

Nil

✓ File No. FDC/MA/19/000129
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No.:011-23236965
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FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

14 FEB 2020

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 clinical trial with the FDC of Silodosin 8mg + Solifenacin Succinate Ph. Eur. 5mg capsule (Vide protocol no. ICR/19/003, version no. 2.0, dated: 09.12.2019)-regarding.

Dear Sir,

With reference to your letter No. nil dated 11.10.2019 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-06/2020 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,



(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:
- III. 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:
- IV. 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;

- V. 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;
- VI. 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;
- VII. 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;
- VIII. 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;
- IX. 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;
- X. 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 electronically in the SUGAM portal;
- XI. 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;
- XII. 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;
- XIII. 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 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;
- XIV. 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 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;
- XV. 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 authorised 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;
- XVI. 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;
- XVII. 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;
- XVIII. 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;
- XIX. The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- XX. **The formulation intended to be used in the study shall be manufactured under GMP conditions using validated procedures.**

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

Permission no.: CT-06-06/2020

1. The Central Licensing 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 **ICR/19/003, version no. 2.0, dated: 09.12.2019** 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:

Date: **14 FEB 2020**

Vh
Central Licensing Authority

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

Annexure:

Details of new drug or investigational new drug:

| | |
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| Names of the new drug or investigational new drug: | Silodosin 8mg + Solifenacin Succinate Ph. Eur. 5mg capsule |
| Therapeutic class: | Silodosin: A selective antagonist of alpha-1 adreno receptor. Solifenacin Succinate: A muscarinic receptor antagonist. |
| Dosage form: | Capsule |
| Composition: | Each capsule contains: Silodosin 8mg + Solifenacin Succinate Ph. Eur. 5mg |
| Indications: | For the treatment of Benign Prostatic Hyperplasia (BPH)/Lower Urinary Tract Symptom (LUTS) with overactive bladder. |

Details of clinical trial site:

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| 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 |

Permission no.: CT-06-06/2020

| S. No. | Name of PI | Site Name | Ethics Committee Name, Address | Ethics Committee Registration number |
|--------|--|---|---|--------------------------------------|
| 1 | Dr. Santosh Bukya (Assistant Professor) | Department of Urology, Osmania General Hospital, Hyderabad | Institutional Ethics Committee, Osmania Medical College, Hyderabad | ECR/300/Inst/AP/2013/RR-19 |
| 2 | Dr. Vinay Tomar (Director, Senior Professor & Unit Head) | Department of Urology, SMS Medical College and Attached Hospitals, Jaipur | Ethics Committee, SMS Medical College & Attached Hospitals, Jaipur | ECR/26/Inst/RJ/2013/RR-19 |
| 3 | Dr. Prof. S. N. Sankhwar (Head of Department) | Department of Urology, King George's Medical University, Lucknow | Institutional Ethics Committee, King George's Medical University, Lucknow | ECR/262/Inst/UP/2013/RR-19 |
| 4 | Dr. G Ravi Chander (Associate Professor and HOD) | Department of Urology, Gandhi Medical College/ Hospital, Secunderabad | Institutional Ethics Committee, Gandhi Medical College and Hospital, Secunderabad | ECR/180/Inst/AP/2013/RR-19 |
| 5 | Dr. Dhananjay V. Selukar (Associate Professor and Head) | Department of Urology, Government Medical College & Super Speciality Hospital, Nagpur | Institutional Ethics Committee, Government Medical College, Nagpur | ECR/43/Inst/MH/2013/RR-19 |
| 6 | Dr. Malay Kumar Bera (Professor and HOD) | Department of Urology, Medical College, Kolkata | Institutional Ethics Committee for Human Research Medical College, Kolkata | ECR/287/Inst/WB/2013/RR-19 |
| 7 | Prof. (Dr.) Rajeev Sood (Professor, Consultant Urologist and Head of Department) | Department of Urology, Dr. Ram Manohar Lohia Hospital & PGIMER, New Delhi | Ethics Committee, PGIMER, Dr. RML Hospital, New Delhi | ECR/78/Inst/DL/2013/RR-19 |
| 8 | Dr. Mahajan Pratikshit Madhav (Consultant Urologist and Andrologist) | Shree Siddhivinayak Maternity & Nursing Home, Nashik | Shree Siddhivinayak Hospital Ethics Committee | ECR/1247/Inst/MH/ 2019 |
| 9 | Dr. Shashikant Ramrao Bhanghe (Consultant Urologist) | Noble Hospital Pvt. Ltd., Pune | Noble Hospital Institutional Ethics, Pune | ECR/259/Inst/MH/2013/RR-19 |

| | | | | |
|----|--|---|--|---------------------------|
| 10 | Dr. Pawan Kumar Jindal (Consultant Urologist) | Opal Hospital Private Limited, Varanasi | Opal Institutional Ethics Committee, Varanasi | ECR/976/Inst/U P/2017 |
| 11 | Dr. Chaudhari Hiralal Narottam (Consultant Urologist) | Oyster & Pearl Hospitals, Pune | O & P Institutional Ethics Committee, Oyster & Pearl Hospitals, Pune | ECR/71/Inst/MH/2013/RR-19 |
| 12 | Dr. Kunal Hemant Aterkar (Consultant Urologist) | Lotus Multispeciality Hospital, Ahmedabad | Lotus Ethics Committee, Ahmedabad | ECR/990/Inst/G J/2017 |

Place:

Date:

14 FEB 2020


Dr. V. G. SOMANI
Drugs Controller General (India)
Central Licensing Authority
Ministry of Health and Family Welfare
FDA, Connaught Place, I.T.O.
New Delhi-110002
Stamp