



State Level Environment Impact Assessment Authority-Karnataka

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

No. SEIAA 30 IND 2020

Date: 11-08-2020

To,

M/s. Cipla Ltd.
Virgonagar, Old Madras Road
Bengaluru - 560 049

Sir,

Sub: Proposed Change in Product Mix for "Bulk Drugs and Intermediates" at Sy. No. 30/1, 30/2, 30/3, 30/4, 31/1, 31/2, 39/1, 39/2, 40/1 Virgonagar Industrial Area, Old Madras Road, Virgonagar, Bengaluru East Taluk, Bengaluru District & Karnataka by M/s. Cipla Ltd.- issue of Environmental Clearance Reg.

This has reference to your online application dated 4th June 2020 bearing proposal No.SIA/KA/IND2/156109/2020 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, and the additional clarification furnished in response to the observations of the SEAC, Karnataka.

2. It is a proposal seeking Environmental clearance for Proposed Change in Product Mix for "Bulk Drugs and Intermediates" at Sy. No. 30/1, 30/2, 30/3, 30/4, 31/1, 31/2, 39/1, 39/2, 40/1 Virgonagar Industrial Area, Old Madras Road, Virgonagar, Bengaluru East Taluk, Bengaluru District & Karnataka by M/s. Cipla 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 Environmental clearance has been issued to this project vide letter No. SEIAA 17 IND 2016 dated 01st October 2019 for Change in Product Mix and Expansion of Production levels of Bulk Drugs and Intermediates on a total land area of 60,986 Sqm with total production capacity of 249.897 TPA.

4. It is inter-alia noted that M/s. Cipla Ltd. have proposed Change in Product Mix for "Bulk Drugs and Intermediates Project. The total plot area is 60,986 Sqm. Industry will develop greenbelt in an area of 22,993 Sqm i.e 37.7 % out of total area of the project site. Details of existing and proposed products with capacities are as given in ANNEXURE.

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Change in Product Mix for "Bulk Drugs and
Intermediates Project by M/s. Cipla Ltd.

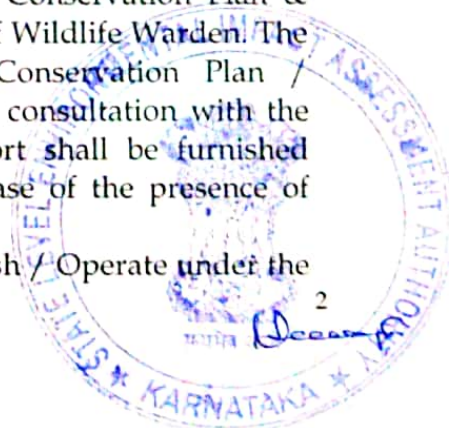
5. The total water requirement for the proposed project is 506 KLD (including recycled water - 184KLD). The waste water generation will be 232 KLD, out of which 40 KLD will be the domestic sewage shall be treated in Combined Effluent Treatment system with capacity of 250 KLD. The effluents are being segregated into High TDS and Low TDS streams. HTDS effluents are collected, neutralized and evaporated in Stripper followed by MEE capacity of 30 KLD & 50 KLD. The condensate from MEE is taken in to the effluent treatment system along with LTDS wastewater. Power requirement is 12,341 KVA and will be met from BESCOM. Existing unit has DG set of 1 No X 1250 KVA and 3 No's X 1500 KVA capacity and it shall be used as standby during the power failure. Existing unit has 2 No. X 3TPH and 1 No. X2TPH Furnace Oil boilers.

6. The project proposal was considered by SEAC during the video conference meeting held on 29th June 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 AM Enviro Engineers, No. 14/1, 2nd Floor, HARIKRUPA, Pattalamma Temple Street, Basavanagudi, Bengaluru - 560 004, the State Level Expert Appraisal Committee (SEAC) apprised the proposal and has recommended for issue of Environmental Clearance.

7. The SEIAA Karnataka has considered the project in its meeting held on 14th July 2020 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.

