

851-

STATE LEVEL ENVIRONMENT IMPACT ASSESSMENT AUTHORITY

SEAC-2015/CR-268/TC-2
Environment department,
Room No. 217, 2nd floor,
Mantralaya Annexe,
Mumbai- 400 032.
Date: 17th October, 2016.

To,
M/s. Anuh Pharma Ltd.
3-A, Shivsagar Estate, North Wing,
Dr. /Annie Besant Road,
Worli, Mumbai- 400 018.

Subject: Environment clearance for Expansion and new project for manufacturing of advanced intermediates and bulk drugs at plot no- E-17/3, E-17/4 & E-18, MIDC Tarapur Boiser, Palghar by M/s. Anuh Pharma Ltd.

Sir,

This has reference to your communication on the above mentioned subject. The proposal was considered as per the EIA Notification, 2006, by the State Level Expert Appraisal Committee-I, Maharashtra in its 127th meeting and decided to recommend the project for prior environmental clearance to SEIAA. Information submitted by you has been considered by State Level Environment Impact Assessment Authority in its 103rd meeting.

2. It is noted that the proposal is considered by SEAC-I under screening category 5(f) B1 as per EIA Notification 2006.

Brief Information of the project submitted by Project Proponent is as:

1	Name of project	M/s AnuhPharma Ltd. Expansion & New project for manufacturing of Advanced Intermediates and Bulk Drugs
2	Name, address, e-mail & contact number of proponent	Mr.Vivek Shah 3-A,Shivsagar Estate, North Wing, Dr. Annie Besant Road, Worli,Mumbai-400018 e-mail : vivek@sk1932.com contact number :022 27781881/82
3	Name of consultant	M/s. Goldfinch Engineering Systems Pvt. Ltd.
4	Accreditation of consultant (NABET Accreditation)	S. No. 75 in QCI NABET List 166 (Jan. 2015)-for the proposed project category (5f) of the MoEF EIA notification Schedule
5	New project/expansion in existing project/modernizatio	Expansion and New project

	n/diversification in existing project																						
6	If expansion/diversification, whether environmental clearance has been obtained for existing project (If yes enclose a copy with compliance table)	No. The facility was started way back in 1980 and there was no requirement of EC at that time. Consent to operate was obtained from MPCB and renewed from time to time.																					
7	Activity schedule in the EIA Notification	5 (f) B																					
8	Area Details	Total plot area - 11580 sq. m. Proposed Built up area - 3491 sq. m.																					
9.	Name of the Notified Industrial Area/ MIDC area	Boiser, Tarapur Industrial Estate																					
10.	TOR given by SEAC? (If yes then specify the meeting)	Yes. 113 th SEAC Meeting																					
11.	Estimated capital cost of the project (Including cost for land, building, plant and machinery separately)	Rs.34.45 Cr.																					
12.	Location details of the project:	Latitude : 19 ^o 48'06.3 N Longitude: 72 ^o 44' 02.7 E. Location : Tarapur MIDC, Palghar, Maharashtra Elevation above mean sea level : approximately 46 ft (13.89 m)																					
13.	Distance from protected areas/ critically polluted areas/ Eco Sensitive area/ inter- state boundaries	No such area in the vicinity.																					
14.	Raw materials (including process chemicals, catalysts & additives)	Please refer table below																					
	<table border="1"> <thead> <tr> <th>S r. N o</th> <th>PRODUCT</th> <th>Monthly Production (Kg)</th> <th>SOLVENTS</th> <th>Consumption/Kg</th> <th>Monthly Consumption (Kg)</th> <th>Monthly Consumption (Tons)</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td rowspan="2">Atorvastatin Calcium</td> <td rowspan="2">20000</td> <td>Cyclohexane</td> <td>20.25</td> <td>405000</td> <td>405.00</td> </tr> <tr> <td>IPA</td> <td>37.25</td> <td>745000</td> <td>745.00</td> </tr> </tbody> </table>						S r. N o	PRODUCT	Monthly Production (Kg)	SOLVENTS	Consumption/Kg	Monthly Consumption (Kg)	Monthly Consumption (Tons)	1	Atorvastatin Calcium	20000	Cyclohexane	20.25	405000	405.00	IPA	37.25	745000
S r. N o	PRODUCT	Monthly Production (Kg)	SOLVENTS	Consumption/Kg	Monthly Consumption (Kg)	Monthly Consumption (Tons)																	
1	Atorvastatin Calcium	20000	Cyclohexane	20.25	405000	405.00																	
			IPA	37.25	745000	745.00																	

