

Diary No: 31600
Date: 04.09.18

F. No 12-73/10-DC (Pt-I)

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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(New Drugs Division)

Dated 22.10.2018

To
M/s Hetero Labs Ltd,
Hetero Corporate, Industrial Estates,
H. No: 7-2-A2, Sanathnagar,
Hyderabad – 500 018, Telangana

Subject: Permission for conducting clinical study entitled, " A prospective, Multicenter, double –blind, comparative , parallel group , randomized study to evaluate the efficacy and safety of Azelnidipine in Indian patient with essential hypertension" - regarding.

CT NOC No. CT/ND/ 52 /2018

Reference: Your application dated 31.08.2018 on the subject mentioned above.

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: HCR/III/AZELNIEH/02/2015 Version No: 2.0, Dated 29.06.2018** submitted to this Directorate.

S.No	Investigator and Trial site	Ethics Committee Name and Registration Number
1	Dr. Sohan Kumar Sharma Department of Cardiology Ground Flor G-2 Dhanvantri OPD Block SMS Hospital Jaipur-302004	Office of Ethics committee SMS Medical college & attached Hospital , Jaipur, First Floor, Dhanvantri OPD Block SMS Hospital, JLN Marg Jaipur-302004, Rajasthan, India ECR/26/Inst/Rj/2013/RR16
2	Dr. Deo Nidhi Mishra Nirmal Hospital Opp. MLB Medical College, gate No.3 Jhansi (UP)-284128	Institutional Ethics Committee, Nirmal hospital Institutional Ethics committee, Nirmal Hospital Campus Opp. MLB Medical College, gate No.3 Jhansi (UP)-284128. ECR/325/Inst/UP/2013/RR16

3	Dr. Darivemula Anil Kumar Department of Medicine Gandhi Hospital, Secunderabad Telangana-500003.	Institutional Ethics Committee, Gandhi Hospital, Secunderabad Telangana- 500003Uttar Pradesh, India. ECR/180/Inst/AP/2013/RR-16
4	Dr. Swapnav Borthakur Down Town Hospital Dispur, G.S Road Guwahati- 781006	Down Town Hospital Dispur, G.S Road Guwahati- 781006 ECR/549/Inst/AS/2014/RR-17
5	Dr. A. Gopal Rao Department of General Medicine, Rajiv Gandhi Institute of Medical sciences & RIMS Govt. General Hospital, Srikakulam-532001 AP, India	Institutional Ethics Committee, Rajiv Gandhi Institute of Medical sciences & RIMS Govt. General Hospital, Srikakulam- 532001 AP India ECR/492/Inst/AP/2013/RR-16
6	Dr. Vikas Agarwal, Surya- Super Specialty, Hospital a-unit of GV Meditech (P)Ltd B 38/46 H Raman Niwas Mahmoorganj, Varanasi-221010, U.P India	GV Meditech Ethics Committee of GV Meditech (P) Ltd B 38/46 H Raman Niwas Mahmoorganj, Varanasi-221010, U.P. India. ECR/14/Inst/UP/2013/RR-16
7	Dr. Kancharala Sudhakar, New Govt. General Hospital, (Associated by Govt. Siddhartha Medical college) Govt. Siddhartha Medical College Campus, Gunadala, Vijayawada- -500003.	Institutional Ethics Committee, Siddhartha Medical Gandhi Medical College and Govt. General /Gandhi Hospital Musheerabad, Secunderabd-500003, Telangana, India ECR/633/Inst/AP/2014/RR-16
8	Dr. Swapan Kumar Halder, NRS Medical College & Hospital,138 AJC Bose Road, Kolkata-700014 West Bengal, India	Ethics Committee, NRS Medical College & Hospital,138 AJC Bose Road, Kolkata- 700014, West Bengal, India. ECR/609/Inst/WB/2014-RR-17
9	Dr. Saroj Mandal , Institute of Post graduate Medical Education and Research, 244 AJC Bose Road, Kolkata- 700020, West Bengal, India	IPGME & R Research Oversight Committee Institute of Post graduate Medical Education and Research, 244 AJC Bose Road, Kolkata-700020, West Bengal, India. ECR/43/Inst/MH/2013/ RR-16
10	Dr. Hemant Gupta Ramsharan, OPD 20, Old Building Grant Government Hospital and Sir JJ Group of Hospital, Byculla Mumbai-400008	Institutional Ethics Committee, Department of Pharmacology, Grant Medical College By culla Mumbai-400008 ECR/382/MH/INST/RR-2016

11	Dr. Jayesh Shah, Hitech multispecialty Hospital, sector 3-D, Plot no:-108, GH Road, Near 11/2 Bus Stand, Gandhinagar-382016	Hi-tech Ethics Committee Hi-tech multispecialty Hospital, sector 3-D, Plot no:- 108, GH Road, Near 11/2 Bus Stand, Gandhinagar-382016 ECR/1057/Inst/GJ/2018
12	Dr. Kuntal Shah, Bodyline Hospital, opp. Annapurna Hall, near Dev Status, New Vikas Gruh Road, Paldi, Ahmedabad-7 Gujrat, India .	Bodyline Hospital Institutional Ethics Committee (IEC), opp. Annapurna Hall, near Dev Status, New Vikas Gruh Road, Paldi, Ahmedabad-7 Gujrat, India . ECR/476/Inst/GJ/2013/RR16
13	Dr. Aman Khanna, Aman Hospital and research center 15/Shaswat Opp, ESI Hospital Gotri Road Vadodra, Gujrat, India-392001	Institutional Ethics Committee Aman hospital and research center 15/Shashwat Opp. ESI Hospital Gotri Road, Vadodra Gujrat India- 3922001 ECR/857/Inst/GJ/2016
14	Dr. Anurag Agrawal, Sai baba Nursing Home Opp. Vijeta Complex New Rajendra Nagar-492001 Chhattisgarh.	Sai baba Nursing Home Institutional Ethics at Sai baba Nursing Home, Opp. Vijeta Complex New Rajendra Nagar-492001 Chhattisgarh ECR/1038/Inst/CG/2018
15	Dr. SK Noushad Ali ACSR Govt. Medical college & Hospital, Dargamitta Nellore- 524004	Institutional Ethics Committee, ACSR Govt. medical college & Hospital, Dargamitta Nellore-524004 ECR/961/Inst/AP/2017
16	Dr. Dr. Vaibhav Bansidhar Patil, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, BELagavi- 590010, Karnatka	Institutional Ethics Committee, KLE University, JN Medical college campus Nehru Nagar, Belagavi-590010, Karnatka, India ECR/211/Inst/KA/2013/RR-2016

Kindly note that the clinical trial permission is subject to the following conditions:-

- 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.
- 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) Bioequivalence with the reference product shall be established before initiation of the clinical trial.
- q) 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)

