15439/18.11.19

File No. 4-130/2009-DC (Pt. Sun)
Govt. 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

To,

M/s. Sun Pharma Laboratories Limited,
Plot No. 754, P.O. Ranipool, East Sikkim-737135.

Dated: 26 DEC 2019

Subject: **Permission for conducting phase IV clinical trial with FDC of Cephalexin Extended releae + Clavulanate Potassium (375mg + 125mg & 750mg + 125mg) tablet (Vide Protocol No. ICR/18/008, Version No. 1.0, dated 21.08.2019) -regarding.**

CT No. **CT/Drugs/120/2019**

Sir,

Please refer to your letter no. SPILUK/11/56 dated 16.11.2019 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. ICR/18/008, Version No. 1.0, dated 21.08.2019** submitted to this Directorate.

1. Dr. Rajesh Kumar Padhy Sparsh Hospital & Critical Care Private Limited, Plot No. A/407, Sahid Nagar, Bhubaneswar- 751007.
2. Dr. Sayantani Chakraborty, R.G. Kar Medical College 1, Khudiram Bose Sarani, Kolkata- 700004
3. Dr. (Mrs) Girija Nair, OPD 69 Department of Pulmonary Medicine Padmashree Dr D Y Patil Medical College Hospital & Research Center, Plot No. 2 Sector 5,Nerul, Navi Mumbai 400706.
4. Dr. Girishkumar Mohanlal Shah Kanoria Hospital and Research Centre, Airport-Gandhinagar Highway, Village: Bhat, Dist. Gandhinagar-382428, Gujarat.
5. Dr. Patel Kalpesh Bhagubhai, Department of ENT, B. J. Medical college & Civil hospital, Asarwa, Ahmedabad-380016,Gujarat.
6. Dr. Basant Kumar Singh Om Research Center, Om Surgical Center & Maternity Home SA 17/3, P-4, Sri Krishna Nagar Colony, Opp Petrol Pump, near Surabhi Hotel, Ghazipur Road, Paharia, Varanasi, Uttar Pradesh- 221007.
7. Dr. Shobhit Shakya Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow- 226010
8. Dr. Nilkanth Tukaram Awad, Lokamnya Tilak Municipal Medical College & General Hospital Dr. Ambedkar Road, Sion, Mumbai- 400022.
9. Dr. Vikas Deep Mishra Opal Hospital Private Limited, 10/60-2, DLW Road, Kakarmatta DLW, Kakarmatta, Varanasi- 221002, U.P.
10. Dr. B. Thrilok Chander Gandhi Hospital, Musheerabad, Secunderabad, Telengana- 500003.
11. Dr. Avula Rajamma, ACSR Government Medical College & Hospital Dargamitta, Nellore- 524004, Andhra Pradesh.
12. Dr. P. Padmaja, Osmania General Hospital, Osmania Medical College Afzalgunj, Hyderabad- 500012.
13. Dr. Mohnish Grover, Department of ENT, 1st floor, Dhanvantari OPD Block, SMS Hospital Jaipur- 302004.
14. Dr. Shrinivas S. Chavan Grant Govt. Medical College & Sir J.J. Group of Hospital Byculla, Mumbai- 400008.

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

a. Clinical trial at each site shall be initiated after approval of the clinical trial pro and other related documents by the Ethics Committee of that site, registered the Central Licencing Authority under rule 8;
b. Where a clinical trial site does not have its own Ethics Committee, clinical tr that site may be initiated after obtaining approval of the protocol from the E Committee of another trial site; or an independent Ethics Committee for cli trial constituted in accordance with the provisions of rule 7:
    i. Provided that the approving Ethics Committee for clinical trial shall in case be responsible for the study at the trial site or the centre, as the may be:
    ii. Provided further that the approving Ethics Committee and the clinical tria or the bioavailability and bioequivalence centre, as the case may be, sha located within the same city or within a radius of 50 kms of the clinical site;
c. In case an ethics committee of a clinical trial site rejects the approval o protocol, the details of the same shall be submitted to the Central Licer Authority prior to seeking approval of another Ethics Committee for the pro for conduct of the clinical trial at the same site;
d. The Central Licencing Authority shall be informed about the approval grante the Ethics Committee within a period of fifteen working days of the grant of approval;
e. Clinical trial shall be registered with the Clinical Trial Registry of India mainta by the Indian Council of Medical Research before enrolling the first subject fo trial;
f. Clinical trial shall be conducted in accordance with the approved clinical protocol and other related documents and as per requirements of Good Cli Practices Guidelines and the provisions of these rules;
g. Status of enrolment of the trial subjects shall be submitted to the Central Licer Authority on quarterly basis or as appropriate as per the duration of treatme accordance with the approved clinical trial protocol, whichever is earlier;
h. Six monthly status report of each clinical trial, as to whether it is ongo completed or terminated, shall be submitted to the Central Licencing Authority.
i. In case of termination of any clinical trial the detailed reasons for such termina shall be communicated to the Central Licencing Authority within thirty days of such termination;
j. Any report of serious adverse event occurring during clinical trial to a subje clinical trial, shall, after due analysis, be forwarded to the Central Licen Authority, the chairperson of the Ethics Committee and the institute where the has been conducted within fourteen days of its occurrence as per Table 5 o Third Schedule and in compliance with the procedures as specified in Chapter
k. In case of injury during clinical trial to the subject of such trial, complete me management and compensation shall be provided in accordance with Chapte and details of compensation provided in such cases shall be intimated to Central Licencing Authority within thirty working days of the receipt of order iss by Central Licencing Authority in accordance with the provisions of the Chapter;
l. In case of clinical trial related death or permanent disability of any subject of trial during the trial, compensation shall be provided in accordance with Chapte and details of compensation provided in such cases shall be intimated to Central Licencing Authority within thirty working days of receipt of the order iss by the Central Licencing Authority in accordance with the provisions of the Chapter;
m. The premises of the sponsor including his representatives and clinical trial s shall be open for inspection by officers of the Central Licencing Authority who be accompanied by officers of the State Licencing Authority or outside expert

authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

n. The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

o. The Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

p. The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

q. Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

r. 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;

s. **Firm should also include microbiological testing as an inclusion criteria and as end point criteria for efficacy.**

t. **The study report shall be presented before the committee**.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

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