		MeOH	24.85	497000	497.00
		Aromatic Derivative	1.065	21300	21.30
		Aliphatic Compound	1.595	31900	31.90
		HCl	0.015		
		NaOH	0.075		
		Calcium Chloride	0.185	3700	3.70
		MIBK	3.5	70000	70.00
		MeOH	5.875		0.00
		Acetone	2.465		0.00
		BCFI	0.53	10600	10.60
		Br-OTBN	0.77	15400	15.40
		TBAB	0.025	500	0.50
		Toluene	4.135	82700	82.70
		NaOH	0.24	4800	4.80
		TEA	0.065	1300	1.30
		TEA.HCL	1.4	28000	28.00
		HCl	0.315		
		Ethyl Acetate	1.97		
		Sodium Sulphate	0.025		
		Sodium bicarbonate	0.095		
		Sodium hydrosulphite	0.05	1000	1.00
		Sodium azide	0.605	12100	12.10
		NaNO ₂	0.24	4800	4.80
		Sodium borohydride	0.04	800	0.80
		Charcoal	0.07		
		K ₂ CO ₃	0.175	3500	3.50
		Hyflow	0.07		
		Acetone	7.98		
		Ethyl Acetate	0.76		
		Butanol	5.54	110833.3	110.83
		MeOH	5.54		
		Benzimidazole Derivative	0.76	15166.7	15.17
		Br-OTBN	0.68	13666.7	13.67
		ammonia	0.06	1166.7	1.17
		Charcoal	0.03		
		Hyflo	0.03		
		KOH	0.19	3833.3	3.83
		NaOH	0.45		
		Acetic Acid	0.71	14166.7	14.17
		MeOH	9.97	199400.0	199.40
		MDC	12.12	242400.0	242.40
	2	Losartan Potassium			
	3	Telmisartan			
	4	Clopidogrel Bisulphate			

			IPA	3		
			Acetone	11.32	226400.0	226.40
			Toluene	3.86		
			2- Chlorophenyl Glycine	0.765	15300.0	15.30
			H2SO4	1.02	20400.0	20.40
			Tartaric Acid	0.625	12500.0	12.50
			NH3	1.72	34400.0	34.40
			Thiophene-2-Ethanol	0.595	11900.0	11.90
			Ethyl acetate	3.9	78000	78.00
			Dipotassium hydrogen phosphate	1.5	30000	30.00
			HCl	0.65	13000	13.00
			Hyflo	0.08	1600	1.60
			PTSCI	0.98	19600	19.60
			Sodium sulphate	0.1	2000	2.00
			Carbon	0.08	1600	1.60
			NaOH	0.79	15800	15.80
			Formaldehyde	6.38	127600	127.60
			Sodium bicarbonate	0.3	6000	6.00
5	Erythromycin	10000	Methylene Chloride	5.7	57000	57.00
			Erythromycin Thiocyanate	0.79	7900	7.90
			Caustic Soda	0.07		
6	Stearate		Methyl Chloride	4.1	41000	41.00
			Erythromycin Thiocyanate	0.55		
			Stearic Acid	0.36	3600	3.60
			Caustic Soda	0.07		
7	Estolate		Acetone	1.41	14100	14.10
			Ethyl Acetate	5.63	56300	56.30
			Propionic Anhydride	0.17	1700	1.70
		Erythromycin Thiocyanate	0.59			
		Caustic Soda	0.12	1200	1.20	
		Sodium Lauryl Sulphate	0.31	3100	3.10	
8	Ethambutol Dihydrochloride	20000	IPA	8.125	162500	162.50
			MeOH	2.462 5	49250	49.25
			2- aminobutanol	6.6	132000	132.00
			EDC	0.457 5	9150	9.15
			NaOH	0.321	6425	6.43

