D. No. 24601
Date: 04-10-2017

Tele No.011-23236965
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F. No. 12-67/2017-DC (Pt- Alkem-SND)
Directorate General of Health Services
Central Drugs standard Control Organization
Office of Drugs Controller General (India)
(Subsequent New Drug Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:- 05 JAN 2018

To,
M/s Alkem Laboratories Ltd.,
Alkem House, Senapati Bapat Road,
Lower Parel (W), Mumbai-400013.

Sub: Phase I clinical Trial on Spironolactone cream 5% in healthy volunteers - Regarding.

CT NOC No. CT/SND/113/2017

Sir,

Please refer your letter no. ALKEM/SND/OCT/2017/001 dated 29-09-2017 on above noted subject.

This Directorate has no objection to your conducting clinical trials with the said drug under the supervision of following investigators mentioned and as per the **protocol No: BA17108802; Version No. 00; dated: 28-09-2017** submitted to this Directorate.

S. No.	PI Name and Address
1.	Dr. Vikash Kumar Singh, Cliantha Research Limited, Ahmedabad.

The clinical trial permission is subject to the conditions:

A. Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.

B. Approval of the Ethics Committee duly registered with the office of DCG (I) shall be obtained before initiating the clinical trial.

C. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study;

D. Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority;

E. Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y;

F. In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the 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. It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

J. Audio-Visual recording shall be carried out as per GSR 611(E), dated 31.07.2015.

Signature: _____

(Dr. G. N Singh)
Drugs Controller General (India)
(Name & Designation of Licensing Authority)

Copy to: All Zonal/sub Zonal Office, CDSCO