

(Constituted by MoEF, Government of India, under section 3(3) of E(P) Act, 1986)

No. SEIAA 54 IND 2020

Date: 05-09-2020

To,

Mr. Sunil Deshmukh Vice President & Site Head M/s. Jubliant Generics Limited, Plot no. 18,56,57-58 & plot no.1 Nanjangud Industrial area, Nanjangud, Mysore District-571302,

Sir,

Sub:

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit at Plot No.18, 56, 57-58 & 1 of Nanjangud KIADB Industrial Area, Nanjangud Taluk, Mysore District, karnataka by M/s. Jubilant Generics Ltd - issue of Environmental Clearance Reg.

* * * *

This has reference to your online application dated 12th August 2020 bearing proposal No.SIA/KA/IND2/167783/2020 addressed to SEIAA, Karnataka on the subject mentioned above. The proposal has been appraised as per procedure prescribed in the provisions under the EIA notification, 2006 on the basis of the mandatory documents enclosed with the application viz., the application in Form-1, Pre-feasibility report, EMP and the additional clarification furnished in response to the observations of the SEAC/SEIAA, Karnataka.

- 2. It is a proposal seeking Environmental clearance for Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit at Plot No.18, 56, 57-58 & 1 of Nanjangud KIADB Industrial Area, Nanjangud Taluk, Mysore District by M/s. Jubilant Generics Ltd. This is a project covered under Sl. No. 5(f) of the Schedule Under of EIA Notification 2006 and amendments made there on.
- 3. It is inter alia noted that the Environmental Clearance has been issued to this project by SEIAA, Karnataka vide letter No. SEIAA 27 IND 2016, dated 28.04.2017 for expansion of manufacturing Active Pharmaceutical Ingredients (API's) & Intermediates of total production capacity of 1,396 MTPA and By-Products of 5,631 MTPA at KIADB Industrial Area of Kallahalli Village, Nanjangud Taluk, Mysore District on a total plot area of 68.55 Acres.
- 4. It is inter-alia noted that M/s. Jubilant Generics Ltd have proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit. The total plot area is 2,77,816.69 Sqm.(68.65 Acres). The Industry

Room No. 706, 7th Floor, 4th Gate, M.S. Building, Bangalore - 560 001 Phone: 080-22032497 Fax: 080-22254377 Website: http://environmentclearance.nic.in http://seiaa.karnataka.gov.in e-mail: msseiaakarnataka@gmail.com

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

will develop greenbelt in an area of 93,041 Sqm i.e 33.49 % out of total area of the project site. The estimated project cost is Rs. 864 Crores. Details of Existing and Proposed Products and By-Products with their capacities are given in Annexure.

The total water requirement for the proposed project is 2041 KLD, and It will be met from the KIADB water supply. The total waste water generation will be 758 KLD, out of which 135 KLD will be the domestic sewage shall be treated in the existing STP of 100 KLD and proposed Additional Sewage treatment plant of 50 KLD. The industrial effluent of 623 KLD shall be segregated into HTDS and LDTS. HTDS effluent of 328 KLD will be treated in existing Physico chemical treatment of 200 KLD followed by MEE of 234 KLD. MEE condensate is treated in existing Biological treatment plant followed by RO and proposed Additional Physico chemical treatment of 200 KLD followed by MEE 200 KLD and ATFD system of 48 KLD. MEE condensate is proposed to be treated in an additional Biological treatment facility followed by RO. LTDS effluent of 295 KLD will be treated in existing Biological treatment plant followed by RO. Incinerator scrubber bleed, RO reject, Evaporator concentrate are treated in Triple effect evaporator followed by ATFD Spray drier. Treated effluent will be recycled for cooling Tower Make up after Ro Existing lean effluent neutralization system is 400 KLD, Biological system is 40 KLD, RO Plant capacity is 150 KLD and proposed additional Biological treatment plant for 400 KLD and RO system of 390 KLD.

