

F. No. ND/MA/25/000117/ ND/MA/25/000118
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-11 0002

To,

**M/s. Sun Pharma Laboratories Limited,
Sun Pharma Advanced Research Centre (SPARC),
Tandalja, Vadodara-390012, Gujarat**

Subject: Grant of permission to conduct Phase-III vide protocol titled “A Prospective, Multicenter, Randomized, Open Label, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Delafloxacin (Injection and Tablets) in comparison to Levofloxacin (Injection and Tablets) in patients with Severe Community Acquired Bacterial Pneumonia” Protocol Number: ICR/25/010, Version 2.0 dated 21-Nov-2025 -regarding.

Sir,

With reference to your application no. **ND/CT21/FF/2025/51243 & ND/CT21/FF/2025/51201 dated 11.08.2025**; please find enclosed herewith the permission in **Form CT-06, vide No. CT/ND/41/2025** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions, as mentioned below.

Yours faithfully
Digitally signed by RAJEEV
SINGH RAGHUVANSHI
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RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Conditions of permission

- (i) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licencing Authority under Rule 8;
- (ii) Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of Rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

- (iii) In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;
- (iv) The Central Licencing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;
- (v) Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;
- (vi) Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;
- (vii) Status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- (viii) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority;
- (ix) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;
- (x) Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI of the New Drugs and Clinical Trials Rules, 2019;
- (xi) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with the Chapter VI of the said Rules and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in *accordance* with the provisions of the said Chapter;
- (xii) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with the Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt

- of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;
- (xiii) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorized by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;
 - (xiv) Where the New Drug or Investigational New Drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;
 - (xv) The Laboratory owned by any person or a company or any other legal entity and utilized by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
 - (xvi) The Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;
 - (xvii) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
 - (xviii) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

FORM CT-06*(See rules 22, 25, 26, 29 and 30)***PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG****CT permission no: CT/ND/41/2025**

The Central Licensing Authority hereby permits **M/s. Sun Pharma Laboratories Limited, Sun Pharma Advanced Research Centre (SPARC), Tandalja, Vadodara-390012, Gujarat, Tel.: (91-265) 6615500 Fax: (91-265) 2354897** to conduct clinical trial of the new drug as per **Protocol Number: ICR/25/010, Version No. 2.0, dated 21.11.2025** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial site:

Names of the new drug or investigational new drug:	(i) Delafloxacin Tablets 450 mg (ii) Delafloxacin for Injection 300 mg/vial
Therapeutic class:	Fluoroquinolone antibacterial
Dosage form:	(i) Tablets (ii) Lyophilized Powder for Solution for Infusion
Composition:	(i) Each film coated tablet contains: Delafloxacin meglumine 649 mg equivalent to delafloxacin 450 mg. Excipients..... q.s. (ii) Each vial contains: Delafloxacin Meglumine 433 mg equivalent to Delafloxacin 300 mg Excipients.... q.s.
Indications:	Indicated in adults for the treatment of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus(methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila, and Mycoplasma pneumoniae.

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
1.	Dr. Surendra Kumar, MBBS, MD Clinical Research Unit, Near Medicine ICU & Maharaj AMRI. Department of Medicine, S.P. Medical College & A.G. of Hospitals, Bikaner-3 34001(Rajasthan)	S.P.Medical College, Bikaner Pawanpuri, Bikaner Bikaner Rajasthan - 334003 India ECR/27/SP/LNST/RJ/2013/RR-24
2.	Dr. Akhilesh. K, MBBS, MD Department of Respiratory Medicine, G Block, 3'd Floor, Amrita Institute of Medical Sciences and Research Centre, Aims Ponekkara P.O, Kochi-682041, Keraia, India.	Amrita Institute of Medical Sciences AIMS-Ponekkara Kochi Edappally Ernakulam Kerala -682041 India ECR/129/LNST/KL/2013/RR-24

