-oxo-piperidin-1-yl)-phenyl]-5,6-dihydro-1H-pyridin-2-one	4.6
40	Levodopa *	5.00	1	S-2-Amino-3(3,4 Dihydropyphenyl) propanoic acid	5.1
41	TRC04186	5.00	2	MSNH	5.1
42	Prucalopride Succinate	5.00	3	4-amino-5-chloro-2,3-dihydro-1-benzofuran-7-carboxylic acid	4.2
43	Clopidogrel Bisulphate form-I *	2.99	6	Thiophene-2-Ethyl amine	1.1
44	Teneligiptin hemipentahydro bromide hydrate	2.99	2	1-(3-Methyl-1-phenyl-1H-pyrazol-5-yl) piperazine	1.7
45	Darifenacin Hydrobromide	0.99	2	2,3-dihydro-1-benzofuran-5-yl acetic acid	0.8
46	Tapentadol Hemipamoate	0.99	1	Tapentadol Hydrochloride	1.1
47	Aripiprazole Lauroxil	0.99	2	7-(4-[4-(2,3-Dichlorophenyl)piperazin-1-yl]butoxy)-3,4-dihydroquinolin-2(1H)-one	1.1
48	Paliperidone	2.99	4	3-Benzylloxy-2-amino pyridine	6.0
49	Ormeloxifene HCL	5.00	1	10% Palladium On Charcoal	0.4
50	Esomeprazolemagnesium Trihydrate	5.00	3	2-Chloromethyl-3,5-Dimethyl-4-Methoxy Pyridine Hydrochloride	3.4

51	LEVOCETIRIZINE DIHYDROCHLORIDE*	8.33	3	1-[(R) - 4 - Chlorophenyl] phenyl methyl] - piperazine	7.15
52	Validation batches/research and development	10.00	-	-	-
Total		630.32			

***Note: The industry shall manufacture either Levocetirizine Dihydrochloride* (or) Clopidogrel Bisulphate form-II* + Levodopa* + Clopidogrel Bisulphate form-I* at any point of time, along with other products.**

2. As per the application, the above activity is to be located within the existing industry premises located at Plot No: 77, JN Pharmacy, Thanam (V), Parawada (M), Visakhapatnam District in an area of 5.23 Acres (21,159 Sq. m).
3. The industry was inspected by the Environmental Engineer & Asst. Environmental Engineer-I, Regional Office, Visakhapatnam, A.P Pollution Control Board on 10.04.2018 and observed that the site is surrounded by

North : M/s. Suven Life Sciences
South : Internal road followed by M/s. Mahidhara Chemicals
East : KRR DRUGS
West : Internal road followed by Vacant plots
4. The Board, after careful scrutiny of the application, verification report of the Regional Officer and recommendation of the CFE Committee, hereby issues **CONSENT FOR ESTABLISHMENT AND CONSENT FOR OPERATION FOR CHANGE OF PRODUCT MIX** to the activity under Section 25 / 26 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 now 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 upto 31.12.2022 (i.e., validity of existing CFO order).**

Encl: Annexure.

Digitally signed by Bandla Siva Sankar Prasad
 DN: cn=[Redacted], ou=[Redacted], email=[Redacted], o=[Redacted]
 Date: 2023.04.26 10:42:31 +0530
BANDLA SIVA SANKAR PRASAD
MEMBER SECRETARY

To

M/s. Torrent Pharmaceuticals Ltd.,
(Formerly M/s. Glochem Industries Ltd.,)
Plot No: 77, JN Pharmacy,
Thanam (V), Parawada (M),
Visakhapatnam
 manishparikh@torrentpharma.com
 sheshagiriraotirlangi@torrentpharma.com

- Copy to:** 1. The JCEE, Z.O: Visakhapatnam for information and necessary action.
 2. The E.E., R.O: Visakhapatnam for information and necessary action.

Annexure

1. 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.
2. 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:

1. The source of water is JNPC, Parawada and the maximum permitted water consumption is as following:

S. No.	Purpose	Quantity as per CFE (Exp) dt. 10.06.2016 (KLD)	Proposed quantity for Change of Product mix (KLD)
1.	Industrial cooling, boiler feed.	32.28	32.28
2.	Domestic & gardening purposes.	31.84	31.84
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.	81.79	101.64
Total		145.91	165.76

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

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

S. No	Purpose	As per CFE (Exp) dt. 10.06.2016 (KLD)			After Change of Product Mix (KLD)		
		HTDS	LTDS	Total	HTDS	LTDS	Total
1.	Process & Washings	25.05	25.02	50.07	25.05	27.015	52.065
2.	Boiler Blow down	0.20	14.88	15.08	0.20	14.88	15.08
3.	Cooling towers Blow Down	0.00	10.00	10.00	0.00	10.00	10.00
4.	Scrubber System	0.90	0.00	0.90	0.90	0.00	0.90
5.	Domestic	0.00	13.07	13.07	0.00	13.07	13.07
6.	Floor washings	0.00	0.16	0.16	0.00	0.16	0.16
7.	Periodical Equipment cleaning	0.00	1.86	1.86	0.00	1.86	1.86
8.	Detoxification of containers	0.00	13.46	13.46	0.00	11.47	11.47
Total		26.15	78.45	104.60	26.15	78.455	104.605

Treatment & disposal:

Source	Treatment	Mode of final disposal
HTDS	Pretreatment (Neutralization)	To M/s. Ramky Pharmacy for forced evaporation.
LTDS	Pretreatment (Neutralization)	To CETP of M/s. Ramky Pharmacy for further treatment and disposal
Domestic waste water	---	The overflow of the Septic tank shall be sent to the CETP for further treatment.