Total Power requirement is 11,000KVA and will be met from Chamundeshwari Electricity Supply Company (CESCOM), a Branch of Karnataka State Power Distribution Corporation Limited (KPTCL). Existing unit has DG sets of 1 No X 2250 kVA, 2 No's X 725 kVA, 1 No X 125 kVA, 1 No X 2000 kVA and proposed additional 4 No's X 2000 KVA capacity DG sets and it shall be used as standby during the power failure. Existing unit has 1 No X 15 TPH, 1 No X 6 TPH and additional 1No X 21 TPH Bio diesel/HSD fired boilers. The industrial unit shall have existing 4 Lakh Kilo Cal and 2.05 Lakh Kilo Cal and additional 4 Lakh Kilo Cal Thermic fluid heater. Boilers are connected with stack height of 12.5 to 30 m AGL and proposed boiler will have APC measures like Mechanical dust collection system and bag filter in addition to chimney of required height for controlling the particulate emission within the statutory limit.

- 6. The project proposal was considered by SEAC during the video conference meeting held on 27th August 2020 as B2 category activity in accordance with the Notification S. O. 1223 (E) dated 27th March 2020. Based on the information submitted by you, presentation made by you and your consultant Hubert Enviro Care System (P) Ltd, Chennai, the State Level Expert Appraisal Committee (SEAC) appraised the proposal and has recommended for issue of Environmental Clearance.
- 7. The SEIAA Karnataka has considered the project in its meeting held on 31st August 2020 and after due consideration of the relevant documents submitted by you and additional clarifications furnished in response to its observations and the

सत्यमेव जयते

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

appraisal and recommendation of the SEAC, decided to accord Environmental Clearance in accordance with the provisions of Environmental Impact Assessment Notification-2006 and its subsequent amendments, subject to strict compliance of the following terms and conditions:

I.Statutory compliance

- 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.
- 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-1 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

II Air quality monitoring and preservation

- 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

सत्यपेव जाने

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

monitoring for common/criterion parameters relevant to the main pollutants released (e.g. PM10 and PM2.5 in reference to PM emission, and SO2 and 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.
- 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 16th November, 2009 shall be complied with

III. 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.
- 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.

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SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

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.

IV. 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

V. Energy Conservation measures

i. The energy sources for lighting purposes shall preferably be LED based.

VI. 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:
 - 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.

VII. Green Belt

i. 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.

सत्यमेव जर्ज

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

VIII. 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.
- 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

IX. Corporate Environment Responsibility

- i. The project authorities shall undertake activities under Corporate Environment Responsibility (CER) with a total cost of not less than Rs. 432 Lakhs towards providing drinking water nearby villages, Sanitation and Waste management and Green Belt Development within five years around the project site in accordance with the O.M. F. No.22-65/2017-IA.III dated 01st May 2018 as submitted vide letter dated 04.05.2020.
- 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 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.

सत्यमेव जयते

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

- 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 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.

X. Miscellaneous

- i. The project proponent shall make public the environmental clearance granted for their project along with the environmental conditions and safeguards at their cost by prominently advertising it at least in two local newspapers of the District or State, of which one shall be in the vernacular language within seven days and in addition this shall also be displayed in the project proponent's website permanently.
- ii. The copies of the environmental clearance shall be submitted by the project proponents to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt.
- iii. The project proponent shall upload the status of compliance of the stipulated environment clearance conditions, including results of monitored data on their website and update the same on half-yearly basis.
- iv. The project proponent shall monitor the criteria pollutants level namely; PM10, 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 project proponent shall submit six-monthly reports on the status of the compliance of the stipulated environmental conditions on the website of the ministry of Environment, Forest and Climate Change at environment clearance portal.
- vi. "The HYCRs with its contents of a covering letter, compliance reports, and environmental monitoring data has to be in PDF format merged into a single document. The email should clearly mention the name of project, EC No & date, period of submission and to be sent to the Regional Office of MOEF&CC by email only at email ID rosz.bng-mefcc@gov.in Hard copy of HYCRs shall not be acceptable".

