ENVIRONMENTAL CLEARANCE

PARIVESH

(Pro-Active and Responsive Facilitation by Interactive, and Virtuous Environmental Single-Window Hub)

Government of India
Ministry of Environment, Forest and Climate Change
(Issued by the State Environment Impact Assessment Authority(SEIAA), Karnataka)

To,

The AVP

M/S STELIS BIOPHARMA (P) LTD

Stelis Biopharma Private Limited, Obadenahalli Village, Doddaballapur Mandal Bangalore Rural -561205

Subject: Grant of Environmental Clearance (EC) to the proposed Project Activity under the provision of EIA Notification 2006-regarding

Sir/Madam,

This is in reference to your application for Environmental Clearance (EC) in respect of project submitted to the SEIAA vide proposal number SIA/KA/IND2/225232/2021 dated 17 Aug 2021. The particulars of the environmental clearance granted to the project are as below.

1.	**EC Identification No.**	**EC22B058KA199611**
2.	**File No.**	SEIAA 51 IND 2021
3.	**Project Type**	Expansion
4.	**Category**	B2
5.	**Project/Activity including Schedule No.**	5(f)-API
6.	**Name of Project**	Proposed Expansion of Integral Bulk Drug Biopharmaceutical facility to manufacture the Biologicals- Monoclonal Antibodies & Therapeutic Proteins
7.	**Name of Company/Organization**	M/S STELIS BIOPHARMA (P) LTD
8.	**Location of Project**	Karnataka
9.	**TOR Date**	N/A

The project details along with terms and conditions are appended herewith from page no 2 onwards.

(e-signed)
Sri Vijay Mohan Raj V.,IFS
Member Secretary
SEIAA - (Karnataka)

Date: 07/03/2022

Note: A valid environmental clearance shall be one that has EC identification number & E-Sign generated from PARIVESH.Please quote identification number in all future correspondence.

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सत्यमेव जयते

State Level Environment Impact Assessment Authority-Karnataka

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

No. SEIAA 51 IND 2021

To,

M/s Stelis Biopharma Limited,
Plot No-2D-1, Obadenahalli Village,
Doddaballpura 3rdphase Industrial area,
Doddaballapur Taluk,
Bengaluru Rural District - 561203

Sir,

Sub: Expansion of Integral Bulk Drug Biopharmaceutical facility to manufacture the Biologicals- Monoclonal Antibodies & Therapeutic Proteins Project at Sy. No. 14/2,14/3,14/4,15/1, 15/2, 15/3, 15/4,15/5,16,17/1,17/2,17/3,17/4 & 17/5 of Plot No-2D-1, and Sy.No. 5, 15/4, 15/3 & 16 of Plot No. 2E-2 of Obadenahalli Village, Doddaballpura 3rdphase Industrial area, Doddaballapur Taluk, Bengaluru Rural District, Karnataka by M/s Stelis Biopharma Limited, - issue of Environmental Clearance Reg.

* * * *

1. This has reference to your online application dated 17th August 2021 bearing proposal No. SIA/KA/IND2/225232/2021addressed 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, and the additional clarification furnished in response to the observations of the SEAC, Karnataka.

2. It is a proposal seeking Environmental Clearance for Expansion of Integral Bulk Drug Biopharmaceutical facility to manufacture the Biologicals- Monoclonal Antibodies & Therapeutic Proteins Project at Sy. No. 14/2,14/3,14/4,15/1, 15/2, 15/3, 15/4,15/5,16,17/1,17/2,17/3,17/4 & 17/5 of Plot No-2D-1, and Sy. No. 5, 15/4, 15/3 & 16 of Plot No. 2E-2 of Obadenahalli Village, Doddaballpura 3rd phase Industrial area, Doddaballapur Taluk, Bengaluru Rural District, Karnataka by M/s Stelis Biopharma Limited. 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 M/s Stelis Biopharma Limited had obtained Environmental Clearance vide letter No. SEIAA 03 IND 2019 dated 22.08.2019 for Upgradation/ Modernization of existing formulation facility to Integral Bulk Drug Biopharmaceutical facility

to manufacture the Biologicals - Monoclonal Antibodies & Therapeutic Proteins project with the total capacity of production of the project was 1910 kg/annum of API and 153 lakh units/ month of formulations.