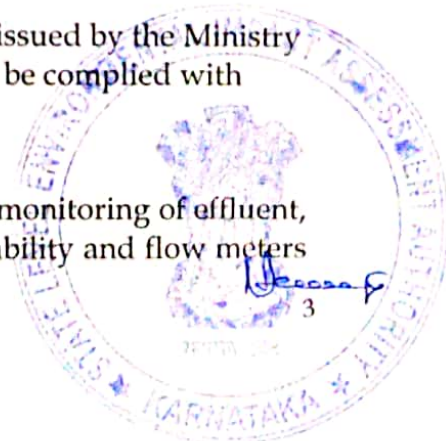
- v. The project proponent shall obtain authorization under the Hazardous and other Waste Management Rules, 2016 as amended from time to time.
- vi. The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended 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 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 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 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

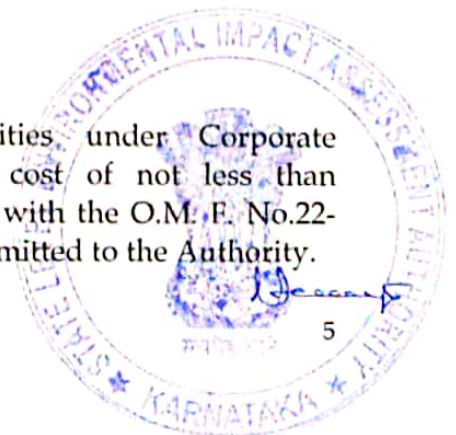
- i. The green belt of 5-10 m width shall be developed in more than 33% of the total project area, mainly along the plant periphery, in downward wind direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.

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.1.5 Lakhs towards CM Cares fundin accordance with the O.M. F. No.22-65/2017-IA.III dated 01st May 2018 and report be submitted to the Authority.



- ii. The company shall have a well laid down environmental policy duly approved 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.
- 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

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- 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

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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,


(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.

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**LIST OF EXISTING PRODUCTS ALONG WITH PROPOSED MODIFICATION
REMARKS**

SL NO	PRODUCTS	Existing Quantity, Kg/year	Proposed Quantity Kg/year	REMARKS
1.	ABIRATERONE ACETATE	100	0	Removed
2.	ALPRAZOLAM	100	0	Removed
3.	AMLODIPINE BESILATE	30000	80000	Increased
4.	AMLODIPINE MALEATE	500	0	Removed
5.	AMLODIPINE MESYLATE	3000	3000	No Change
6.	ANAGRELIDE HYDROCHLORIDE	50	60	Increased
7.	ANASTROZOLE	25	0	Removed
8.	APREMILAST	100	500	Increased
9.	BICALUTAMIDE	1000	200	Reduced
10.	CANAGLIFLOZIN	300	0	Removed
11.	CAPECITABINE	8000	1000	Reduced
12.	CARBOPLATIN	60	60	No Change
13.	CISPLATIN	30	40	Increased
14.	DABIGATRAN ETEXILATE MESYLATE	300	0	Removed
15.	DEXLANSOPRAZOLE	2000	2000	No Change
16.	DONEPEZIL HYDROCHLORIDE	2000	1000	Reduced
17.	DULOXETINE HCL	500	0	Removed
18.	ELVITEGRAVIR	300	0	Removed
19.	EMPAGLIFLOZIN	300	0	Removed
20.	ESOMEPRAZOLE MAGNESIUM	40000	90000	Increased
21.	ETOPOSIDE	200	700	Increased
22.	EZETIMIBE	500	0	Removed
23.	FELODIPINE	3000	5000	No Change
24.	FLUTAMIDE	2000	150	Reduced
25.	GRANISETRON	40	150	Increased
26.	IMATANIB MESYALATE	1000	0	Removed
27.	IRINOTECAN HYDROCHLORIDE	20	0	Removed
28.	LAMOTRIGINE	4000	1000	Reduced
29.	LANSOPRAZOLE	5000	8000	Increased

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30.	LEFLUNOMIDE	500	2500	Increased
31.	LETROZOLE	100	0	Removed
32.	LEVOFLOXACIN	35000	40000	Increased
33.	LINAGLIPTIN	300	500	Increased
34.	LOPINAVIR	2000	3000	Increased
35.	LURASIDONE	300	0	Removed
36.	MITOXANTRONE	5	0	Removed
37.	MONTELUKAST SODIUM	2000	0	Removed
38.	OMEPRazole	30000	30000	No Change
39.	OMEPRazole MAGNESIUM	150	2300	Increased
40.	OMEPRazole SODIUM	1500	2000	Increased
41.	OXALIPLATIN	40	40	No Change
42.	PALIPERIDONE	500	0	Removed
43.	PANTOPRAZOLE SODIUM SESQUIHYDRATE	20000	10000	Reduced
44.	R&D PRODUCTS (NON COMMERCIAL)	1000	2000	Increased
45.	RABEPRAZOLE SODIUM	1000	0	Removed
46.	RALOXIFENE	300	0	Removed
47.	RIFAXIMIN	300	0	Removed
48.	RILPIVIRINE HCL	300	0	Removed
49.	RILUZOLE	100	0	Removed
50.	RISPERIDONE	2000	1500	Reduced
51.	RITONAVIR	5000	10000	Increased
52.	R-RABEPRAZOLE	100	0	Removed
53.	SAXAGLIPTIN	300	300	No Change
54.	SITAGLIPTIN PHOSPHATE	1000	1000	Increased
55.	S-PANTOPRAZOLE	100	0	Removed
56.	TEDIZOLID PHOSPHATE	300	0	Removed
57.	TICAGRELOL	300	0	Removed
58.	TOFACITINIB MONOCITRATE	50	0	Removed
59.	TOPIRAMATE	35000	60000	Increased
60.	TOPOTECAN HYDROCHLORIDE	2	0	Removed
61.	VALCICLOVIR	300	0	Removed
62.	VALGANCYCLOVIR	300	0	Removed
63.	VILDAGLIPTIN	1000	2000	Increased
64.	VINBLASTINE SULPHATE	10	0	Removed
65.	VINCRISTINE SULPHATE	10	0	Removed
66.	VINORELBIN TARTARATE	5	0	Removed

