Government of India
Central Drugs Standard Control Organisation(Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/24/000085 Dated 18-02-2025

To,

M/s Sun Pharmaceutical Industries Limited,
Tandalja Vadodara Vadodara (India) - 390012.

Subject: Application for grant of permission to conduct Phase III clinical trial titled – "A Prospective, Multicenter, Double-Blind, Active-Controlled, Parallel-Group, Phase III Study to Compare the Efficacy, Safety and Immunogenicity of Sun's Aflibercept with Reference Biologic in Patients with Neovascular Age-Related Macular degeneration (wet AMD)" vide Protocol No. ICR/24/006, Version No. 2.0 dated 06.11.2024– regarding

Ref.: Your Application No BIO/CT04/FF/2024/44438 dated 18-07-2024.

Sir,

With reference to your Application No. BIO/CT04/FF/2024/44438 dated 18-07-2024, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

(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 Licensing 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 Licensing 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 Licensing 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 Licensing Authority electronically in the SUGAM portal;

(IX) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing 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 Licensing 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;

(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 Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorised by the Central Licensing 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) The laboratory owned by any person or a company or any other legal entity and utilised 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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

(XV) The Central Licensing 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;

(XVI) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(XVII) 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.

(XVIII) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of two years from the date of its issue, unless extended by the Central Licencing Authority.

(XIX) The firm should submit Clinical study report (CSR) to this office after completion of trial.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

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

File. No. BIO/CT/24/000085

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits **M/s Sun Pharmaceutical Industries Limited, Tandalja Vadodara Vadodara (India) – 390012** to conduct clinical trial of the new drug or investigational new drug study titled – "A Prospective, Multicenter, Double-Blind, Active-Controlled, Parallel-Group, Phase III Study to Compare the Efficacy, Safety and Immunogenicity of Sun's Aflibercept with Reference Biologic in Patients with Neovascular Age-Related Macular degeneration (wet AMD)" vide Protocol No. ICR/24/006, Version No. 2.0 dated 06.11.2024 in the below mentioned clinical trial sites.

2. Details of new drug and clinical trial site [as per Annexure].
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.

Place: New Delhi
Date: 18.02.2025

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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Date: 2025.02.18 17:25:10 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:

Details of new drug or investigational new drug:

Name of the new drug to be manufactured	Aflibercept Injection 40 mg/ml, (0.278 ml/ vial)
Therapeutic Class	VEGF Inhibitor
Dosage form:	Solution for injection
Composition:	Each ml contains:

Name of Ingredient	**Quantity per ml (mg)**	**Function**
Aflibercept, In house	40 mg	Active Ingredient
Sodium chloride,USP/IP	2.338 mg	Osmogen
Polysorbate-20, USP/Ph. Eur./IP	0.3 mg	Stabilizer
Sucrose, USP/IP	50 mg	Osmogen
Sodium dihydrogen phosphate monohydrate, USP/IP	1.105 mg	Buffer
Disodium hydrogen phosphate heptahydrate, USP/IP	0.533 mg	Buffer
Water for Injection, In house/USP/IP	q.s. to 1.0 mL	Vehicle

Indication:	For the treatment of neovascular (wet) age-related macular degeneration (wet AMD)

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Ophthalmology Department, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer - 305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan – 305001 India ECR/1156/Inst/RJ/2018/RR-22	Dr. Rakesh Porwal
2	Department of Opthalmology, G.S.V.M. Medical College,	Ethics Committee, G.S.V.M. Medical College, Swaroop	Dr. Perwez Khan

