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ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಾಲಿನ್ಯ ನಿಯಂತ್ರಣ ಮಂಡಳಿ
Karnataka State Pollution Control Board
"ಪರಿಸರ ಭವನ", 1 ರಿಂದ 5ನೇ ಮಹಡಿಗಳು, ನಂ. 49, ಚರ್ಚ್ ಸ್ಟ್ರೀಟ್, ಬೆಂಗಳೂರು - 560 001, ಕರ್ನಾಟಕ, ಭಾರತ
"Parisara Bhavana", 1st to 5th Floor, # 49, Church Street, Bengaluru - 560 001, Karnataka, INDIA

No: KSPCB/NEIA/CEO-2/TAC-388/2016-17/ 6920 Dated: 10 MAR 2017

KARNATAKA STATE POLLUTION CONTROL BOARD

PROCEEDINGS OF THE 388TH TECHNICAL ADVISORY COMMITTEE MEETING HELD ON 01.03.2017 IN THE BOARD MEETING HALL, 3RD FLOOR, "PARISARA BHAVANA", CHURCH STREET, BANGALORE - 560001.

Members Present:

1.	Dr. Jai Prakash Alva, Board Member, KSPCB, No.2, 5th Cross, 4th Main, Pampa Extension, Kempapura, Bangalore – 560 024.	Chairman
2.	Sri. J.G. Kaveriappa, Board Member, KSPCB, No.40, Sri Krishna, 4th 'A' Cross, I Stage, Anandanagar, R.T. Nagar Post, Bangalore – 560032.	Member
3.	Sri. Mohankumar Kondaji, Board Member, KSPCB, No.218, 15th 'C' Cross, Mahalakshmipuram, Bangalore – 560 086.	Member
4.	Dr. H.N. Chanakya, Chief Scientist, Centre for Sustainable Technologies, Indian Institute of Science (IISc), Bangalore – 560 012.	Member
5.	Dr. Sandeep Mudliar, Principal Scientist, E-II, Central Food Technological Research Institute (CFTRI), Mysore – 570 020.	Member (Absent with intimation)
6.	Dr. B.S. Jai Prakash, Vice President, Academy of Certified Hazardous Material Managers – India Chapter, Bangalore Institute of Technology, K.R. Road, Bangalore.	Member
7.	Sri.B.G. Mohankrishna, Chief Environmental Officer-2, Karnataka State Pollution Control Board, Bangalore.	Convener

Officers of the Board present	
1.	Dr. A. Ramesh, Senior Environmental Officer, Board Office.
2.	Smt. Vijaya Hegde, Environmental Officer, Board Office.
3.	Sri. Yoganand, Environmental Officer, Board Office.
4.	Sri. R. Padmanabha, Environmental Officer, Board Office.
5.	Dr. D. R. Ravi, Deputy Environmental Officer, Board Office.

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Industry Representatives		
Sl.No	**Name & Address of the Industry**	**Name & designation of the industry representatives**
1.	Re-examination to ascertain whether intermediates manufactured by M/s. SRC Laboratories Private Limited, Raichur are intermediates of final products having EC.	Sri. T. Appi Reddy, AGM Sri. D. Mohan Reddy, SCM
2.	Re-examination to ascertain whether intermediates manufactured by M/s. Trimax Bio-Sciences Prive Ltd., Raichur are intermediates of final products having EC.	Dr. K. Nageshwara Rao, Executive Director
3.	Re-examination to ascertain whether intermediates manufactured by M/s. Jayanth Pharmaceuticals Pvt. Ltd., Raichur are intermediates of final products having EC.	Sri. Reddy, Managing Director
4.	Re-examination to ascertain treatment and disposal method followed for Sewage and trade effluent of M/s Kemwell Bio-Pharma Pvt Ltd., 34 KM Tumkur Road, T-Begur, Nelamangala taluk, Bangalore Rural District	Sri. Ariff Khan, President Sri. Sanjay Lodha, Vice President Sri. Vasanth Kumar, Sr. Maganer Sri. Mahesh D. R, Jr. Executive (EHS Department)
5.	M/s. JERS Environmental Technologies Private Limited, to introduce a new technology under the Municipal Solid Waste Management.	Sri. Shiva Shankar E., Managing Directors Sri. Capt. S. Raja Rao, Consultant-Chairman-EPTPL Dr. Shivalingahiah, Consultant. Narayana Swamy Consultant. Timmappa Shetty Consultant.

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ITEM NO: 388:01

The proceedings of 387th meeting was read and discussed. The committee confirms the proceedings with the following observations/additions.