4. It is inter-alia noted that M/s Stelis Biopharma Limited have proposed Expansion of Integral Bulk Drug Biopharmaceutical facility to manufacture the Biologicals- Monoclonal Antibodies & Therapeutic Proteins Project. The total plot area is 47,757.33 Sq.m (11.8Acres) (Existing land area is 40,473 Sq.m - 10 Acres + Proposed area is 7,284.33Sq.m - 1.8 Acres). Industry developed greenbelt in an area of 15,776.96 Sqm.i.e.33.04% out of total area of the project site. The estimated project cost is Rs. 170.00Crores. The details of proposed products to be manufactured with capacities are given in ANNEXURE: -1

The total water requirement for the proposed project is 413 KLD (including recycled water – 186KLD), and It will be met from the KIADB water supply/in-house bore well/Private water tanker, the waste water generation will be 170 KLD (including domestic sewage – 20KLD). The domestic sewage shall be treated in existing STP of 20 KLD Capacity. The Industrial effluents will be treated in existing ETP of capacity of 170 KLD and followed by RO and MEE Capacity of 25 KLD. Details of untreated effluent characteristics are given in ANNEXURE – 2. Power requirement is 5750KVA and will be met from BESCOM.

It is proposed to install DG set of 2 No's X 2010 KVA with the existing 3 No's X 1010 KVA, the proposed DG set will be standby during the power failure. The industry unit shall havel No. X 5 TPH, 2 No's X 3 TPH (Existing) and 1 X 6 TPH capacity Boiler (Proposed). The details of hazardous waste is given in ANNEXURE -3.

5. The project proposal was considered by SEAC during the meeting held on 04.01.2022 as B2 category activity in accordance with the Notification S.O. 1223 (E) dated 27th March 2020, Notification S.O. 3636 (E) dated 15th October 2020 and Notification S.O. 2859 (E) dated 16th July 2021. Based on the information submitted by you, presentation made by you and your consultant, the State Level Expert Appraisal Committee (SEAC) apprised the proposal and has recommended for issue of Environmental Clearance.

6. The SEIAA Karnataka has considered the project in its meeting held on 5th February 2022 and after due consideration of the relevant documents submitted by you and additional clarifications furnished in response to its observations and the 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.

iii. The project proponent shall prepare a Site-Specific Conservation Plan & Wildlife Management Plan and approved by the Chief Wildlife Warden. The recommendations of the approved Site-Specific Conservation Plan / Wildlife Management Plan shall be implemented in consultation with the State Forest Department. The implementation report shall be furnished along with the six-monthly compliance report. (Incase of the presence of schedule-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 systems from time to time according to equipment supplier specification through labs recognised under Environment (Protection) Act, 1986 or NABL accredited laboratories.

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

iii. The project proponent shall install system to carryout Ambient Air Quality monitoring for common/criterion parameters relevant to the main pollutants released (e.g. 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.
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 of 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.

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. Firefighting 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 Proponent shall comply with provision contained in OM vide F.No. 22-65/2017-IA.III Dated 20th October 2020, of the Ministry of Environment, Forest and Climate Change as applicable, regarding Corporate Environment Responsibility and shall execute the action plan of providing drinking water supply to nearby villages, Infrastructure development to local Government hospitals, School infrastructure development and Lake development, etc., as submitted vide letter dated 26/11/2021.
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 shareholder's / stake holders. The copy of the board resolution in this regard shall be submitted to the MoEF & CC as a part of six-monthly report.

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

iv. Action plan for implementing EMP and environmental conditions along with responsibility matrix of the company shall be prepared and shall be duly approved by competent authority. The year wise funds earmarked for environmental protection measures shall be kept in separate account and not to be diverted for any other 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. Effort shall be made to replace Hexane, Toluene and Bromine by alternatives as per the SEAC condition.

ii. 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.

iii. 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.

iv. 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.

v. 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.

vi. 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.

vii. "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".

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

ix. The 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.

x. The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board and the State Government.

xi. 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.

xii. 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).

xiii. 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.