	Swaroop Nagar, Kanpur-208002, UP	Nagar, Kanpur, Kanpur Nagar Uttar Pradesh - 208002 India ECR/680/Inst/UP/2014/RR-20	
3	Glaucoma Department, M&J Institute of Ophthalmology, 1st floor, Manjushri Mill Compound, Asarwa, Ahmedabad - 380016, Gujarat India	Institutional Ethics Committee, B.J. Medical College and Civil Hospital, Office of Medical Superintendent Civil Hospital, Ahmedabad Gujarat - 380016, India ECR/72/Inst/GJ/2013/RR-24	Dr. Purvi Raj Bhagat
4	Department of Ophthalmology, Motilal Nehru Medical College, George Town, Civil Lines, Prayagraj UP 211002.	Institutional Ethics Committee, Motilal Nehru Medical College, George Town, Prayagraj, Allahabad, Uttar Pradesh – 211002, India ECR/922/Inst/UP/2017/RR-22	Dr. Vinod Kumar Singh
5	Regional Institute of Ophthalmology, Rajendra Institute of Medical Sciences, Baritu, Ranchi 834009	Institutional Ethics Committee, Rajendra Institute of Medical Sciences, 4th Floor, Administrative Building Bariatu, Ranchi, Jharkhand – 834009, India ECR/769/Inst/JH/2015/RR-21	Dr. Sunil Kumar
6	Department of Ophthalmology, SMS Hospital, Department of Ophthalmology Charak Bhawan OPD Block Jaipur - 302004, Rajasthan.	Ethics Committee, S.M.S. Medical College and Attached Hospitals, J.L.N. Marg Jaipur, Rajasthan – 302004, India ECR/26/Inst/RJ/2013/RR-19	Dr. Sandeep Parwal
7	Umaprem Netralaya Eye Hospital, N6/13 E-1-2, Indira Nagar Colony, Extension-2, Chitapur, Varanasi- 221005, Uttar Pradesh, India.	Janta Hospital Ethics Committee, Janta Hospital and Maternity Center Servey Number 374, Amara-Akhari Bypass, Chunar Road Varanasi Varanasi Uttar Pradesh – 221011, India ECR/839/Inst/UP/2016/RR-19	Dr. Arun Kumar Gupta
8	Department of Ophthalmology, Career Institute of Medical science and Hospital Sitapur - Hardoj Bypass Road, Near I.I.M, Ghailla, Lucknow, Uttar	Institutional Human Ethics Committee, Udyaan Health Care, 730, Udyaan-1, Eldeco, Near Bangla Bazar, Lucknow,	Dr. Vijay Kumar Singh

	Pradesh -226020	Uttar Pradesh - 226002 India ECR/1300/Inst/UP/2019	
9	Dhadiwal Hospital in coalition with Shreeji healthcare, Opp. New CBS (Thakker's Bazar), Trimbak Road, Nashik-422002.	Shree Institutional Ethics Committee, Dhadiwal Hospital in Coalitation with Shreeji Health Care, Opp New CBS Trimbak Road Nashik, Maharashtra - 422002 India ECR/1149/Inst/MH/2018 /RR-21	Dr. Shah Anup Vijay kumar
10	Shanti Saroj Netralay, A.N. Gaikwad, 901, 902 Beside sundar nagar, Anand Nursing Home Road, off sangali - Miraj Rd, Maharashtra - 416410	Institutional Ethics Committee, Saishwari Clinic - Hospital for Mental Health, Saishwari Clinic - Hospital for Mental Health Yashwant Co Op Housing Society Sangali Road, Miraj, Sangli, Maharashtra – 416410, India ECR/1245/Inst/MH/2019	Dr. Bhomaj Sharad Shantinath
11	Department of Vitreo-Retina, Kar Vision Eye Hospital, Plot no 10, Janpath Road, Industrial Area, Satyanagar, Bhubaneshwar, 751001	Kar Vision Institutional Ethics Committee, Kar Vision Eye Hospital 10 Janpath Road Satya Nagar Bhubaneswar Khordha Orissa – 751007, India ECR/1630/Inst/OD/2021	Dr. Kanungo Sanghamitra
12	Netralaya Super Speciality Eye Hospital, OPD Area room no D1 & R1, 1st Floor, Kay DEE House, Above Union Bank, Parimal Garden Cross Road, Chimanlal Girdharlal Rd, Ambawadi, Ahmedabad, Gujarat 380006	Swarnim Ethics Committee, Netralaya Super Speciality Eye Hospital, 1st Floor KayDee House Opp. Gujarat Gas Parimal Garden Cross Road Ellisbridge, Ahmedabad Gujarat - 380006 India ECR/1922/Inst/GJ/2 024	Dr. Rana Parth Jagdishkumar
13	Sankara Eye Hospital, Varthur main road, Kundalahalli gate, Bangalore 560037	Institutional Ethics Committee, Sankara Eye Hospital, Varthur Main Road, Kundalahalli Gate, Bengaluru (Bangalore) Rural, Karnataka – 560037, India ECR/705/Inst/KA/2015/RR-21	Dr. Mishra Divyansh Kailash Chandra

14	Shantilal Shanghvi Eye Institute, CSNo.3/207, 4/207, R J Gaikwad Road, Barkat Ali Naka, Wadala East, Mumbai 400037	Shantilal Shanghvi Foundation Ethics Committee, Shantilal Shanghvi Eye Institute, SSEI - 4/207, RJ Gaikwad Road Barkat Ali Naka, Wadala East, Mumbai, Maharashtra - 400037, India ECR/2006/Inst/PB/2024	Dr. Sheth Jay Umed

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