				25			
				HCl	0.3575	7150	7.15
9	Pyrazinamide			2-Cyanopyrazine	0.8525	17050	17.05
				NaOH	0.005		
				HCl	0.01		
10	Vildagliptin			MDC	26	52000	52.00
				Acetonitrile	5.785	11570	11.57
				L-Prolinamide	0.9	1800	1.80
				Dimethyl acetamide	2.7	5400	5.40
				THF	2.7	5400	5.40
				2-Butanone	5.785	11570	11.57
				Na2SO4	0.45	900	0.90
				NaCl	0.45	900	0.90
				TEABC	0.305	610	0.61
				Chloroacetylchloride	0.72	1440	1.44
				NaHCO3	0.45	900	0.90
				Trifluoroacetic anhydride	1.645	3290	3.29
				3-amino-1-adamantol	1.29	2580	2.58
				K2CO3	1.855	3710	3.71
				Ethyl Acetate	2.70	5400	5.40
				Cyclohexane	2.70	5400	5.40
			2000	MDC	13.00		
				MeOH	6.50	13000	13.00
11	Linagliptin			Xanthine Derivative	1.35	2700	2.70
				Boc amino Pipridine	0.75	1500	1.50
				DMSO	4.30	8600	8.60
				NaCO3	0.48	950	0.95
				CF3COOH	3.20	6400	6.40
				K2CO3	3.20	6400	6.40
				Toluene	6.35	12700	12.70
				IPA	17.04	34080	34.08
				Thiazole derivative	0.58	1160	1.16
12	Teneligliptin			Piperidine derivative	0.58	1160	1.16
				Sodium triacetoxymborohydride	0.57	1140	1.14
				48% Hydrobromic acid	0.97	1940	1.94
				NaHCO3	0.345	690	0.69

			Charcoal	0.06	120	0.12
			Hyflow	0.06	120	0.12
1 3	Olmesartan	2000	Acetone	24.69	49383.3	49.38
			Acetonitrile	4.32	8633.3	8.63
			MDC	25.13	50266.7	50.27
			Ethyl Acetate	5.72	11433.3	11.43
			Imidazole	0.58	1150.0	1.15
			TTBB	1.47	2933.3	2.93
			Potassium Iodide	0.10	200.0	0.20
			KOH	0.28	550.0	0.55
			K ₂ CO ₃	1.23	2450.0	2.45
			TBAB	0.05	100.0	0.10
			Dimethyl acetamide	0.54	1083.3	1.08
			Medoxomil	0.45	900.0	0.90
			HCl	2.26	4516.7	4.52
			1 4	Erythromycin in 11,12 Carbonate	750	Toluene
IPA	4.09	3067.5				3.07
Acetone	2.1	1575				1.58
Erythromycin	0.97	727.5				0.73
Potassium Carbonate	2	1500				1.50
Ethylene Carbonate	0.8	600				0.60
NaCl	0.31	232.5				0.23
1 5	Succinate	2500	Acetone	2.08	5200	5.20
			Ethyl Acetate	4.63	11575	11.58
			Erythromycin Thiocyanate	0.73	1825	1.83
			Caustic Soda	0.16	400	0.40
			3-ECPC	0.25	625	0.63
			Sodium Bicarbonate	0.32	800	0.80
1 6	Rosuvastatin Calcium	1000	MeOH	6.825	6825	6.83
			MDC	27.3	27300	27.30
			Toluene	21.12 5	21125	21.13
			Acetone	2.425	2425	2.43
			K ₂ CO ₃	0.507 5	507.5	0.51
			NaCO ₃	5.875	5875	5.88
			Hypo Solution	2.775	2775	2.78
			HBR	1.3	1300	1.30
			tRIPHENYLPHOSPHINE	1	1000	1.00
			Aliphatic compound (D5)	1.125	1125	1.13
			DMSO	9.375	9375	9.38