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SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

- vii. 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.
- viii. The project proponent shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities, commencing the land development work and start of production operation by the project.
 - ix. The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board and the State Government.
 - x. The project proponent shall abide by all the commitments and recommendations made in the EIA/EMP report, commitment made during Public Hearing and also that during their presentation to the Expert Appraisal Committee.
 - xi. No further expansion or modifications in the plant shall be carried out without prior approval of this Authority or the Ministry of Environment, Forests and Climate Change (MoEF&CC).
- xii. Concealing factual data or submission of false/fabricated data may result in revocation of this environmental clearance and attract action under the provisions of Environment (Protection) Act, 1986.
- xiii. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.
- xiv. The SEIAA reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.
- xv. The Regional Office of MoEF&CC shall monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer (s) of the Regional Office by furnishing the requisite data / information/monitoring reports.
- xvi. The above conditions shall 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, Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and Rules and any other orders passed by the Hon'ble Supreme Court of India / High Courts and any other Court of I aw relating to the subject matter.

सत्यपेव जयते

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SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

xvii. Any appeal against this EC shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.



Yours faithfully,

(Vijayakumar Gogi) Member Secretary, SEIAA, Karnataka.

Copy to:

- 1) The Secretary, Ministry of Environment, Forests and Climate Change, Indira Paryavaran Bhavan, Jor Bagh Road, Aliganj, New Delhi- 110 003.
- 2) The Member Secretary, Karnataka State Pollution Control Board, Bangalore.
- 3) The APCCF, Regional Office, Ministry of Environment & Forests (SZ), Kendriya Sadan, IV Floor, E & F wings, 17th Main Road, Koramangala II Block, Bangalore 560 034.
- 4) Guard File.

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

Annexure List of Existing and Proposed products and byproducts

Existing and after expansion Products

S.No	PRODUCTS	CFO Volume	Available EC Quantity, KGPA	Proposed	Proposed EC Quantity, KGPA
	Anti IBS			84. ¹ N	
1	Tegaserod		50	0	50
	Sub Total	0	50	0	50
1	Alpha/Beta Adrenergic Agonists				
2	Droxidopa	50	300	0	300
5.	Sub Total	50	300	0	300
1	Anesthetic				
. 3	Ropivacaine	15	15	35	50
	Sub Total	15	15	35	50
	Anti anginals				
4	Ranolazine	10000	10000	10000	20000
	Sub Total	10000	10000	10000	20000
	Anti Convulsant/Antiepileptics				
5	Lacosamide	1500	4000	2953	6953
	Sub Total	1500	4000	2953	6953
	Anti hypertension				
6	Macitentan		50	0	50
	Sub Total	0	50	0	50
	Anti Parkinson's				
7	Safinamide	50	50	50	100
8	Pimavanserin tartrate	100	100	0	100
	Sub Total	150	150	50	200
	Antialzheimer				
9	Donepezil	5300	7000	0	7000
10	Galanthamine	150	250	1048	1298
	Sub Total	5450	7250	1048	8298
	Anti-androgen		and the second		NENTAL IM
11	Bicalutamide		20	0 0	20
17/12	Sub Total	0	20	0/3/	20
	Antibacterial			1/200/	74.54
12	Azithromycin	90000	124236	-33481	90755
13	Roxithromycin		50	QUI	50

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

S.No	PRODUCTS	CFO Volume	Available EC Quantity, KGPA	Proposed	Proposed EC Quantity, KGPA
14	Telithromycin		50	0	50
15	Gemifloxacin	l squake	50	0	50
16	Linazolid	500	6000	-5900	100
17	Halogenated aromatic heterocyclic aliphetic derivatives (e.g. Ro 4935028, Oxazolidinone etc)		500	. 0	500
	Sub Total	90500	130886	-39381	91505
50	Anticancer				
18	Anastrozole		10	0	10
19	Docetaxel / Paclitaxel		10	- 10	0
20	Gemcitabine		10	0	10
21	Temozolomide	24	10	0	10
22	Pemetrexed		30	0	30
23	Letrozole	A CONTRACTOR	10	0	10
24	Oxaliplatin	(118.4)	10	0	10
25	Fulvestrant		20	-20	0
26	Irinotecan/Topotecan	*	20	0	20
27	Azacitidine		10	0	10
28	other Nische API like Erlotinib, Necarabine, etc.		70	0	70
	Sub Total	0	210	-30	180
	Anticholinergic bronchodilator			1500	
29	Tiotropium Bromide	=	50	0	50
1	Sub Total	0	50	0	50
	Anticoagulant			7 E 1 7 St. 2 La 10 PP	
30	Dabigatran etexilate Mesylate	1250	1250	13221	14471
31	Rivaroxaban	40	40	3715	3755
32	Apixaban	20	20	730	750
33	Betrixaban	50	50	0	50
	Sub Total	1360	1360	17666	19026
	Anticonvulsant/Anti- Epiliptic				TAL IMPAC
34	Oxcarbazepine	167564	167564	24436	192000
35	Carbamazepine	250000	250000	40000/	290000
36	Tiagabine	1 - 1 Res	50	0.	50
37	Lamotrigine	38467	38467	26533	65000

