

Tele No.011-23236965
Fax.No.011-23236973

Nil

F. No. SND/CT/18/000010
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

Dated **16 APR 2019**

To,

M/s Apex Laboratories Pvt Ltd.,
III Floor, SIDCO Garment Complex, Guindy,
Chennai- 600032, Tamil Nadu, India.

Subject: Permission for conducting Phase-III clinical trial "A multicentric, open label, randomized, case-control study on Safety and Efficacy of Sofinox Gel (Sodium Fusidate equivalent to Fusidic acid 2% w/w) in Diabetic wound Healing." - regarding.

CT NOC No. CT/SND/29/2019

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigator and as per the **Protocol No: DUW-SHG/IN-01, Version 002, dated 04-08-2018** submitted to this Directorate.

S.No	Investigator and Trial site	Ethics Committee Name and Registration Number
1	Dr. R. Radhakrishnan, Professor of Vascular Surgery, Sri Ramachandra Hospital, Department of surgery, No.1, Ramachandra Nagar, Porur, Chennai, Tamilnadu.	Ethics Committee, Institutional Ethics committee, Sri Ramachandra University, Porur, Chennai. ECR/203/Inst/TN/2013/RR-16
2	Dr.TV Raja, Consultant, Orthopedic Surgeon and Foot Specialist, Visa Hospital. No 27, South West Boag Road, T Nagar, Chennai, Tamilnadu.	Ethics Committee - Chennai Meenakshi Multispecialty Hospital Limited, New No. 72, Old No.148, Luz Church road, Mylapore, Chennai - 600004 ECR/516/Inst/TN/2014/RR17
3	Dr. VB Narayana Murthy,	Ethics Committee - Chennai Meenakshi

	Consultant Plastic Surgeon, Diabetic Foot Surgeon, Hycare for Wounds, Aysha Hospital, 91-A, Millers road, Kilpauk, Chennai, Tamilnadu.	Multispecialty Hospital Limited, New No.72, Old No.148, Luz Church Road, Mylapore, Chennai – 600004. ECR/516/Inst/TN/2014/RR17
4	Dr. V. Kumarvel Velayutham, Director and Endocrinologist, Alpha Hospital and Research centre, 2B/2C, Gate lock road, Mela Anupannady, Madurai, Tamilnadu.	Ethics Committee - Alpha Hospital & Research centre, Institute of Diabetes & Endocrinology, 2B/2C, Gate Lock Road, Mela Anupannady, Madurai -625009 ECR/907/Inst/TN/2017
5	Dr. S. Sivakumar, Prof. & Consultant Plastic Surgeon, Shanmuga Medical Research Foundation Trust, Department of surgery, 24, saradha - college road, Salem, Tamilnadu.	Ethics Committee - Shanmuga Medical Research Foundation Trust, No. 24, saradha college road, Salem, Tamilnadu - 636007. ECR/1046/Inst/TN/2018
6	Dr. Abbay Kumar Sahoo, Professor - Department of Endocrinology, Institute of Medical Sciences and SUM Hospital, K8, Kalinga Nagar, Shampur, Bhubaneswar Orissa - 751003.	Ethics Committee - Institute of Medical Sciences and SUM Hospital, K8, Kalinga Nagar, Shampur, Bhubaneswar, Orissa - 751003. ECR/627/Inst/OR/2014
7	Dr. Pravin Kamble, Consultant Surgeon, Life point Multispecialty Hospital, No 145/1 Mumbai Bypass Rd, Near Hotel Sayaji, Pune, Maharashtra.	Ethics Committee - LPR ethics committee, Life point Multispecialty Hospital Pvt. Ltd, No 145/1 Mumbai Bypass Rd, Near Hotel Sayaji, Pune, Maharashtra – 411057. ECR/751/Inst/MH/2015
8	Dr. P. Saravanan, Radiology oncologist, Saravana Multispecialty Hospital, 7-A Maruthupandiar Nagar, 4th Main Road, Narimedu, Madurai, Tamilnadu.	Ethics Committee - Asirvatham Speciality Hospital, 22, Rajaji Street, Gandhi Nagar Madurai, Tamil Nadu - 625020. ECR/265/Inst/TN/2013/RR-16
9	Dr. Jubbin Jagan Jacob,	Ethics Committee - Christian Medical

	Diabetologist, Christian Medical College and Hospital, Brown Road, Ludhiana, Punjab -141008.	College Hospital, Brown Road, Ludhiana. Punjab - 141008. ECR/120/Inst/PB/2013/RR-16
10	Dr. Sunil. V. Kari, Diabetic Foot Surgeon, Sushruta Multispecialty Hospital & Research centre Private Limited, P.B. road, Vidyanagar, Hubli, Karnataka- 580021.	Ethics Committee, Sushruta Hospital Ethics Committee C/O Sushruta Multispecialty Hospital & Research Centre Private Limited, P.B. Road, Vidyanagar, Hubli, Karnataka - 580021. ECR/372/Inst/KA/2013/RR-16
11.	Dr. Jayaprakash appajigol, Assistant Prof. of General Medicine, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi, Karnataka-590010.	Ethics Committee, KLE University, JN Medical College, Nehru Nagar, Belagavi Karnataka – 590010. ECR/211/Inst/KA/2013/RR-2016.
12	Dr. Neeta Deshpande, Diabetologists and Endocrinologist, Belgaum Diabetes Centre, Ground and Second Floor, Maruti Street, Belgaum, Karnataka-590001.	Ethics Committee, Institutional Ethical Committee Belagavi Institute of Medical Sciences, Dr. B.R. Ambedkar Road, Belagavi Karnataka - 590001. ECR/801/Inst/KA/2016

Kindly note that 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 this Directorate and other applicable regulations.
- b) Approval of Institutional Ethics Committee duly registered with CDSCO (under Rule 122DD of Drugs & Cosmetics Rules) should be obtained and submitted to this Directorate before initiation of the study.
- c) Clinical trials shall be registered at Clinical Trials Registry of India (CTRI) 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) Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.
- j) The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc.
- k) The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.
- l) 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.

- m) **The bulk drug to be used in manufacturing of finished formulation intended to be used in the clinical trial and clinical trial batches of finished formulation shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.**
- n) If the clinical trial batches are different from that of the primary batches for which data have been submitted, stability reports for clinical trial batches are to be submitted as per Appendix IX of schedule Y of drugs and Cosmetics Rules for Drug substances and formulation along with Clinical Study Report.
- o) 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.
- p) 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 respective Ethics Committee and submitted to CDSCO before enrolling first subject at the respective site.

Yours faithfully,



(Dr. S. Eswara Reddy)
Drugs Controller General (India)
& Licensing Authority