23819/27.06.18

**File No. 4-17/2016-DC**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**(FDC Division)**

Tele. No. : 011-23236965
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FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 05 SEP 2018

To,

**M/s. Natco Pharma Ltd.,**
**Natco House, Road No. 2,**
**Banjara Hills, Hyderabad-500034.**

**Subject: Permission for conducting phase IV clinical trial with FDC of Daclatasvir Dihydrochloride Eq. to Daclatasvir 60mg + Sofosbuvir 400mg film coated tablets (Vide Protocol No. HEPCNATPL-4 Version No. 1, dated 12.06.2018) - regarding.**

**CT No. CT/Drugs/40/2018**

Sir,

Please refer to your letter no. nil dated 25.06.2018 on the subject mentioned above. This Directorate has no objection to your conducting clinical trial with the said drug under the supervision of following investigators mentioned and as per the **Vide Protocol No. HEPCNATPL-4 Version No. 1, dated 12.06.2018** submitted to this Directorate.

1. Dr. Anil Arora, Institute of Liver, Gastroenterology and Pancreaticobiliary Sciences (ILGPS) Sir Ganga Ram Hospital, Karol Bagh, New Delhi-110060.
2. Dr. Dharmesh Kapoor, Sr. Consultant Hepatologist, Gleneagles Global Clinical Research Services, Global Hospitals # 6-1-1070/1 to 4 Lakdikapool Hyderabad 500004.
3. Dr. Abhijit Chowdhury, Professor & Head, Dept. of Hepatology, School of Digestive & Liver Disease IPGME&R/SSKM Hospital 244 AJC Bose Road, Kolkata-700020

The clinical trial permission is subject to the following conditions:-

a. Clinical trial shall be conducted in compliance with the approved protocols requirements of Schedule Y, Good Clinical Practice Guidelines issued by thi Directorate and other applicable regulations;
b. Approval of the Ethics Committee duly registered with the office of DCG (I) sha be obtained before initiating the clinical trial.
c. Clinical trials shall be registered at Clinical trials Registry of India befor enrolling the first patient for the study;
d. Annual status report of each clinical trial, as to whether it is ongoing, complete or terminated, shall be submitted to the Licensing Authority, and in case termination of any clinical trial the detailed reasons for the same shall b communicated to the said Licensing Authority;
e. Any report of serious adverse event occurring during clinical trial study to th subject, after due analysis, shall be forwarded within fourteen days of i occurrence as per Appendix XI and in compliance with the procedure prescribed in Schedule Y;
f. In case of an injury or death during the study to the subjects, the applicant sha provide complete medical management and compensation in the case of tri related injury or death in accordance with rule 122 DAB and the procedure prescribed under Schedule Y, and the details of compensation provided in suc cases shall be intimated to the Licensing Authority within thirty days of th receipt of the order of the said authority;

g. The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations;

h. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

i. In addition to the requirement of obtaining written informed consent, an audio-video recording of the informed consent process in case of vulnerable subjects in clinical trial of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record; provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record, as per Government of India, Gazette Notification vide G. S. R. no. 611(E) dated 31.07.2015.

j. Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect as per the requirements specified in Appendix V of Schedule Y of the Drugs and Cosmetics Rules, 1945 must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

k. **The sample size should be increased to 400.**

l. **In patients with compensated liver cirrhosis included, the trial should be of 24 weeks duration of treatment.**

Yours faithfully,

**(Dr. S. Eswara Reddy)**
**Drugs Controller General (India)**

**Copy to:-**
All Zonal/Sub Zonal offices of CDSCO.