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

xv. The SEIAA reserves the right to stipulate additional conditions if found necessary. The Company in a time bound manner shall implement these conditions.

xvi. 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.

xvii. 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 Law relating to the subject matter.

xviii. 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,

(Vijay Mohan Raj V)
Member Secretary,
SEIAA, Karnataka.

07/03/22

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

ANNEXURE – 1

THE LIST OF PROPOSED PRODUCTSWITH CAPACITIES

Sl. No	Name of the product	Existing (Kg/Annum)	Proposed (Kg/Annum)	After Expansion (Kg/Annum)
1	Bevacizumab	100	0	100
2	Adalimumab	50	0	50
3	Aflibercept	50	0	50
4	Denosumab	20	0	20
5	Trastuzumab	20	0	20
6	Olaratumab	10	0	10
7	Omalizumab	10	0	10
8	Palivizumab	10	0	10
9	Panitumumab	10	0	10
10	Tocilizumab	10	0	10
11	Trastuzumabemtansine	10	0	10
12	Infliximab	10	0	10
13	Eculizumab	10	0	10
14	Etanercept	10	0	10
15	Ziv-aflibercept	10	0	10
16	Rituximab	10	0	10
17	Ramucirumab	5	0	5
18	Raxibacumab	5	0	5
19	Sarilumab	5	0	5
20	Inotuzumabozogamicin	4	0	4
21	Brodalumab	2	0	2
22	Abatacept	2	0	2
23	Abciximab	2	0	2
24	Agalsidasebeta	2	0	2
25	Alemtuzumab	2	0	2
26	Alglucosidasealfa	2	0	2
27	Alirocumab	2	0	2
28	Alteplase,cathfloactivase	2	0	2
29	Anakinra	2	0	2
30	Asfotasealfa	2	0	2
31	Atezolizumab	2	0	2
32	Avelumab	2	0	2
33	Basiliximab	2	0	2
34	Belatacept	2	0	2
35	Belimumab	2	0	2
36	Benralizumab	2	0	2
37	Bezlotoxumab	2	0	2
38	Blinatumomab	2	0	2
39	Brentuximab vedotin	2	0	2
40	Canakinumab	2	0	2
41	Cerliponasealfa	2	0	2

42	Certolizumab pegol	2	0	2
43	Cetuximab	2	0	2
44	Daclizumab	2	0	2
45	Daratumumab	2	0	2
46	Darbepoetin alfa	2	0	2
47	Dinutuximab	2	0	2
48	Dornasealfa	2	0	2
49	Dulaglutide	2	0	2
50	Dupilumab	2	0	2
51	Durvalumab	2	0	2
52	Elosulfasealfa	2	0	2
53	Elotuzumab	2	0	2
54	Emicizumab	2	0	2
55	Epoetinalfa	2	0	2
56	Evolocumab	2	0	2
57	Follitropin	2	0	2
58	Galsulfase	2	0	2
59	Gemtuzumabozogamicin	2	0	2
60	Golimumab	2	0	2
61	Guselkumab	2	0	2
62	Ibritumomab tiuxetan	2	0	2
63	Idarucizumab	2	0	2
64	Idursulfase	2	0	2
65	Ipilimumab	2	0	2
66	Ixekizumab	2	0	2
67	Laronidase	2	0	2
68	Mepolizumab	2	0	2
69	Methoxypolyethyleneglycol - epoetinbeta	2	0	2
70	Natalizumab	2	0	2
71	Necitumumab	2	0	2
72	Nivolumab	2	0	2
73	Obiltoxaximab	2	0	2
74	Obinutuzumab	2	0	2
75	Ocrelizumab	2	0	2
76	Ofatumumab	2	0	2
77	Pembrolizumab	2	0	2
78	Pertuzumab	2	0	2
79	Reslizumab	2	0	2
80	Rilonacept	2	0	2
81	Secukinumab	2	0	2
82	Siltuximab	2	0	2
83	Somatropin	2	0	2
84	Tenecteplase	2	0	2
85	Ustekinumab	2	0	2
86	Vedolizumab	2	0	2
87	Vestronidasealfa	2	0	2
88	Itolizumab	2	0	2

