

File No CT/26/12-DCG(I)

Clinical Trial NOC No:- GCT/14/13

54975/28/10/13

Government of India

Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)

(Global Clinical Trial Division)

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File No: CT/26/12-DCG (J)

Dated: 11/12/13

To

M/S Amneal Pharmaceutical Pvt. Ltd,
882/1-871, Sarhej-Bhavla Highway, Near Hotel Khankavti,
Ahmadabad-382220

Subject: Permission for conducting a clinical study entitled, "A Multi-Center, Double-Blind, Vehicle-Controlled, Parallel-Group Study Comparing a Generic Diclofenac Sodium Topical Gel, 1% to Voltaren® Gel (Diclofenac Sodium Topical Gel) 1% in the Treatment of Subjects with Osteoarthritis of the Knee" - regarding.

Clinical Trial NOC No. GCT/14/13

Reference: Your letter no. nil dated 28/10/13 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 investigators and as per the **Protocol No: AM-DCG-001 version 3 dated 08-4-2013** submitted to this Directorate.

1. Dr. Vijay Goni, Post Graduate Institute of Medical Education & Research (PGIMER), Dept. of Orthopedics, H.No:117, Sector-248, Chandigarh-160023.
2. Dr. Alok Sobhan Datta, Institute of Post Graduate Medical Education & Research, Dept. of Orthopedics, 244 A.J.C Bose Road, Kolkata - 700020
3. Dr. Ashok Kumar, King George Hospital, Dept of Orthopedics, H.No:17, Medicine New Block, Beside Nizam's Medicals, Maharani-pet, Vishakapatnam-532001
4. Dr. Joe Joseph Cherian, St. John's Medical College Hospital, Dept of Orthopedics, Sarjapur Road, Bangalore- 560 034
5. Dr. Pardha Saradhi, Andhra Medical college, Dept of Orthopedics, H.No:18, Medicine New Block, Beside Nizam's Medicals, Maharani-pet, Vishakapatnam-532001.A.P
6. Prof. Parikh AMC Met Medical College & Sheth LG General Hospital, Dept. of Orthopedics, Maninagar, Ahmedabad-380008.Gujarat
7. Dr. Ashish Kumar, King George Medical University, Dept of Orthopedic Surgery, Lal Bahadur Sastri Bhawan (R.A.L.C. Campus), Lucknow, Uttar Pradesh

8. Prof. Arvind Gore Gaonkar, LTM Medical College and Hospital, Head of dept. of Orthopedics, Sion, Mumbai-400022, Maharashtra
9. Dr. Rajesh Kumar Dulani, Jawaharlal Nehru Medical College & Hospital, Dept. of Orthopedics
10. Dr. Ankit Kedia, BJ Medical College & Civil Hospital, Dept of Orthopedics, Ahmedabad-380016
11. Dr. Suresh Kumar Kejriwal, Kolkata Medical College & Hospital, Dept of Orthopedics, #88, College Road, Kolkata-700073, West Bengal
12. Dr. Gaurav Jugal Kishore Rath, Rath Orthopedic & Research Centre, Nr Anupam Shopping Centre, Jodhpur Cross roads, Satellite, Ahmedabad 380 015
13. Dr. Naresh Shetty, M. S. Ramaiah Medical College & Hospitals, Dept. of Orthopedic Surgery, MSRIT Post, New BEL Road, Bangalore-560 054, Karnataka.
14. Dr. Ajit Yadav, Global Hospitals and Health City, Dept. of Orthopedics, 439, Cheran Nagar, Perumbakkam, Chennai -600 100
15. Dr. Pannala Krishna Subrahmanya Kumar, Kamineni Hospitals, Dept. of Orthopedics, L.B. Nagar, Hyderabad - 500 068.
16. Dr. D. Raj Kiran, Care Hospitals, Dept. of Rheumatology, Road No. 1, Banjara Hills, Hyderabad 500 034
17. Dr. Sarath Chandra Mouli Veerapalli, Krishna Institute of Medical Sciences Ltd. Dept. of Rheumatology, 1-8-31/1, Minister Road, Secunderabad, AP, 500003
18. Dr. Rajiv Gupta, Malpani Multispeciality Hospital, SP-6, Vishwakarma Institutional Area, Road-1, Sikar Road, Jaipur- 302013
19. Dr. Kunal Bhalia, MV Hospital & Research Centre, 314/30, Mirza Mandi, Chowk Lucknow- 226003
20. Dr. Raja Pandian, Apollo Speciality Hospitals, Dept. of Orthopedics, Lake View Road, K.K. Nagar, Madurai, Tamil Nadu- 625020
21. Dr. Surendra Umesh Kamath, Kasturba Medical College Hospital, Dept. of Orthopedics, Manipal University, Madhav Nagar, Manipal - 576 104
22. Dr. Smruti Ramteke, Jasleen Hospital, 10-B, PanCo-operative Housing Society heel Sq, D'Toll, R'Peth, Wardha Road, Resi-A 2nd Floor, Flat No 2, Sitabuldi, Nagpur, - 440012
23. Dr. Parag Sancheti, Sancheti Institute for Orthopaedics and Rehabilitation, 11/12 Thube Park, 16, Shivaji Nagar Pune - 411005. Maharashtra
24. Dr. Harshil Kalaria, Shree Giriraj Multispeciality Hospital, 150 ft Road, 27, Navjyot Park Main Road, Rajkot, Gujarat 360005
25. Dr. Sushil H. Mankar, NKPSIMS & Lata Mangeshkar Hospital, Dept of Orthopedics, Ligoloh Hills, Hingus road, Nagpur, Maharashtra-India
26. Dr. Girish Chandra Bartakke, BJ Medical College, Dept of Orthopedics, Near Pune Railway Station, Pune - 411001
27. Dr. Sajal R. Mitra, Government Medical College, Dept of Orthopedics, Nagpur
28. Dr. Somesh P. Singh, GMERS Medical & Hospital, Dept. of Orthopedics, Sola, Ahmedabad 380 061, Gujarat.

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 the Ethics Committee shall be obtained before initiation of the study;
- 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 ten 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. However, under no circumstances the number of trials should be more than three at a time.
- 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. You are also informed that audio visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done duly adhering to the principles of confidentiality. Such audio-visual recording and related documentation shall be preserved.
- m. All the sponsors /investigators /institutes/Organizations and other stake holders involved in conduct of clinical trials in the country are hereby directed to adhere to the above requirement of audio-visual recording of informed consent process of trial subjects with immediate effect.
- n. 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.

Yours faithfully,


(Dr. G.N. Singh)
Drugs Controller General (India)