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

S.No	PRODUCTS	CFO Volume	Available EC Quantity, KGPA	Proposed	Proposed EC Quantity, KGPA
38	Levetiracetam	30000	30000	-29000	1000
39	Eslicarbazepine	3000	3000	22000	25000
40	Brivaracetam	500	500	0	500
41	Pregabalin	50	50	-50	0
291	Sub Total	489581	489631	83919	573550
- 14	Antidepressant				
42	Citalopram	20184	34474	-9474	25000
43	Escitalopram	5292	5292	10708	16000
44	Paroxetine	520	5250	250	5500
45	Bupropion	54000	75616	-55616	20000
46	Duloxetine	2000	9500	-8500	1000
47	Atomoxetine		50	0	50
48	Vilazodone	75	75	725	800
49	Perphenazine	16	16	1984	2000
50	Vortioxetine		0	500	500
	Sub Total	82087	130273	-59423	70850
	Antidiabetic				-
51	Repaglinide	50	50	0	50
52	Saxagliptin	16	16	284	300
53	Sitagliptin	150	150	49850	50000
54	Vildagliptin	3600	3600	46400	50000
55	Canagliflozin	500	500	-500	0
56	Empagliflozin	50	50	4950	5000
57	Dapagliflozin	50	50	-50	0
	Sub Total	4416	4416	100934	105350
	Antiemetic				
58	Aprepitant	300	800	200	1000
59	Dronabinol	Se	10	0	10
60	Rolapitant		90	-90	0
61	Netupitant	a T.	300	0	300
	Sub Total	300	1200	110	1310
	Antifibrotic agent			//	FAL IMPACE
62	Pirfenidone	50	50	2750	2800
47 (3)	Sub Total	50	50	2750	2800
	Antifungal			12/	(E. Jan Jan)
63	Voriconazole	425	425	1575	2000
	Sub Total	425	425	1575	2000

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

S.No	PRODUCTS	CFO Volume	Available EC Quantity, KGPA	Proposed	Proposed EC Quantity, KGPA
	Antigout				
64	Febuxostat	1400	4500	4500	9000
-, 1	Sub Total	1400	4500	4500	9000
	Antihistamine				effection -
65	Cetirizine	250	500	500	1000
66	Levocetirizine	200	200	0	200
67	Meclizine	4140	4140	12000	16140
68	Fexofenadine	100	100	0	100
	Sub Total	4690	4940	12500	17440
* -	Antihypertensive			, A -411	11,0
69	Losartan	26670	26670	53330	80000
70	Valsartan	135697	135697	74303	210000
71	Irbesartan	36990	38396	26604	65000
72	Eprosartan	50	50	0	50
73	Telmisartan	6000	14388	-4388	10000
74	Candesartan	500	5000	-4000	1000
75	Olmesartan	3600	11067	933	12000
76	Lisinopril		50	-50	0
77	Bosentan	160	160	0	160
78	Guanfacine	10	10	40	50
79	Labetalol	is to the contract of	7000	-7000	0
80	Sacubitril	100	100	15900	16000
10.5	Sub Total	209777	238588	155672	394260
	Antilipemic				
81	Simvastatin		50	0	50
82	Atorvastatin	850	850	650	1500
83	Ezetimibe		50	0	50
84	Fluvastatin		50	0	50
85	Rosuvastatin	1150	12000	-12000	0
. [11]	Sub Total	2000	13000	-11350	1650
	Antihyperlipidemic			1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
86	Niacin	10000	75000	-50000	25000
	Sub Total	10000	75000	-50000	25000
190	Antimigraine	y. ×		1	2000
87	Rizatriptan	50	100	0/3/	100
88	Zolmitriptan	25	30	120	150
89	Eletriptan		30	0.	30