89	Nimotuzumab	2	0	2
90	Insulinglargine	350	0	350
91	Insulinlispro	250	0	250
92	Insulinaspart	200	0	200
93	Rh-Insulin	100	0	100
94	Teriparatide	10	0	10
95	Hyaluronicacid	50	0	50
96	Streptokinase	50	0	50
97	Filgrastim	50	0	50
98	Insulindeglutec	50	0	50
99	Insulindetemir	50	0	50
100	Insulinglulisine	50	0	50
101	Collagenase	20	0	20
102	Pegfilgrastim	10	0	10
103	Peginterferonalfa-2a	10	0	10
104	Peginterferonalfa-2b	10	0	10
105	Peginterferonbeta-1a	10	0	10
106	Pramlintide	10	0	10
107	Ranibizumab	10	0	10
108	Tbo-filgrastim	10	0	10
109	Interferonalfa-2b	10	0	10
110	Interferonbeta-1a	10	0	10
111	Dulaglutide	10	0	10
112	Interferon alfa-n3	5	0	5
113	Interferon beta-1b	5	0	5
114	Interferon gamma-1b	5	0	5
115	Albiglutide	5	0	5
116	Exenatide	5	0	5
117	Liraglutide	5	0	5
118	Lixisenatide	5	0	5
119	Parathyroid hormone	4	0	4
120	Aldesleukin	2	0	2
121	Asparaginase	2	0	2
122	Becaplermin	2	0	2
123	Ecallantide	2	0	2
124	Glucarpidase	2	0	2
125	Metreleptin	2	0	2
126	Ocriplasmin	2	0	2
127	Oprelvekin	2	0	2
128	Palifermin	2	0	2
129	Pegaspargase	2	0	2
130	Pegloticase	2	**0**	**2**
131	Rasburicase	2	0	2
132	Reteplase	2	0	2
133	Romiplostim	2	0	2
134	Sargramostim	2	0	2

135	Semaglutide	2	0	2
136	Somatropin	2	0	2
Total		**1910**	**0**	**1910**

Formulation products Quantity

Description	**Unit**	**Quantity**
Cartridges	Lakhs unit/month	36
Prefilled Syringes	Lakhs unit/month	27
Vials and lyophilized vials	Lakhs unit/month	90
Total Quantity	**Lakhs unit/month**	**153**

List of Formulation Products

S. No	**Name of Products (Injectables-Cartridges, Pre Filled Syringes, Vials/Lyophilized Vials)**
1	Acetazolamide Inj
2	Acyclovir Inj.
3	Adenosine Inj.
4	Alprostadil Inj.
5	Amifostine Inj.
6	Amiodarone Inj.
7	Amphotericin B Inj.
8	Amphotericin B Liposomal Inj.
9	Anectine Inj.
10	Aquasol-A (vit A) Inj,
11	Argatroban Inj.
12	AtracuriumBesylate Inj.
13	Azithromycin Inj.
14	Bacitracin Inj.
15	Bumetanide Inj.
16	Bupivacaine Inj.
17	Calcium folinate Inj.
18	Caspofungin Inj.
19	CisatracuriumBesylate Inj.
20	Clindamycin Inj.
21	Cyanocobalamin Inj.
22	Dantrolene Sod Inj.
23	Daptomycin Inj.
24	Deferoxamine Inj.
25	Diltiazem Inj.
26	Dipyrimadole Inj.
27	Eptifibatide Inj.
28	Erythromycin Inj.