3.	Dr. Rahul Gupta, MBBS, MD Jaipur National University Institute for Medical Sciences and Research Centre, Near New Rto Office, Agra Road, Jagatpura, Jaipur, Rajasthan, 302017	JNU Institute for Medical Sciences and Research Centre Jagatpura Jaipur Rajasthan -302017 India ECR/905/INST/RJ/2017/RR-25
4.	Dr. Raghumanda Sunil Kumar, MBBS, MD Department of Pulmonology, Government Hospital for Chest And Communicable Diseases (Ghccd), Andhra Medical Collage, Pedda Waltair, Visakhapatnam-530017, Andhra Pradesh, India	King George Hospital Maharanieta Collector Office Junction Visakhapatnam -530002 Andhra Pradesh -India. ECR/197/INST/KGH/2013/RR-20
5.	Dr. Ramaniwas, MBBS, MD OPD Building Department of Pulmonary Medicine, All India Institute of Medical Sciences, Bathinda, Mandi Dabwali Road, Jodhpur Romana, Bathinda, Punjab-151001, India	All India Institute of Medical Sciences, Bathinda Jodhpur Romana, Mandi Dabwali Road, Bathinda Punjab -151001 India ECR/1466/INST/PB/2020
6.	Dr. Bhim Ram, MBBS, MD Indira Gandhi Institute of Medical Sciences Sheikhpura, Patna Bihar -800014 India	Indira Gandhi Institute Of Medical Sciences Sheikhpura Raja Bazar Patna Patna Bihar -800014 India ECR/640/INST/BR/2014/RR-20
7.	Dr. Vijay Hadda, MBBS, MD AIIMS, Room No. 8, 3 Rd Floor Porta-Cabin, New Private Ward Block, Department of Pulmonary, Critical Care & Sleep Medicines, All India Institute of Medical Sciences, Ansari Nagar New Delhi -110029-India	Old Ot Block, Room No. 102, Aiims Hospital Ansari Nagar, New Delhi-110029-India ECR/538/INST/DL/2014/RR-25
8.	Dr. Rajesh Kumar Chawla, MBBS, MD Indraprastha Apollo Hospital, Sarita Vihar, Mathura Road, New Delhi-110076	Indraprastha Apollo Hospitals Delhi-Mathura Road, Sarita Vihar Delhi New Delhi, Delhi -110076 ECR/5/INST/DL/2013/RR-24
9.	Dr. Hirennappa B. Udnur, MBBS, DTCD, DNB, FCCP Medstar Speciality Hospital #641/17/1/3, Kodigehalli Main Road, Sahakarnagar, Bangalore-560092, Karnataka, India	Medstar Speciality Hospital Ethics Committee Medstar Speciality Hospital No 641/17/1/3 Kodigehalli Main Road sahakarnagar Post Bangalore Bengaluru ECR/1324/Inst/KA/2019/RR-24
10.	Dr. Ajit Singh, MBBS, MD SMS Medical College & Attached Hospitals, Dhanvantri OPD Block, Room no. 16, First floor, Division of Allergy & Pulmonary Medicine, JLN Marg, Jaipur -302004, Rajasthan, India	Ethics Committee S.M.S. Medical College and Attached Hospitals J.L.N. Marg Jaipur, Rajasthan -302004 India ECR/26/Inst/RJ/2013/RR-24
11.	Dr. Pankaj Magar, MBBS, DNB Pulse Multispeciality Hospital sr. no. 51/7/B/1 1 st floor, Vishwa Arcade Opp. Deccan Pavillion Hotel, Mumbai-Bangalore Highway, Narhe Pune.	Pulse Multispeciality Hospital Survey No. 51/7/B/1 Vishwa Arcade, Bombay Bangalore Highway, At Post Narhe PUNE Pune Maharashtra -411041 India ECR/1339/Inst/MH/2020/RR-25
12.	Dr. Surya Kant, MBBS, MD, D.Sc. Department of Respiratory Medicine, Ground Floor, HOD Room, King George's Medical University, U.P., Lucknow-226003	King Georges Medical University Shahmina Road, Chowk, Lucknow Lucknow Uttar Pradesh -226003 India ECR/262/Inst/UP/2013/RR-24

13.	Dr. Randeep Guleria, MBBS, MD Medanta-The Medicity CH Baktawar Singh Rd, Medicity Islampur Colony, Sector 38, Gurugram, Haryana	Medanta-The Medicity, Sector 38, Gurugram, Haryana 122001 ECR/282/Inst/HR/2013/RR-20
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3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

RAJEEV SINGH
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(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority
Stamp

New Delhi