

Nil

File No. FDC/MA/21/000175  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(FDC Division)

Tele. No.: 011-232369  
Fax No. : 011-23236973

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated:

17 SEP 2021

To,

M/s. Sun Pharma Laboratories Ltd.,  
Sun House, Plot No. 201 B/1,  
Western Express Highway, Goregaon (E),  
Mumbai-400063.

**Subject:** Permission to conduct Phase III clinical trial with the FDC of Silodosin 8mg - Tadalafil IP 5mg capsules (Vide protocol no. ICR/21/008, version no. 1.0, dated 05.07.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 30.07.2020 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-149/2021** under the provision of Drugs and Cosmetics Act and Rules. The permission is subject to the conditions mentioned below.

Kindly acknowledge receipt to this letter and its enclosures.

Yours faithfully,

*Vh*

(Dr. V. G. Somani)  
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:
  - i. 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;
  - ii. 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;

**FORM CT-06**

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

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

Permission no.: **CT-06-149/2021**

1. The Central Licencing Authority hereby permits **M/s. Sun Pharma Laboratories Ltd., Sun house, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai-400063.** (Name and full address with contact details of the applicant) to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. ICR/21/008, version no. 1.0, dated: 05.07.2021)** in the below mentioned clinical trial sites.
2. Details of new drug or investigational 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: .....

**17 SEP 2021**

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Silodosin 8mg + Tadalafil IP 5mg capsules
Therapeutic class:	Alpha1 adrenoceptor blocker and PDE5 inhibitor
Dosage form:	Capsules
Composition:	Each capsule contains: Silodosin 8mg + Tadalafil IP 5mg
Indications:	For the treatment of Lower Urinary Tract symptoms associated with Benign Prostatic Hyperplasia and Erectile Dysfunction.

Details of clinical trial site:

Names and address of clinical trial site:	As per annexure- A
Ethics committee details:	As per annexure- A
Name of principal investigator:	As per annexure- A

**Central Licencing Authority**

**Stamp**

**Dr. V. G. SOMANI**  
Drugs Controller General (India)  
Dte. General of Health Services  
Ministry of Health and Family Welfare  
FDABha, New Delhi, I.T.O.  
New Delhi-110002