29	Esomeprazole Inj.
30	Famotidine Inj.
31	Flucanozole
32	Fluphenazine Inj.
33	Fomepizole Inj.
34	Fosphenytoin Inj.
35	Furosemide Inj.
36	Ganciclovir Inj.
37	Ganciclovir Inj.
38	Ganciclovir Inj.
39	Gentamycin Inj.
40	Gentamycin Inj.
41	Glucagon Inj.
42	Granisetron Inj.
43	Haloperidol Decanoate Inj.
44	Haloperidol Inj.
45	Heparin Inj.
46	Ibuprofen Inj.
47	Iron Ferric (Sucrose)
48	Ketorolac Inj.
49	Labetalol Inj.
50	Leucovorin Calcium Inj.
51	Levetiracetam Inj.
52	Levofloxacin Minibag
53	Levothyroxine inj.
54	Lidocaine Inj.
55	Magnesium sulfateMinibag
56	Methocarbamol Inj.
57	Metoprolol Inj.
58	Metronidazole Minibag
59	Midazolam Inj.
60	Milrinone Inj.
61	MilrinoneMinibag
62	MoxifloxacinMinibag
63	Mycophenolate Inj.
64	Nalbuphine Inj.
65	Nesiritide Inj.
66	Nicardipine Inj.
67	Norepinephrine Inj. (Noradrenaline)
68	Octreotide Inj.
69	Olanzapine Inj.
70	Omeprazole Inj.
71	Ondansetron Inj.
72	Other New Products
73	Paliperidone Inj.
74	Pantoprazole Inj.

75	Polymyxin Inj.
76	Procainamide Inj.
77	Propofol Inj.
78	Ranitidine Inj.
79	RocuroniumInj
80	RocuroniumInj
81	RopivacaineMinibag
82	Sincalide Inj.
83	Sulphamethoxazole+Trimethoprim
84	Thiotepa Inj.
85	Tigecycline Inj.
86	Tobramycin Inj.
87	Tranexamic Acid Inj.
88	Vancomycin Inj.
89	Vecuronium Inj.
90	Zoledronic Inj.

ANNEXURE – 2

UNTREATED EFFLUENT CHARACTERISTICS

Sl. No.	Parameter	Expected range
1	pH	6.0 – 8.0
2	TDS (mg/l)	800 - 2000
3	COD(mg/l)	4000 - 4500
4	BOD(mg/l)	1300 - 1500
5	TSS(mg/l)	200 - 400

ANNEXURE – 3

SOLID, HAZARDOUS WASTE & BIO-MEDICAL WASTE DETAILS AND ITS MANAGEMENT

Waste Category	Waste	Unit	Existing Qty	Proposed Qty	After Expansion Qty	Disposal Method
5.1	Used/ Spent Oil	KL/A	10	0	10	Sent to Authorized recyclers
28.1	Process residue and waste	T/A	0.5	0	0.5	Sent to Authorized Incinerator
28.3	Spent Carbon	T/A	5.0	0	5.0	Distilled in house or stored in secured manner and disposed to authorized re-Processors.

28.4	Off Specification Products	T/A	3.0	0	3.0	Stored in secured manner and disposed to KSPCB authorized incinerator.
28.5	Date Expired and off Specification Medicines and drugs / Chemicals	T/A	2.0	0	2.0	Stored in secured manner and disposed to KSPCB authorized incinerator
28.6	Spent solvents	T/A	6.0	0	6.0	Disposed to KSPCB authorized TSDF
33.1	Empty barrels/ Containers /liner contaminated with Hazardous chemicals/ waste	T/A	3.0	0	3.0	Sent to KSPCB authorized recyclers
	Ash from incinerator and flue gas cleaning residue	T/A	10.0	0	10.0	Sent to KSPCB authorized recyclers
35.3	Chemical sludge from waste water treatment plant	T/A	10.0		10.0	Disposed to KSPCB authorized TSDF
-	Metal and metal alloy waste in metallic non-dispersible form	T/A	40.0	0	40.0	Sent to KSPCB authorized recyclers
-	DB-3020 Paper board and paper products waste	T/A	15.0	0	15.0	Sent to KSPCB authorized recyclers
-	B3040-Rubber waste	T/A	5.0	0	5.0	Sent to KSPCB authorized recyclers
-	B1090 Waste batteries	T/A	2.0	0	2.0	Sent to KSPCB authorized recyclers
-	B3050-Untreated cork &wood waste	T/A	50.0	0	50.0	Sent to KSPCB authorized recyclers

(Vijay Mohan Raj V)
Member Secretary,
SEIAA, Karnataka.
07/03/22

Signature Not Verified
Digitally signed by Sri Vijay Mohan Raj V.,IFS
Member Secretary
Date: 3/7/2022 5:15:58 PM