3. Effluents shall not be discharged on land or into any water bodies or aquifers under any circumstances.
4. The industry shall properly maintain online real time monitoring system along with web camera facilities as per the directions of CPCB. The industry shall maintain the connection to APPCB / CPCB websites as per CPCB directions.
5. 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:

6. The Air pollution Control equipment shall be maintained properly to comply with the following for controlling air pollution after Change of Product Mix:

After Change of Product Mix:

Sl. No	Details of Stack	Stack 1	Stack 2	Stack 3
a)	Attached to:	Boiler	Thermic Fluid Heater	D.G. Set
b)	Capacity	2.0 TPH	2 Lakh. Kilo calories	2 X 380 KVA (1 standby)
c)	Fuel	Coal / Briquette 2.50 TPD	----	Diesel
d)	Stack height:	30 m		10 m
e)	Control Equipment:	Cyclone & Bag filter	---	Acoustic enclosures

7. 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.
8. The industry shall provide 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.
9. The industry shall provide 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.
10. The industry shall provide VOC monitoring system with auto recording facility.
11. The industry shall implement adequate measures to control all fugitive emissions from the plant.
12. The proponent shall ensure compliance of the National Ambient Air quality standards notified by MoEF, Gol 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.
13. The proponent shall not use or generate odour causing substances or Mercaptans and cause odour nuisance in the surroundings.
14. The industry shall send the used / spent solvents to the recyclers (or) process them at their own solvent recovery facility within the premises.

15. 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:

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

S. No.	Description	Existing Quantity	Quantity after CPM	Method Of Disposal
1.	Process residue and Organic residue from Distillation bottom	641.65 TPA	641.65 TPA	Sent to TSDF, Parawada, for incineration/ Authorised Cement plants for co-processing.
2.	Spent Carbon	62.18 TPA	62.18 TPA	
3.	Inorganic process salts	241.19 TPA	241.19 TPA	Sent to TSDF, Parawada, for secured land filling.
4.	ETP Sludge	25.0 TPA	25.0 TPA	
5.	Spent solvents	9803.87 kg/day	9803.87 kg/day	Shall be sent to APPCB authorized agency
6.	Used Oils	2000 LPA	5000 LPA	Authorized reprocessors/recyclers
7.	Container and container liners of hazardous waste	12,000 Nos per Annum	20,000 Nos per Annum	After complete detoxification shall be disposed to outside agencies for recycling.
8.	Used lead acid batteries	85 nos per Annum	150 nos per Annum	Shall be sent back to suppliers on buy back basis.
9.	Mixed solvent	4977.6 kg/day	4977.6 kg/day	Shall be sent to APPCB authorized agency
10.	Spent acids	2739.8 Kg/day	2739.8 Kg/day	Shall be sent to APPCB authorized agency
11.	Contaminated Sand (used for spill collection & control)	1.5 TPA	2.0 TPA	Sent to TSDF, Parawada, for secured land filling.
12.	Rejected raw material	3695.62 TPA	Actuals	
13.	Rejected Products	1568.15 TPA	Actuals	
14.	Hepa Filters	0.37 TPA	3.0 TPA	Sent to TSDF, Parawada, for incineration.
15.	Insulation wool	0.99 TPA	0.99 TPA	
16.	Thermocol	0.063 TPA	0.50 TPA	
17.	Contaminated glassware	4105 nos per Annum	20,000 nos per Annum	After complete detoxification shall be disposed to outside agencies.
18.	PPEs	1.6 TPA	3.50 TPA	Sent to TSDF, Parawada, for incineration.
19.	Sodium Hydride bags	0.234 TPA	0.50 TPA	Sent to TSDF, Parawada, for incineration.
20.	HDPE Bags	8.78 TPA	8.78 TPA	Sent to TSDF, Parawada, for incineration/for recycling to authorized recyclers.
21.	Expired Laboratory chemicals	0.48 TPA	1.0 TPA	Sent to TSDF, Parawada, for incineration.
22.	Filtration bags	220 nos per Annum	500 nos per Annum	Sent to TSDF, Parawada, for incineration.
23.	Coal Ash	251 TPA	251 TPA	Disposed to local Ash Bricks manufacturers.
24.	Cooling Tower Sludge	---	10 TPA	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
25.	Cooling Tower Packing material	---	2.0 TPA	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
26.	Foam	---	1.0 TPA	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.

27.	Oil Contaminated Waste (DG Set oil filters)	---	1.0 TPA	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.
28.	General Waste	---	25.0 TPA	Sent to TSDF/CWMP, Parawada, Visakhapatnam District for incineration.

17. 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.
18. The following rules and regulations notified by the MoE&F, 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:

19. Green belt shall be developed all along the boundary & vacant spaces with tall growing trees with good canopy and it shall not be less than 33% of the total area.
20. 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.
21. 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.
22. 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.
23. 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.

Bandla Siva
Sankar
Prasad



MEMBER SECRETARY

To

**M/s. Torrent Pharmaceuticals Ltd.,
(Formerly M/s. Glochem Industries Ltd.,)
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Thanam (V), Parawada (M),
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