13

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

S.No	PRODUCTS	CFO Volume	Available EC Quantity, KGPA	Proposed	Proposed EC Quantity, KGPA
90	Naratriptan		10	0	10
91	Almotriptan		10	0	10
	Sub Total	75	180	120	300
	Antimuscarinic		qishve.		
92	Solifenacin	1262	1628	372	2000
93	Darifenacin	261	261	-111	150
	Sub Total	1523	1889	261	2150
	Antiparkinsonian				
94	Rivastigmine	120	708	-528	180
95	Entacapone	50	50	0	50
96	Cabergoline		50	-50	0
	Sub Total	170	808	-578	230
	Antiplatelet				
97	Clopidogrel	4000	50500	-50400	100
	Sub Total	4000	50500	-50400	100
	Antipsychotic		1		
- 98	Risperidone	1322	1322	1678	3000
99	Quetiapine	15000	18570	20000	38570
100	Olanzapine	2922	2931	2569	5500
101	Ziprasidone	450	2063	0	2063
102	Lurasidone	200	200	800	1000
103	Paliperidone	50	80	420	500
104	Brezpiprazole	40	40	0	40
105	Aripiprazole	1508	1508	371	1879
, 13	Sub Total	21492	26714	25838	52552
κ.	Antiulcerative				141 (2)
106	Rabeprazole	543	543	-343	200
107	Pantoprazole	13000	13831	169	14000
108	Lansoprazole	1550	3950	-3950	0
108	Esomeprazole magnesium	25046	28075	1925	30000
110	Esomeprazole Sodium		0	250	250
111	Dexlansoprazole	10	10	0	TALIOPAC
la kij	Sub Total	40149	46409	-1949	44460
	Antiviral			//29/	A TOP
112	Valacyclovir	14836	31397	-26397	5000
113	Adefovir	1	50	0	50
114	Emtricitabine		50	0	50

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

S.No	PRODUCTS	CFO Volume	Available EC Quantity, KGPA	Proposed	Proposed EC Quantity, KGPA
115	Remdesivir		0	500	500
116	Oseltamivir		0	150	150
0.0	Sub Total	14836	31497	-25747	5750
	Autonomic Drugs (Smoking Cessation)				
117	Varenicline	50	50	250	300
	Sub Total	50	50	250	300
	Bone resorption inhibitor		4, 19		
118	Zoledronic Acid	50	50	0	50
119	Residronate	400	464	239	703
120	Alendronate	1000	3300	-2300	1000
121	Ibandronate		50	0	50
	Sub Total	1450	3864	-2061	1803
	Calcimimetic				
122	Cinacalcet	50	50	0	50
	Sub Total	50	50	0	50
	Central Nervous System Agent (Anti Multiple sclerosis)				
123	Fampridine	120	120	880	1000
	Sub Total	120	120	880	1000
	Chelating agent			MATE STATE	
124	Deferasirox	1150	4247	2253	6500
	Sub Total	1150	4247	2253	6500
6.5	CNS Stimulant	~			
125	Dex Methylphenidate		50	0	50
<i>i</i> .	Sub Total	0	50	0	50
*	Estrogen for harmone replacement therapy			1 Tarker Tr	
126	Equilin	(37.9)	50	0	50
TEST	Sub Total	0	50	0	50
1	Gastrointestinal disorders				
127	Pinaverium bromide	21050	21050	18950	40000
1	Sub Total	21050	21050	18950	40000
1000	Immunosuppressant			(65)	22700
128	Mycophenalate mofetil		20	0.	20
	Sub Total	0	20	0	20