				Na ₂ S ₂ O ₃	4.85	4850	4.85
				Aromatic compound Z7	1.2	1200	1.20
				Pet ether	4.7	4700	4.70
				KBr	0.1	100	0.10
				NaOH	2.35	2350	2.35
				MTBE	4.725	4725	4.73
				HCl	2.975	2975	2.98
				Calcium acetate	0.35	350	0.35
	17	Pregabalin	5000	MeOH	5.55	27750	27.75
				MDC	83.3	416500	416.50
				Racemic carbamoyl	5.95	29750	29.75
				R- benzylamine	2.38	11900	11.90
				TEA	1.67	8350	8.35
				NaOH	1.71	8550	8.55
				Sodium Hypochlorite	4.91	24550	24.55
				HCl	2.61	13050	13.05
				Charcoal	0.06	300	0.30
				Hyflow	0.06	300	0.30
	18	Levetiracetam	10000	Ethyl Acetate	7.00	70000	70.00
				2-aminobutyramide hydrochloride	0.95	9475	9.48
				4-chlorobutyrylchloride	1.06	10600	10.60
				Sodium Sulphate	1.7	17000	17.00
				KOH	1.7	17000	17.00
				A.C.N	13.25	132500	132.50
	19	Ambroxol Hydrochloride	5000	MeOH	3.73	18650	18.65
				IPA	3.205	16025	16.03
				2-amino-3,5-dibromobenzaldehyde	0.745	3725	3.73
				4-aminocyclohexane	0.345	1725	1.73
Sodium borohydride				0.115	575	0.58	
HCl				0.24	1200	1.20	
20				Moxifloxacin Hydrochloride	750	Acetonitrile	5.67
	MDC	10.20	7650			7.65	
	Charcoal	0.07	50			0.05	
	Propionic anhydride	1.23	925			0.93	
	Boric Acid	0.17	125			0.13	

			Nonane	0.33	247.5	0.25
			Sodium carbonate	0.53	400	0.40
			Gati ester	0.83	625	0.63
			Hyflow	0.07	50	0.05
			HCl	1.23	925	0.93
			MeOH	15.15	11362.5	11.36
			NH3	1.57	1175	1.18
2	Sulfadoxine	10000	Methanol	4.495	44950	44.95
1			Sulfanilamide	1.812 5	18125	18.13
			Caustic Soda	1.162 5	11625	11.63
			Glacial Acetic Acid	0.787 5	7875	7.88
			Activated Charcoal	0.02	200	0.20
			Hyflo	0.02	200	0.20
			HCl	1.375	13750	13.75
2	Sofosbuvir	500	MDC	43	21500	21.50
2			MeOH	3.675	1838	1.84
			Ethyl Acetate	23.5	11750	11.75
			Heptane	13.27 5	6638	6.64
			Alanine ester	1.275	638	0.64
			Phenyl dichlorophosphate	1.325	663	0.66
			N-methyl imidazole	3.9	1950	1.95
			Uridine derivative	1.25	625	0.63
			HCl	3.125	1563	1.56
			NaHCO3	3.125	1563	1.56
			Na2SO4	1.55	775	0.78
			Pyridine	34.4	17200	17.20
	t-butyl dimethylsilyl chloride	0.15	75	0.08		
	MTBE	11.72 5	5863	5.86		
2	Pantoprazole Sodium	9000	2-chloromethyl-3,4-dimethoxy pyridine	0.72	6493	6.49
3			Methylene chloride	5.60	50400	50.40
			5-Difluoromethoxy-2-mercaptobenzimidazole	0.73	6557	6.56
			NaOH	0.15	1350	1.35

