

ND/CT21/BO/2020/19891  
Dated: 27.05.2020

**F. No. ND/MA/20/000075**  
**Government of India**

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**Directorate General of Health Services**  
**Central Drugs Standard Control Organization**  
**(New Drugs Division)**

FDA Bhawan, Kotla Road,  
New Delhi-110002  
Dated:

22 JUL 2020

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

**Subject:- Permission for conducting clinical study entitled, "A Comparative, Randomized, Two Arm, Double Blind, Parallel Group, Multicentric, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Netarsudil Ophthalmic Solution 0.02% w/v Versus Timolol Maleate Eye Drops 0.5% w/v in treatment of elevated intraocular pressure (IOP) in subjects with open angle glaucoma or ocular hypertension" vide Protocol Number ICR/19/015 Version No. 1.0 dated 08.01.2020.- regarding.**

Sir,

With reference to your application No. ND/CT21/BO/2020/19891, Dated: 27.05.2020, please find enclosed herewith the permission in Form CT-06, No. **CT/ND/63/2020** 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**



**(Dr. V. G. Somani)**  
**Central Licensing Authority**

**Condition 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 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;
  - (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 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 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.
  - (xix) Inclusion criteria should be revised to include patients with vision 6/12 or better.**
  - (xx) The central corneal thickness mentioned in exclusion criteria should be revised to 580  $\mu\text{m}$  in either eye instead of 620  $\mu\text{m}$ .**
  - (xxi) Accordingly, revised protocol should be submitted.**

**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 Licensing Authority hereby M/s Sun Pharmaceutical Industries Limited, Tandalja, Vadodara (India) – 390012 to conduct clinical trial of the new drug as per **Protocol Number ICR/19/015 Version No. 1.0 dated 08.01.2020** in the below mentioned clinical trials sites.

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

<b>Names of the new drug or investigational new drug:</b>	Netarsudil Ophthalmic Solution 0.02% w/v	
<b>Therapeutic class:</b>	Rho kinase inhibitor	
<b>Dosage form:</b>	Ophthalmic solution	
<b>Composition:</b>	Netarsudil Ophthalmic Solution 0.02% Each ml contains: Netarsudil Dimesylate eq. to Netarsudil....0.2mg  Benzalkonium Chloride Solution IP.....0.015% w/v (As preservative)  Aqueous Buffered Vehicle..... q. s.	
<b>Indications:</b>	Indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or Ocular Hypertension.	
<b>Details of clinical trial sites-</b>		
<b>Sr. No.</b>	<b>Name of Principal Investigator &amp; Trial Sites</b>	<b>Ethics Committee Name/ Registration Number</b>
01	<b>Dr. Radha Annamala</b> Sri Ramachandra Institute of Higher Education and Research (DU), Clinical Research Division, Dental College Basement, No.1, Ramachandra Nagar, Porur, Chennai - 600116, Tamil Nadu, India	Institutional Ethics Committee SRIHER <b>ECR/203/Inst/TN/2013/RR-19</b>
02	<b>Dr. Sodimalla Kalyani Vijaya Kumar</b> PBMA's H.V. Desai Eye Hospital, S. No. 93, Tarawade Vasti, Mohammadwadi Hadapsar, Pune -	Institutional Ethics Committee, PBMA's H.V. Desai Eye Hospital <b>ECR/234/Inst/MH/2013/RR-19</b>

	411060 Maharashtra.	
03	<p><b>Dr. Shitole Satish Chandrakant</b></p> <p>OPD No. 69,1st Floor, Department of Ophthalmology, B. J. Govt. Medical College And Sassoon General Hospital,Pune- 411001</p>	<p>IEC Of B.J .G.M. C And Sassoon General Hospital</p> <p><b>ECR/280/Inst/Maha/2013/RR-19</b></p>
04	<p><b>Dr. Tanmay Kabra</b></p> <p>Department of Ophthalmology Charak Bhawan OPD Block, J.L.N Marg SMS Hospital Jaipur- 302004 Rajasthan</p>	<p>Ethics Committee, S.M.S. Hospital</p> <p><b>ECR/26/Inst/RJ/2013/RR-19</b></p>
05	<p><b>Dr. Purvi Bhagat</b></p> <p>M &amp; J Institute of Ophthalmology, Room 113, Glaucoma Department ,First floor Manjushri Mill compound , Asarwa, Ahmedabad -16, Gujarat, India</p>	<p>Institutional Ethics Committee, B.J. Medical College &amp; Civil Hospital</p> <p><b>ECR/72/Inst/GJ/2013/RR-19</b></p>
06	<p><b>Dr. Swati Samant</b></p> <p>Institute of Medical Sciences (IMS) &amp; SUM Hospital S 'O' A University, K8, Kalinganagar, Bhubaneswar- 751003, Odisha, India</p>	<p>IEC, IMS and SUM Hospital</p> <p><b>ECR/627/Inst/OR/2014/RR-17</b></p>
07	<p><b>Dr. B. Kantha Sree</b></p> <p>Dept. of Ophthalmology, Gandhi Hospital, Secunderabad, Telangana – 500003</p>	<p>Institutional Ethics Committee, Gandhi Hospital</p> <p><b>ECR/180/Inst/AP/2013/RR-19</b></p>
08	<p><b>Dr. Bhagyajyothi Balappa Khanagavi</b></p> <p>KLEs Dr Prabhakar Kore Hospital &amp; MRC, Nehru Nagar, Belagavi- 590010</p>	<p>Institutional Ethics Committee, KLE University</p> <p><b>ECR/211/Inst/KA/2013/RR-19</b></p>
09	<p><b>Dr. Srivastava Rajat Mohan Om Prakash</b></p> <p>Department of Ophthalmology, King George's Medical University, Shahmina Road, Chowk, Lucknow- 226003, Uttar Pradesh, India</p>	<p>Institutional Ethics Committee, King George's University</p> <p><b>ECR/262/Inst/UP/2013/RR-19</b></p>
10	<p><b>Dr. Rupali Chopra</b></p>	<p>Institutional Ethics Committee, CMC Hospital</p>

	Dept. of Ophthalmology, Christian Medical College and Hospital, Brown Road, Ludhiana, Punjab-141008	<b>ECR/120/Inst/PB/2013/RR-19</b>
<b>11</b>	<b>Dr. Dahiya (Miss) Sumita</b> Dr. D.Y. Patil Medical College Hospital & Research Centre, Plot No.2 Sector 5, Nerul, Navi Mumbai 400706.	Institutional Ethics Committee, D.Y. Patil Medical College <b>ECR/195/Inst/MH/2013/RR-19</b>

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.



**(Dr. V. G. Somani)**  
**Central Licensing Authority**  
**Stamp**

**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

**New Delhi**

**Date: .....**

**22 JUL 2020**