

**F. No. J-11011/456/2006-IA-II(I)**

Government of India  
Ministry of Environment, Forest & Climate Change  
Impact Assessment Division

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Indira Paryavaran Bhavan,  
Vayu Wing, 3<sup>rd</sup> Floor, Aliganj,  
Jor Bagh Road, New Delhi-110 003

Dated: 20<sup>th</sup> July, 2020

To  
M/s Natco Pharma Limited  
Manali Industrial Area, Taluk Thiruvottiyur,  
District **Thiruvallur** (Tamil Nadu)

**Sub: Bulk Drug Manufacturing Unit at Manali Industrial Area, Taluk Thiruvottiyur, Thiruvallur, Tamil Nadu by M/s Natco Pharma Limited - Amendment in Environmental Clearance**

Sir,

This refers to your online proposal No. IA/TN/IND2/146309/2020 dated 14<sup>th</sup> May, 2020 for amendment in the environmental clearance to the above project.

2. The Ministry of Environment, Forest and Climate Change has examined the above proposal for amendment in the environmental clearance granted by the Ministry vide letter dated 15<sup>th</sup> June, 2007 in favor of M/s NATCO Organics Ltd for bulk drug unit. Further, the SEIAA vide letter dated 20<sup>th</sup> February, 2019 has also granted EC in favour of M/s Natco Pharma Limited for Bulk Drugs (APIs) manufacturing Unit at Manali Industrial Area, Thiruvottiyur Taluk (formerly Vaikkadu, Ambattur Taluk) Thiruvallur District (Tamil Nadu).

3. The project proponent has requested for amendment in the EC with the details are as under:-

S. No.	Para of ToR	Details as per the EC	To be revised read as	Justification / reasons
1.	<b>EC dated 15-06-2007</b> Specific condition No. 4A(v) of	"Use of toxic solvents like Methylene Chloride (M.C.) etc. shall be minimum and Benzene shall be replaced with alternate solvents. All venting equipment shall have vapour recovery system. Methylene Chloride shall be phased out in a time bound	Amendment is for relaxation in usage of MDC & Chloroform in manufacturing Oncology products as per the specific condition No. 4A(v) in EC vide F.No. J-11011/456/06/2006-IA-II(I) dated 15-06-2007.	Replacing solvents like MDC and Chloroform with other solvents is leading to formation of new impurities in most of the cases contributing to generation of waste on higher levels. Also the product viability is drastically reduced and affecting the

		manner. A report shall be submitted to the Ministry after 2 year on the status of replacement of Methylene Chloride and Chloroform Solvent"	overall yields. Hence we request you to kindly allow the usage of MDC and Chloroform.
2.	<b>EC dated 20-02-2019</b> Page No. 33 of 33: <b>Annexure-01</b> of Proposed Products No. 40 and 41	Proposing to drop 2 products S.No. 40. Sertaline HCl-6TPA & S.No. 41. Sumatriptan Succinate-3TPA	Dropping 2 products from total 42 products i.e. Maximum 16 products from total 40 products
			Due to high usage of MDC and Chloroform.

4. The proposal was considered by the Expert Appraisal Committee (Industry-2) in the Ministry in its meeting held on 15-17 June, 2020. The EAC, after detailed deliberations, **recommended** the amendment in EC dated 15<sup>th</sup> June, 2007 and 20<sup>th</sup> February, 2019 as proposed by the project proponent mentioned in the above table.

5. Based on recommendations of the EAC, the Ministry of Environment, Forest and Climate Change hereby accords approval to the proposed amendment in the environmental clearance dated 15<sup>th</sup> June, 2007 and 20<sup>th</sup> February, 2019, **as stated in para 3 above**, to the project for 'Bulk Drugs (APIs) manufacturing Unit at Manali Industrial Area, Thiruvottiyur Taluk (formerly Vaikkadu, Ambattur Taluk) Thiruvallur District (Tamilnadu)'.

6. All other terms and conditions stipulated in the environmental clearance dated 15<sup>th</sup> June, 2007 and 20<sup>th</sup> February, 2019 shall remain unchanged.

(डा. आर. बी. लाल)  
(Dr. R. B. LAL)  
वैज्ञानिक 'ई' / Scientist 'E'  
पर्यावरण, वन एवं जलवायु परिवर्तन मंत्रालय  
Min. of Environment and Climate Change  
भारत सरकार, नई दिल्ली  
Govt. of India, New Delhi

**(Dr. R. B. Lal)**  
**Scientist 'E' / Additional Director**

**Copy to: -**

1. The Principal Secretary, Department of Environment, Ground Floor, Panagal Buildings 1, Jeenis Road, Saidapet, Chennai - 600 015.
2. The APCCF(C), MoEF&CC, Regional Office (SEZ), 1<sup>st</sup> and 2<sup>nd</sup> Floor, Handloom Export Promotion Council, 34, Cathedral Garden Road, Nungambakkam, **Chennai-34**
3. Member Secretary, Tamil Nadu Pollution Control Board, 76, Anna Salai, Guindy Industrial Estate, Race View Colony, Guindy, **Chennai - 32 (Tamil Nadu)**
4. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhawan, Jor bagh Road, **New Delhi**
5. Parivesh Portal

**(Dr. R. B. Lal)**  
**Scientist 'E' / Additional Director**