			HCl 30%	0.05	450	0.45
			Methanol	4.80	43200	43.20
			Ammonium Chloride	1.55	13950	13.95
			Hypo solution	4.00	36000	36.00
			Acetone	6.00	54000	54.00
			Activated carbon	0.10	900	0.90
			Hyflo	0.10	900	0.90
2 4	Saxagliptin	500	Ethyl Acetate	39.95	19975	19.98
			MDC	36.55	18275	18.28
			MeOH	12.18	6090	6.09
			Toluene	4.81	2405	2.41
			Adamantane derivative	1.97	985	0.99
			Azabicyclo derivative	0.985	492.5	0.49
			N- methyl morpholine	3.32	1660	1.66
			Butyl Acetate	4.67	2335	2.34
			Catalyst	4.63	2315	2.32
			NaOH	2.55	1275	1.28
			NaCl	0.41	205	0.21
			Na2SO4	0.61	305	0.31
			THF	20.8	10400	10.40
			Pyridine	1.95	975	0.98
			Trifluoroacetic anhydride	1.34	670	0.67
			K2CO3	3.57	1785	1.79
			Diethyl ether	10.4	5200	5.20
			HCl	2.37	1185	1.19
			Carbon	0.02	10	0.01
			Hyflow	0.02	10	0.01
2 5	Sitagliptin	10000	Ethyl Acetate	29.3	293000	293.00
			IPA	23	230000	230.00
			Triazole derivative	1.19	11900	11.90
			Butanoic acid derivative	1.45	14500	14.50
			Carbomoyldimida zole	0.845	8450	8.45
			HCl	5.24	52400	52.40
			NH3	7.36	73600	73.60
			Orthophosphoric acid	0.54	5400	5.40
15	Production Details					

Sr. No.	Existing Products	Quantity MT / Month
1	Erythromycin Salts	52.55
2	Pyrazinamide Salts	
3	Chloramphenicol	
4	ChloramphenicomPalimitate	
5	Sulphadoxine	
Sr. No.	Proposed Products	Quantity MT /Month
Cardiovascular Products		
1	Atorvastatin	20
2	Losartan Potassium	
3	Telmisartan	
4	Clopidogrel	
Erythromycin Derivatives		10
5	Erythromycin	
6	Erythromycin Stearate	
7	Erythromycin Estolate	
Anti-Tuberculosis Products		20
8	Ethambutol	
9	Pyrazinamide	
Gliptins		2
10	Vildagliptin	
11	Linagliptin	
12	Teneligliptin	
Individual Products		
13	Olmesartan	2
14	Erythromycin 11,12 Carbonate	0.75
15	Erythromycin Ethyl Succinate	2.5
16	Rosuvastatin	1
17	Pregabalin	5
18	Levetricetam	10
19	Ambroxol Hydrochloride	5
20	Moxifloxacin Hydrochloride	0.75
21	Sulfadoxine	10
22	Sofobuvir	0.5
23	Pantoprazole	9
24	Saxagliptin	0.5
25	Sitagliptin	10
	Total /Month	109
	Total /Year	1308
Quantity of the product may vary individually in each group keeping total quantity of all groups same.		
Total production capacity will be 52.5 MT/M + 109 MT/M = 161.5 MT/M		

16	Rain water Harvesting (RWH)	To be proposed.								
17.	Total Water Requirement									
	Source	Consumption(CMD)			Loss(CMD)			Effluent(CMD)		
		Existi ng	Propose d	Total	Existin g	Propose d	Tot al	Existi ng	Propose d	Tota l
	Domesti c	17	12	29	3.5	2.5	6	13.5	9.5	23 (STP)
	Industria l Processi ng	15	120	135	3	29	32	12	91	103
	Cooling Tower	50	98	148	45	88	133	5	10	15
	Boiler Feed	6	15	21	5.5	13.5	19	0.5	1.5	2
	Gardenin g	-	Treated water from STP	-	-	-	-	-	-	-
	Total	88	245	333	57	133	190	31	112	143
18.	Storm water drainage	Natural water drainage pattern: Proper and separate storm water drains available, as per natural slope.								
19.	Sewage generation and treatment	Amt of sewage generation (CMD):23CMD Proposed treatment for the sewage: STP Capacity of STP (CMD): (If Applicable) 30CMD								
20.	Effluent Characteristics	Sr. No.	Parameter s mg/l except pH	Inlet Effluent Characteristi cs	Outlet Effluent Characterist ics	Effluent discharge standards (MPCB)				
		1	pH	5-9	7-8	6.5 -9.0				
		2	TSS	300-350	50-80	<100				
		3	COD	5000-6000	200-240	<250				
		4	BOD 27°C for 3 days	2000-3000	80-90	<100				
		5	TDS	2000-2100	1600-1900	<2100				
			O&G	20-25	5-6	<10				

21.	ETP details	Amount of effluent generation (CMD): 120 CMD Capacity of the ETP:130 CMD Amount of water send to the CETP: 120CMD Membership of CETP (if require): Yes
22.	Note on ETP technology to be used	Primary, Secondary and tertiary treatment will be used to treat the trade effluent. Treated water will be sent to CETP for further treatment.
23.	Disposal of The ETP sludge	ETP sludge will be disposed to CHWTHDF at MWML Taloja.