Permission no.: CT-06-149/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Andankar Mukund Gopalkrishna	T.N. Medical College & B.Y.L. Nair Hospital, Topiwala National Medical College Nair Hospital, Dr. A.L. Nair Road, Mumbai Centre, Mumbai City Maharashtra-400008..	Institutional Ethics Committee TNM Nair Hospital, Topiwala National Medical College Nair Hospital, Dr. A Nair Road, Mumbai Centre, Mumbai City Maharashtra-400008. ECR/22/Inst/Maha/2013/RR-19
2	Dr. Chaudhari Hiralal Narottam	Oyster & Pearl Hospitals, Ganeshkhind Road, Shivajinagar, Pune.	O & P Ethics Committee, phadnis Clinic Pvt Ltd., Shivajinagar, Pune ECR/71/Inst/MH/2013/RR-19
3	Dr. Dhanajay Selukar	Government Medical College and Super Speciality Hospital, Tukdoji Square, Nagpur-440009, Maharashtra, India.	Institutional Ethics Committee, GMC Nagpur, ECR/43/Inst/MH/2013/RR-19
4	Dr. Prashant Darakh	Darakh Nursing Home & kidney stone center, Raghuveer Nagar, Jain Road, Aurangabad-431001, India	Ethics Committee Ajanta Superspeciality Hospital, Aurangabad Maharashtra-431003, India. ECR/1499/Inst/MH/2021
5	Dr. Darshan Patel	V. S. General Hospital, 605, Paldi Rd, Madalpur Gam, Paldi, Ahmedabad, Gujarat 380006.	Institutional Ethics Committee, Sang Hospital, 2nd floor, Sangini Complex near Doctor House, Parimal Crossing Ahmedabad ECR/147/Inst/GJ/2013/RR-19
6	Dr. Darshil Sunilbhai Shah	K D Hospital, SG Road, Vaishnodevi Cir, Ahmedabad, Gujarat 382421	K D Hospital Institutional Ethics Committee, SG Road, Vaishnodevi C Ahmedabad, Gujarat 382421. ECR/1294/Inst/GJ/2019
7	Dr. Shah Ishan Hemamtkumar	Dr. M K Shah Medical college, Visat Gandhi Nagar Highway, Ahmedabad-382424.	Institutional Ethics Committee, Dr. M K Shah Medical college, Visat Gandhi Nagar Highway, Ahmedabad 382424. ECR/1383/Inst/GJ/2020
8	Dr. Pawan Kumar Jindal	Opal Hospital Private Limited, Varanasi, N-10/60-2, KAKARMATTA, DLW ROAD, VARANASI, Uttar Pradesh, India	Opal Institutional Ethics Committee, N 10/60-2, KAKARMATTA, DLW ROAD, VARANASI, Uttar Pradesh, India, ECR/976/Inst/UP/2017/RR-20
9	Dr. Vinay Kumar	GSVM Medical College, Kanpur- 208002, UP, India	Ethics Committee, GSVM Medical College, Kanpur- 208002, Uttar Pradesh ECR/680/Inst/UP/2014/RR-17
10	Dr. Suresh Ulivvepa Kadli	Basaveshwara Medical College and Hospital Chitradurga-577502, Karnataka, India.	Institutional Ethics Committee, Basaveshwara, Medical College & Hospital, KHB Colony, Kelagote, Near NH-48, Chitradurga-577502. ECR/1218/Inst/KA/2019
11	Dr. Tapan Kumar Mandal	NRS Medical College, 138, Acharya Jagadish Chandra Bose Rd, Sealdah, Raja Bazar, Kolkata, West Bengal 700014.	Ethics Committee NRS Medical College, 138, Acharya Jagadish Chandra Bose Rd, Sealdah, Raja Bazar, Kolkata, West Bengal 700014. ECR/609/Inst/WB/2014/RR-17
12	Dr. Das Subodh Kumar	AMRI hospital Ltd, Plot No. 01, Near Satyasai Enclave Khandagiri, Bhubaneswar, Orissa-751030	Institutional Ethics Committee, Plot No 01, Near Satyasai Enclave Khandagiri, Bhubaneswar, Orissa-751030 ECR/903/Inst/OR/2017/RR-20

13	Dr. Malay Kumar Bera	Medical College Kolkata, 88, College St, Calcutta Medical College, College Square, Kolkata, West Bengal 700073	Medical College Kolkata, 88, College St, Calcutta Medical College, College Square, Kolkata, West Bengal 700073 ECR/287/Inst/WB/2013/RR-19
14	Dr. Prakash H S	KR Hospital Attached to Mysore Medical college and Research Institute, Irwin Road, Mysuru, Karnataka-570001.	Institutional Ethics Committee, Mysore Medical college and Research Institute and Associated Hospital ECR/134/Inst/KA/2013/RR-19
15	Dr. Sanjeev Tonshal	Saptagiri Institute of Medical Science & Research Centre, Hesaraghatta main Raod, Bangalore-560090.	Institutional Ethics Committee, Saptagiri Institute of Medical Science & Research Centre ECR/583/Inst/KA/2014/RR-20
16	Dr. Avinash TS	Sparsh Super Specialty Hospital, 4/1, Tumkur Rd, Yashwanthpur, Bengaluru, Karnataka 560022.	Institutional Ethics Committee Sparsh Hospital SPARSH Super Speciality Hospital, 146, Infantry Rd, Vasanth Nagar, Bengaluru, Karnataka 560001 ECR/520/Inst/KA/2014/RR-20
17	Dr. G Ravi Chander	Gandhi Hospital, Secunderabad, Telangana	Institutional Ethics Committee, Gandhi Medical College/Gandhi Hospital, Musheerabad, Secunderabd-500003, Telangana, India ECR/180/Inst/AP/2013/ RR-19
18	Dr. Mallikarjuna G.	Osmania Medical College and Osmania General Hospital, Hyderabad	Institutional Ethics Committee, Osmania Medical College, Hyderabad ECR/300/Inst/AP/20 13/RR-19

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Drugs Controller General (India)  
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