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

S.No	PRODUCTS	CFO Volume	Available EC Quantity, KGPA	Proposed	Proposed EC Quantity, KGPA
	Intravenous MR Contrast agent for CNS	3			
129	BOPTA		40	0	40
	Sub Total	0	40	0	40
i e de	Iron Chilating agent	157		1.1.184 1 A	
130	Pentetic acid	400	800	0	800
	Sub Total	400	800	0	800
	Musculoskeletal Agent (Antipsoriasis)	12/1			
131	Apremilast	130	130	120	250
	Sub Total	130	130	120	250
· ·	Opioid Analgesic		-		
132	Tramadol	78000	82000	12550	94550
	Sub Total	78000	82000	12550	94550
	Oral Contraceptive				
133	Drospirenone		50	0	50
	Sub Total	0	50	0	50
	PDE5 inhibitor				
134	Tadalfil	450	1780	0	1780
135	Vardenifil		0	100	100
	Sub Total	450	1780	100	1880
-130	Phosphate binder	f			1.44
136	Lanthum Carbonate	(1)	200	0	200
	Sub Total	0	200	0	200
	Platelet Aggregation Inhibitor			22.7.20	
137	Ticagrelor	274	274	801	1075
	Sub Total	274	274	801	1075
	Sedative-Hypnotic Drugs	han of a	an man i i	-	
138	Zopiclone	100	100	0	100
	Sub Total	100	100	0	100
	Selective alpha-1 antagonist				
139	Terazosin	50	50	1750	1800 C
	Sub Total	50	50	1750	1800
-2	Tetracycline Antibiotic		2000 2000 1	/29/	CA POPEN
140	Minocycline	A CONTRACT OF THE PROPERTY OF THE	50	/0/	50
T.	Sub Total	0	50	9	50
4-5	Urinary antispasmodics	(V)			200

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

S.No	PRODUCTS	CFO Volume	Available EC Quantity, KGPA	Proposed	Proposed EC Quantity, KGPA
141	Mirabegron	530	530	0	530
	Sub Total	530	530	0	530
	OTHERS				
142	Aldehyde ketone aromatic heterocyclic aliphatic derivatives (e.g. Sergeant etc)	100	500	0	500
143	Aminated hydroxy nitro aromatic heterocyclic aliphatic derivatives (e.g. Amino alcohol etc)	100	500	0	500
144	New products for Development and Validations	5000	5000	0	5000
	Sub Total	5200	6000	0	6000
	Hormone antagonist				Table 1
145	Elagolix		0	1000	1000
	Sub Total	0	0	1000	1000
	Oncology				
146	Tofacitinib		0	120	120
147	Ruxolitinib		0	50	50
	Sub Total	0	0	170	170
1,000	Anti Malarial			5 1,1	
148	Hydroxychloroquine		0	200	200
	Sub Total	0	0	200	200
Đại Đại	Antihemorrhagics	- 1 (4)			
149	Eltrombopag	70 9	0	250	250
	Sub Total	0	0	250	250
	Total	1105000	1395866	218286	1614152

Summary for products

S.N o	Description	Present EC	Dropped	Added	Total After Expansion (for proposed EC)
1	No. of Products	139	11	10	138
2	No. of Therapeutic products	53	0	4	57
3	Total Capacity (MTPA)	1395.866	-304.208	522.494	1614.152

(Constituted by MoEF, Government of India under section 3(3) of E(P) Act, 1986)

SEIAA 54 IND 2020

Proposed Expansion of Active Pharmaceutical Ingredients (APIs) & Intermediates in existing Manufacturing Unit by M/s. Jubilant Generics Ltd

Existing and after expansion By products

S.No	By - Products	Existing, MTPA	Additional MTPA	Total after expansion MTPA
1	Acetic Acid	1090	174	1264
2	Sodium Sulphide	2328	373	2701
3	Magnesium Salts	193	0	193
4	Formyl Mixture (Acetic & Formic Acid)	22	0	22
5	Sodium Benzoate	297	43	340
6	Ammonium Bromide & Chloride	20	3	23
7	Potassium Carbonate	5	0	5
.8	Sulphuric Acid	180	124	304
9	Dimethyl Sulfoxide	59	0	59
10	Ammonium Sulfate	283	0	283
11	Ammonium Acetate	662	0	662
12	Mono Chloro Acetate	334	0	334
13	Sodium Bromide	28	0	28
14	TEA HCL	130	0	130
	Total	5631	717	6348

Summary for by products

S.No	Description	Present EC	Dropped	Added	Total After Expansion (for proposed EC)
1	No. of byproducts	14	0	0	14
2	Total capacity (MTPA)	5631	0	717	6348



(Vijayakumar Gogi) Member Secretary, SEIAA, Karnataka.