In respect of agenda No: 387: 04, 387: 05 and 387: 06 was discussed and Dr. Jai Prakash B.S, TAC-Member has raised an objection for stating that (at first line para 4 of the above agenda) "The issue need not be discussed in the TAC since this pertains to the implementation of MoEF directions" and opined that such sentences may appeal that TAC is discussing some un-related issues. He also reiterated that, if Board feels not to discuss certain issues, the concerned section may not bring the subject before TAC, but the TAC is a technical body reviewing the subject technically in respect of Water and Air pollution control and giving its opinion only based on the agenda deliberated and the presentation made by the respective industries in the meeting. Sri. B. G. Mohan Krishna CEO-2 has informed that this sentence was added in view of the verification to be made, of products manufactured by M/s. Trimax, M/s. Jayanth and M/s. SRC laboratories as an intermediate of the bulk drug for which they have obtained consent and EC from the Board and MoEF respectively. It is also due to the fact that there is an notification by MoEF for the product change based on the "no increase in pollution load increase" concept. After detailed deliberation, the committee has opined that the sentence *"The issue need not be discussed in the TAC since this pertains to the implementation of MoEF directions"* may be deleted from the proceedings. With this correction the, the committee confirmed the 387th proceedings held on 19.12.2016.

ITEM NO: 388:02

Re-examination to ascertain whether intermediates manufactured by M/s. SRC Laboratories Private Limited, Raichur are intermediates of final products having EC.

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The authorities have made a presentation on the activities which they have undertaken. They said that they are manufacturing Pregablin which is a anti-epiliptic drug having gamma amino butyric acid structure which has anti-convulsant effect. They have stated that for Pregablin intermediates, it was given as CSILERIBULIN. They have also presented the brief manufacturing process wherein at stage-6 when Eribulin and react with Ethyl Chloro Formate they get Eribulin, this product they are selling as intermediate. They are producing about 11.9 kgs and requested the Board to give permission to manufacture Eribulin as intermediate of Pregablin. The Drug Controller who was present in the meeting has informed that manufacturing of intermediate doesn't fall under the purview of Drug Controller. However, they also cannot exactly say that Eribulin is an intermediate of Pregablin. They have informed that the industry has obtained license for manufacturing Pregablin from Department of Drug Controller. However, the TAC has opined that they cannot manufacture intermediate of any drug and sell the same to any of the customer, as they have obtained statutory license from different Departments to manufacture each bulk drug like Abacavir Sulfate, Fexofenadine Hydrochloride, Montelukast Sodium, Tamsulosin Hydrochloride etc.,

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After detail deliberation and discussion, the industry was asked to submit the following details;

1. Chemical synthetic steps adopted with stoichiometry equation at each stage along with the raw materials used for manufacture of Pregablin.
2. The proponent shall submit the IR spectrum of the intermediate that is stated to be sold with each vibrartion indexed for the functional groups present.

The industry in response to the TAC queries submitted the IR Spectrum analysis for the intermediate of Pregablin and the same was examined by Dr. Jai Prakash-TAC Member and has submitted his opinion that the said product is an intermediate of Pregablin. In view of the above, the Board can take further action on the matter.

ITEM NO: 388:03

Re-examination to ascertain whether intermediates manufactured by M/s. Trimax Bio-Sciences Prive Ltd., Raichur are intermediates of final products having EC.

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The industry has obtained CFE and EC for manufacturing 18 different products. However, they were selling Amonoketal and BCFI at the intermediate stage as these two are intermediates of Atorvastatin Calcium, Montelukast Sodium and Valsartan. The authorities have made a presentation and stated that they are manufacturing Pregablin wherein the intermediates of Pregablin i.e., 3-carbamoyl methyl-5- methyl hexanoic acid and the same will be sold as intermediates. They also submitted the chemical reaction of each stage with different chemicals like toluene, hydrochloric acid, ethyl acetate and finally with sodium hypo-chlorite, sodium hydroxide and methanol. They also presented the root synthesis of Lamivudine which is produced through 4-stage reaction with different chemicals like Methanol, Gluoxalic acid, Cycolohexane, Toluene, Thionyl chloride etc., the same will be sold as intermediates. Finally, they presented root synthesis Atorvastatin Calcium, Valsartan. However, the TAC has opined that they cannot manufacture intermediate of any drug and sell the same to any of the customer as they have obtained statutory license from different Departments to manufacture each bulk drug like Atorvastatin Calcium, Montelukast Sodium, Valsartan etc.,

After detail deliberation and discussion, the industry was asked to submit the following details;

1. Chemical synthetic steps adopted with stoichiometry equation at each stage along with the raw materials used for manufacture of Pregablin.
2. The proponent shall submit the IR spectrum of the intermediate that is stated to be sold with each vibrartion indexed for the functional groups present.

The industry in response to the TAC queries submitted the IR Spectrum analysis for the intermediate of Pregablin and the same was examined by Dr. Jai Prakash-TAC Member and has submitted his opinion that the said product is an intermediate of Pregablin. In view of the above, the Board can take further action on the matter.

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