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67.	VORTIOXETINE HYDROBROMIDE	300	0	Removed
68.	ZIDOVUDINE (AZIDOTHYMIDE)	4000	1000	Reduced
TOTAL QUANTITY IN TONNES		249.582	361.00	

LIST OF EXISTING FORMULATION PRODUCTS

S.NO.	FORMULATION PRODUCTS	Quantity (Q)in lakhs No.s /Year
1	ANAGRALIDE HYDROCHLORIDE CAPSULES 0.5 MG	250
2	ANAGRALIDE HYDROCHLORIDE CAPSULES 1.0 MG	100
3	FINCAR 5 MG TABLETS	400
4	FINASTERIDE TABLETS 1 MG	400
5	LEFLUNAMIDE TABLETS 10/20 MG	200
6	LEFLUNAMIDE TABLETS 100 MG	10
7	MYCOPHENOLATE MOFETIL 250 MG TABLETS	50
8	MYCOPHENOLATE MOFETIL 500 MG TABLETS	50
9	TAMSULOSINE HYDROCHLORIDE CAPSULES 0.2 MG	500
10	TAMSULOSINE HYDROCHLORIDE CAPSULES 0.4 MG	8500
TOTAL QUANTITY IN LAKS NUMBERS /YEAR		10460

LIST OF PROPOSED PRODUCTS

SL. NO	PRODUCTS	Qty. in TPA
1	AMLODIPINE BESYLATE NEW PROCESS	60
2	AMLODIPINE BESYLATE OLD PROCESS	20
3	AMLODIPINE MESYLATE	3
4	ANAGRELIDE HYDROCHLORIDE	0.06
5	APRIMILAST	0.5
6	AZIDOTHYIMIDINE (ZIDOVUDINE)	1
7	BICALUTAMIDE	0.2
8	CAPECITABINE	1
9	CARBOPLATIN	0.06
10	CISPLATIN	0.04
11	DEXLANSOPRAZOLE	2
12	DONEPEZIL HYDROCHLORIDE	1
13	ES OMEPRAZOLE MAGNESIUM DIHYDRATE	85
14	ES OMEPRAZOLE MAGNESIUM TRIHYDRATE	5
15	ETOPOSIDE	0.7

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16	FELODIPINE	5
17	FLUTAMIDE	0.15
18	GRANISETRON BASE	0.1
19	GRANISETRON HYDROCHLORIDE	0.05
20	LAMOTRIGINE	1
21	LANSOPRAZOLE NEW PROCESS	5
22	LANSOPRAZOLE OLD PROCESS	3
23	LEFLUNOMIDE	2.5
24	LEVOFLOXACIN HEMIHYDRATE	40
25	LINAGLIPTIN	0.5
26	LOPINAVIR	3
27	NINTEDANIB ESYLATE	1
28	OMEPRAZOLE	30
29	OMEPRAZOLE MAGNESIUM	2.3
30	OMEPRAZOLE SODIUM	2
31	OXALIPLATIN	0.04
32	PANTOPRAZOLE SODIUM SESQUIHYDRATES	10
33	PREGABALIN	3
34	RISPERIDONE	1.5
35	RITONAVIR	10
36	SAXAGLIPTIN	0.3
37	SITAGLIPTIN PHOSPHATE	1
38	TENOFOVIR ALAFENAMIDE FUMERATE	5
39	TOPIRAMATE	60
40	VILDAGLIPTIN	2
41	R&D PRODUCTS (NON- COMMERCIAL)	2
	TOTAL	370