24.	Solid Waste Management	Sr. No.	Description	Cat	Existing	Proposed	Total	Method of Disposal
		1	Spent Solvent	28.5	--	100 M3/M	100 M3/M	Downstream User
		2	ETP Sludge	34.3	0.05 MT/M	3.6 MT/M	3.65 MT/M	MWML
		3	Carbon Waste	28.8	---	3.4 MT/M	3.4 MT/M	MWML
		4	Empty Drums	33.3	100 nos.	200 nos.	300 nos.	Downstream User

2 5.	Atmospheric Emissions (Flue gas characteristics SPM, SO ₂ , NO _x , CO etc.)	Sr. No.	Pollutant	Source of Emission	Emission rate		Concentration in flue gas
					Existing	Proposed	
		1.	SPM	Boiler	0.01kg/hr	0.04 kg/hr	<150 mg/m ³
2.	SO ₂	Boiler	2.37 kg/hr	5.94 kg/hr	<135 kg/d		

2 6.	Stacks emission Details	Boiler TPH		DG KVA		
		Attached to	Existing	Proposed	Existing	Proposed
		Capacity	0.6 (2 no.)	1.5 (3 No.) One standby	82.5 & 62.5 KVA	150 KVA 2 no.

		Fuel type	LDO	LDO/Briquette	HSD	HSD		
		Fuel qty kg/day	792 kg/day	5940 / 13200	30lit/hr	60 lit/hr.		
		MOC		MS	MS	MS		
		Shape		Round	Rectangular	Rectangular		
		Height m (above ground level)	14	27	-	3.5 above enclosure		
		Control equipments	Stack	Stack	Stack, Acoustic enclosure	Stack, Acoustic enclosure		
27.	Details of Fuel to be used:	Sr. No.	Fuel	Daily consumption (TPD/KLD)		Calorific value (Kcals/kg)	% Ash	% Sulphur
				Existing	Proposed			
		1	LDO	792 kg/day	5940 kg/day	10000	0.02	1.8
		2	Briquette	-	13200 kg/day,	4000	5	-
		3	HSD	30 lit/hr.	60 lit/hr.	11000	0.01	0.05
		Source of Fuel : From market/ out sider fuel companies						
		Mode of Transportation of fuel to site : By Road & through						
28.	Energy	Power Supply : Existing Power requirement : 679 KVA Proposed power requirement : 1018 KVA DG sets: Existing- 2 no. 82.5 & 62.5 KVA capacity Proposed – 2 no. 150 KVA each						
29.	Green Belt Development	Green belt area: 1010 sq. m. Number of species of trees & shrubs to be planted: 50 nos.						
30.	Details of pollution control Systems:	Sr. No.	Source	Existing pollution control system		Proposed to be installed		
		1	Air	By dispersal into atmosphere through chimney of		By dispersal into atmosphere through chimney of adequate/ recommended height.		

				adequate/ recommended height.	
		2	Water	ETP consisting of Primary treatment only.	New ETP consisting of Primary, secondary and Tertiary treatment. Treated effluent will be sent to CETP
		3	Noise	PPE & Acoustic enclosure for existing DG set.	Acoustic enclosure for proposed D.G of 150 KVA & PPE
		4	Solid Waste	Hazardous waste is being disposed to CHWTSDF	Hazardous waste will be disposed to CHWTSDF There is no increment in Non- hazardous waste

