



GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
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File No. CT/21/000005

To,

M/s Kendle India Private Limited,
Building 14, Tower B, 14th Floor, DLF Cybercity
(SEZ), DL Phase III, Haryana (India) – 122001.

Sir,

With reference to your application No. GCT/CT04/FF/2021/23563 (GCT/05/21) dated 12/01/2021, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A randomized, active-controlled, double-masked, parallel group phase 3 study to compare efficacy and safety of CT-P42 in comparison with Eylea in patients with diabetic macular edema”, Protocol Number: CTP42 3.1 Protocol Version 1.0 dated 22-October-2020** under the provisions of New Drugs and Clinical Trial Rules, 2019

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

- (i) **Company should provide post trial access of reference drug for reference group of patients as per ND & CT Rules 2019.**
- (ii) 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;
- (iii) 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;
- (iv) 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;
- (v) 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;
- (vi) 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;
- (vii) 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;

- (viii) 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;
- (ix) 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;
- (x) 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;
- (xi) 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;
- (xii) 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;
- (xiii) 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;
- (xiv) 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;
- (xv) 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;
- (xvi) 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;
- (xvii) 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;
- (xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xix) 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.

Yours faithfully,

VENUGOPAL
GIRDHARILA
L SOMANI

(Dr. V. G. Somani)

Drugs Controller General (India)
Central Licencing Authority
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Digitally signed by VENUGOPAL
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FORM CT-06
(See rules 22,25,26,29 and 30)

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

1. The Central Licensing Authority hereby permits **M/s. Kendle India Private Limited, Kendle India Private Limited Building 14, Tower B, 14th Floor, DLF Cybercity (SEZ), DLF Phase III Gurugram (India) – 122001** to conduct clinical trial of the new drug or investigational new drug as per **Protocol Number: CTP42 3.1 Protocol Version 1.0 dated 22-October-2020** in the below mentioned clinical trial sites [As per Annexure].-
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 _____

**VENUGOPAL
GIRDHARILA
L SOMANI**
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(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
Stamp

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	CT-P42
Therapeutic class:	Recombinant Protein composed of VEGF Receptor
Dosage form:	IVT Injection
Composition:	Endotoxin <0.4000 EU/mL In House Specification Individual Impurity Isoaspartate Assay <=0.3000 molisoaspartate per mol aflibercept In House Specification Inactive SEC-HPLC 95.0000 to100.0000 % In House Specification Active CE-SDS (Non-Reduced) 79.0000 to100.0000 % In House Specification Active CE-SDS (Reduced) 90.0000 to100.0000 % In House Specification Active
Indications:	Diabetic Macular Edema

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	BB Eye Foundation VIP Shree Tower II, 2nd floor, RAA 36, Raghunathpur, Kolkata - 700059, West Bengal, India	BB Eye Foundation VIP Unit (Unit Of Kolkata Eye Care Pvt. Ltd.) Shree Tower II, 2nd Floor, RAA 36, Raghunathpur, VIP road, Kolkata - 700059, West Bengal, India ECR/1019/Inst/WB/2017	Dr. Rupak Kanti Biswas
2.	Dr. Virendra Laser Phaco & Surgery Centre, Tonk Phatak, Behind Toyota Car Showroom, Tonk Road, Gandhi Nagar Jaipur-302015, Rajasthan, India	Institutional Ethics Committee, Dr Virendra Laser Phaco Surgery Centre, Address: Tonk Phatak, Behind Toyota Car Showroom, Tonk Road, Gandhi Nagar Jaipur - 302015, Rajasthan, India ECR/1097/Inst/RJ/2018	Dr. Virendra Agrawal
3.	PBMA's H.V. Desai Eye Hospital, Department of Medical Retina, 93, Tarawade Vasti, Mohmmadwadi, Hadapsar, Pune 411060, Maharashtra, India	Institutional Ethics Committee, PBMA's H. V. Desai Eye Hospital S.No. 93, Tarawade Vasti, Mohammdwadi Road Hadapsar, Pune - 411060, