F. No. IND/Form44/FF/2018/9693
CDSCO File No. IND/CT/18/000001
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road
New Delhi.
Dated: 08.04.2019

To
M/s Wockhardt Limited,
Wockhardt Towers,
Bandra-Kurla Complex,
Bandra (East), Mumbai.

Subject: Permission for conducting clinical study entitled, "A Phase III, Randomised, Multicentre, Double-Blind, Comparative Study to determine the Efficacy and Safety of Oral Nafithromycin versus Oral Moxifloxacin in the treatment of Community-Acquired Bacterial Pneumonia (CABP) in adults" - regarding.

CT NOC No. CT/ND/04/2019

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: WCK-4873-301, Protocol Amendment 03, Dated 05.02.2019** submitted to this Directorate.

S. No.	Investigator and Trial site	Ethics Committee Name and Registration Number
01	**Dr. Prakash Kurmi,** Shivam Hospital, C/4, Satyanarayan Society, Gor's Kuvo, Jashodanagar Char Rasta, Maninagar (E), Ahmedabad 380008	Shivam Ethics Committee, Shivam Hospital, C/4, Satyanarayan Society, Gor's Kuvo, Jashodanagar Char Rasta, Maninagar (E), Ahmedabad 380008 **ECR/63/Inst/GJ/2013/RR-13**
02	**Dr. Revati Chitko,** Vijan Cardiac and Critical Care Centre, Dr. Vijan Hospital Marg, College Road, Nashik-422005, Maharashtra.	Ethics committee, Vijan Cardiac and Critical Care Centre, Dr. Vijan Hospital Marg, College Road, Nashik-422005, Maharashtra. **ECR/406/Inst/MH/2013/RR-16**
03	**Dr. Bharat Jain,** ACE Hospital, Survey No. 32/2A, Erandwane, Pune, 411004	Ethical Committee, ACE Hospital & Research Center, S. No. 32/2A, Erandwane, Pune-411004, India **ECR/474/Inst/MH/2013/RR-16**
04	**Dr. Sushant H. Meshram,** Government Medical College, 1-A, Hanuman Nagar, Nagpur, Maharashtra 440009.	Institutional Ethics committee (IEC), Government Medical College, -A, Hanuman Nagar, Nagpur, Maharashtra 440009. **ECR/43/Inst/MH/2013/RR-16**

05	**Dr. Tushar Patel,** Shree Giriraj Multi Speciality Hospital, 27, Navjyot Park Main Road, 150 Feet Ring Road, Rajkot, Gujarat	Shree Giriraj Multispecialty Hospital Ethics committee, 27, Navjyot Park Main Road, 150 Feet Ring Road, Rajkot, Gujarat 360005 **ECR/74/Inst/GJ/2013/RR-16**
06	**Dr. Sumer Sanjiv Choudhary,** NKP Salve Institute of Medical Sciences, Digdoh Hills, Hingna Road, Nagpur 440019	Institutional Ethics Committee N.K.P. Salve Institute of Medical Sciences. Digdoh Hills, Hingna Road, Nagpur 440019. **ECR/88/Inst/MH/2013/RR-16**
07	**Dr. Anil Kumar Awasthi,** Ajanta Hospital and IVF Centre, 765, ABC Complex, Kanpur Road, Lucknow-226005.	Ethics Committee, Ajanta Hospital and IVF Center. 765, ABC Complex, Kanpur Road, Lucknow-226005 **ECR/611/Inst/UP/2014/RR-17**
08	**Dr. Srikanth Krishnamurthy,** Sri Bala Medical Centre Hospital, 604, Trichy Road, Ramanatha Puram, Ramanatha Puram, Coimbatore, Tamil Nadu - 641018	Institutional Human Ethics Committee (IHEC) Sri Bala Medical Centre & Hospital, 604, Trichy Road, Ramanatha Puram, Ramanatha Puram, Coimbatore, Tamil Nadu - 641018 **ECR/31/Inst/TN/2013/RR-16**
09	**Dr. Sandeep Nayar,** BLK Super Speciality Hospital, Building No-5, Pusa Road, Rajinder Nagar, New Delhi, Delhi 110005.	Dr. B. L. Kapur Memorial Hospital Ethics Committee, Pusa Road, Rajinder Nagar, New Delhi, Delhi 110005. **ECR/3/BLK/Inst/DL/2013/RR-16**
10	**Dr. Monica Gupta,** Samvedna Hospital, B27/884, Durgakund Rd, Opp. IP Vijaya Mall, Bhelupur, Varanasi, Uttar Pradesh 221005	Samvedna Hosptial Ethics Committee. B27/884, Durgakund Rd, Opp. IP Vijaya Mall, Bhelupur, Varanasi, Uttar Pradesh 221005 **ECR/ 45 /Inst/UP/2013/RR-16**
11	**Dr. Samir P Gami,** Unique Hospital Multispeciality and Research Institute, Opp. Kiran Motor, Near Canal Civil Hospital-Char Rasta Sosyo Circle Lane Off, Ring Rd, Surat, Gujarat 395002	Ethics Committee, Unique Hospital Multispeciality and Research Institute. Opp. Kiran Motor, Near Canal Civil Hospital-Char Rasta Sosyo Circle Lane Off, Ring Rd, Surat, Gujarat 395002. **ECR/595/Inst/GJ/2014/RR-17**
12	**Dr. Neeraj Manikath,** Government Medical College, Kozhikode, Medical College Road, Kozhikode, Kerala 673008	Institutional Ethics Committee, Government Medical college, Kozhikode, Medical College Road, Kozhikode, Kerala 673008 **ECR/395/Inst/KL/2013/RR-16**
13	**Dr. Rajesh Nair,** MAGJ Hospital, Mookkannoor P.O, Angamaly, Mookkannoor Ezhattumugham Rd, Ernakulam, Kerala 683577	Institutional Ethics Committee MAGJ Hospital, Mookkannoor, Ezhattumugham Rd, Ernakulam, Kerala 683577 **ECR/402/Inst/KL/2013/RR-16**
14	**Dr. K. G. Prakash,** Victoria Hospital, 63/A, Ground Floor, Dept. of medicine "C" block, BMC & RI, K. R. Road, fort, Bangalore 560002	Ethics Committee of Bangalore Medical college & Research Institute, Victoria Hospital, RI, K. R. Road, fort, Bangalore 560002 **ECR/302/Inst/Ka/2013/-RR-16**
15	**Dr. Mahesh PA,** J S S Medical College, Opposite J.S.S.Pharmacy College, Mysore-Bangalore Rd, Bannimantap, Mysuru, Karnataka 570015	Institutional Ethics Committee, JSS Medical College & Hospital, Mysore-Bangalore Rd, Bannimantap, Mysuru, Karnataka 570015 **ECR/387/Inst/KA/2013/-RR-16**

16	**Dr Hitesh Patel,** Saviour Multispeciality Hospital, Near Bharat Petrol Pump, Nr. Lakhudi Talav, Stadium road, Navrangpura, Ahemdabad-380014	Saviour Hospital Ethics Commiittee, Saviour Multispeciality Hospital, Near Bharat Petrol Pump, Nr. Lakhudi Talav, Stadium road, Navrangpura, Ahemdabad-380014 **ECR/656/Inst/GJ/2014/RR-17**
17	**Dr. Parul Mitesh Bhatt,** GMERS Medical College and Civil Hospital, 225, Sola Rd, Shenbhai Nagar, Sola, Ahmedabad, Gujarat 380081	Institutional Ethics Committee GMERS Medical College and Civil Hospital, 225, Sola Rd, Shenbhai Nagar, Sola, Ahmedabad, Gujarat 380081. **ECR/404/Inst/GJ/2013/RR-16**
18	**Dr Vinay Bhomia,** Sanjivani Super Speciality Hospital Pvt Ltd, I, New Uday Park Soc, Near Sunrise Park, Vstrapur, Ahmedabed-380015, Gujarat, India	Sanjivani Hospital Ethics Committee, Sanjivani Super Speciality Hospital Pvt Ltd, I, New Uday Park Soc, Near Sunrise Park, Vstrapur, Ahmedabed-380015, Gujarat, India. **ECR/183/Inst/Ahm./2013-RR-16**
19	**Dr Rajkumar Nikalje,** Lifepoint Multispeciality Hospital, Sr. No. 145/1, Mumbai Bypass Rd, Near Hotel Sayaji,, Wakad, Pimpri-Chinchwad, Maharashtra 411023	LPR Ethics Committee, Lifepoint Multispeciality Hospital, Sr. No. 145/1 Mumbai Bypass Rd, Near Hotel Sayaji, Wakad, Pimpri-Chinchwad, Maharashtra 411023 **ECR/751/Inst/MH/2015/RR-18**
20	**Dr Abdul Gafur,** Apollo Speciality Hospitals, No. 320, Padma complex, Anna Salai, Chennai-6000035, Tamil Nadu, India	Institutional Ethics Committee, Apollo Hospital, 21, Greams Lane, Off. Greams Road, Chennai, Tamilnadu 600006 **ECR/37/Inst/TN/2013/RR-16**
21	**Dr Chirag Rathod,** GMERS Medical College Gotri, Gotri Road, Vadodara 390021, Gujarat, India.	Institutional Human Ethics Committee (IRB) GMERS Medical College Gotri, Gotri Road, Vadodara 390021, Gujarat India. **ECR/28/Inst/GJ/2013/RR-16**

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 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) Investigational products 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 got approved from the 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)
and Licensing Authority