Sr. No.	Description	Existing (MTPM)	Proposed (MTPM)	Total (MTPM)
Existing Products				
1	Erythromycin Salts	52.50	NIL	52.50
2	Pyrazinamide Salts			
3	Chloramphenicol			
4	Chloramphenicom Palmitate			
5	Sulphadoxin			
6				
Proposed Products				
A Cardiovascular Products				
1	Atorvastatin	NIL	20	20
2	Losartan Potassium			
3	Telmisartan			
4	Clopidogrel			
B Erythromycin Derivatives				
5	Erithromycin	NIL	10	10
6	Erythromycin Stearate			
7	Erythromycin Estolate			
C Anti Tuberculosis Products				
8	Ethambutol	NIL	20	20
9	Pyrazinamide			
D Gliptins				
10	Vildagliptin	NIL	2	2
11	Linagliptin			
12	Teneligliptin			
E Individual Products				
13	Olmesartan		2	2
14	Erythromycin 11,12 Carbonate		0.75	0.75
15	Erythromycin Ethyl Succinate		2.5	2.5
16	Rosuvastin		1	1
17	Pregabilin		5	5

18	Levetricetam	NIL	10	10
19	Ambroxol Hydrochloride		5	5
20	Moxifloxacin Hydrochloride		0.75	0.75
21	Sulfadoxin		10	10
22	Sofobuvir		0.5	0.5
23	Pantoprazole		9	9
24	Saxagliptin		0.5	0.5
25	Sitagliptin		10	10

Total Production capacity will be 52.50 + 109 Mt/M = 161.50 MT/M

3. The proposal has been considered by SEIAA in its 103rd meeting & decided to accord environmental clearance to the said project under the provisions of Environment Impact Assessment Notification, 2006 subject to implementation of the following terms and conditions:

General Conditions for Pre- construction phase: -

- (i) This environment clearance is issued subject to achieving Zero Liquid Discharge (ZLD).
- (ii) Project Proponent to take utmost precaution for the health and safety of the people working in the unit as also for protecting the environment.
- (iii) No additional land shall be used /acquired for any activity of the project without obtaining proper permission.
- (iv) PP to take utmost precaution for the health and safety of the people working in the unit as also for protecting the environment.
- (v) For controlling fugitive natural dust, regular sprinkling of water & wind shields at appropriate distances in vulnerable areas of the plant shall be ensured.
- (vi) Proper Housekeeping programmers shall be implemented.
- (vii) In the event of the failure of any pollution control system adopted by the unit, the unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieve.
- (viii) A stack of adequate height based on DG set capacity shall be provided for control and dispersion of pollutant from DG set. (If applicable).
- (ix) A detailed scheme for rainwater harvesting shall be prepared and implemented to recharge ground water.
- (x) Arrangement shall be made that effluent and storm water does not get mixed.
- (xi) Periodic monitoring of ground water shall be undertaken and results analyzed to ascertain any change in the quality of water. Results shall be regularly submitted to the Maharashtra Pollution Control Board.
- (xii) Noise level shall be maintained as per standards. For people working in the high noise area, requisite personal protective equipment like earplugs etc. shall be provided.
- (xiii) The overall noise levels in and around the plant are shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers,

enclosures, etc. on all sources of noise generation. The ambient noise levels shall confirm to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989.

- (xiv) Green belt shall be developed & maintained around the plant periphery. Green Belt Development shall be carried out considering CPCB guidelines including selection of plant species and in consultation with the local DFO/ Agriculture Dept.
- (xv) Adequate safety measures shall be provided to limit the risk zone within the plant boundary, in case of an accident. Leak detection devices shall also be installed at strategic places for early detection and warning.
- (xvi) Occupational health surveillance of the workers shall be done on a regular basis and record maintained as per Factories Act.
- (xvii) The company shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling.
- (xviii) The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the Hazardous Waste (Management and Handling) Rules, 2003 (amended). Authorization from the MPCB shall be obtained for collections/treatment/storage/disposal of hazardous wastes.
- (xix) The company shall undertake following Waste Minimization Measures :
 - Metering of quantities of active ingredients to minimize waste.
 - Reuse of by- products from the process as raw materials or as raw material substitutes in other process.
 - Maximizing Recoveries.
 - Use of automated material transfer system to minimize spillage.
- (xx) Regular mock drills for the on-site emergency management plan shall be carried out. Implementation of changes / improvements required, if any, in the on-site management plan shall be ensured.
- (xxi) A separate environment management cell with qualified staff shall be set up for implementation of the stipulated environmental safeguards.
- (xxii) Separate funds shall be allocated for implementation of environmental protection measures/EMP along with item-wise breaks-up. These cost shall be included as part of the project cost. The funds earmarked for the environment protection measures shall not be diverted for other purposes and year-wise expenditure should reported to the MPCB & this department
- (xxiii) The project management shall advertise at least in two local newspapers widely circulated in the region around the project, one of which shall be in the marathi language of the local concerned within seven days of issue of this letter, informing that the project has been accorded environmental clearance and copies of clearance letter are available with the Maharashtra Pollution Control Board and may also be seen at Website at <http://ec.maharashtra.gov.in>

- (xxiv) Project management should submit half yearly compliance reports in respect of the stipulated prior environment clearance terms and conditions in hard & soft copies to the MPCB & this department, on 1st June & 1st December of each calendar year.
- (xxv) A copy of the clearance letter shall be sent by proponent to the concerned Municipal Corporation and the local NGO, if any, from whom suggestions/representations, if any, were received while processing the proposal. The clearance letter shall also be put on the website of the Company by the proponent.
- (xxvi) The proponent shall upload the status of compliance of the stipulated EC 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 MoEF, the respective Zonal Office of CPCB and the SPCB. The criteria pollutant levels namely; SPM, RSPM, SO₂, NO_x (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the project shall be monitored and displayed at a convenient location near the main gate of the company in the public domain.
- (xxvii) The project proponent shall also submit six monthly reports on the status of compliance of the stipulated EC conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF, the respective Zonal Office of CPCB and the SPCB.
- (xxviii) 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 EC conditions and shall also be sent to the respective Regional Offices of MoEF by e-mail.
4. The environmental clearance is being issued without prejudice to the action initiated under EP Act or any court case pending in the court of law and it does not mean that project proponent has not violated any environmental laws in the past and whatever decision under EP Act or of the Hon'ble court will be binding on the project proponent. Hence this clearance does not give immunity to the project proponent in the case filed against him, if any or action initiated under EP Act.
5. The Environment department reserves the right to revoke the clearance if conditions stipulated are not implemented to the satisfaction of the department or for that matter, for any other administrative reason.
6. **Validity of Environment Clearance:** The environmental clearance accorded shall be valid for a period of 7 years as per MoEF & CC Notification dated 29th April, 2015 to start of production operations.
7. In case of any deviation or alteration in the project proposed from those submitted to this department for clearance, a fresh reference should be made to the department to assess the adequacy of the condition(s) imposed and to incorporate additional environmental protection measures required, if any.
8. The above stipulations would be enforced among others under the Water (Prevention and Control of Pollution) Act, 1974, the Air (Prevention and Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 and rules there under, Hazardous Wastes (Management and Handling) Rules, 1989 and its amendments, the public Liability Insurance Act, 1991 and its amendments.

9. Any appeal against this environmental clearance shall lie with the National Green Tribunal (Western Zone Bench, Pune), New Administrative Building, 1st Floor, D-, Wing, Opposite Council Hall, Pune, if preferred, within 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.


(S. M. Gaval)

Member Secretary, SEIAA.

Copy to:

1. Shri T. C. Benjamin, IAS (Retired), Chairman, SEAC-I, 602, PECAN, Marigold, Behind Gold Adlabs, Kalyani Nagar, Pune – 411014. .
2. Additional Secretary, MoEF & CC, Indira Paryavaran Bhavan, Jorbagh Road, Aliganj, New Delhi-110003.
3. Member Secretary, Maharashtra Pollution Control Board, with request to display a copy of the clearance.
4. The CCF, Regional Office, Ministry of Environment and Forest (Regional Office, Western Region, Kendriya Paryavaran Bhavan, Link Road No- 3, E-5, Ravi-Shankar Nagar, Bhopal- 462 016). (MP).
5. Regional Office, MPCB, Thane.
6. Collector, Palghar
7. IA- Division, Monitoring Cell, MoEF & CC, Indira Paryavaran Bhavan, Jorbagh Road, Aliganj, New Delhi-110003.
8. Select file (TC-3)

(EC uploaded on)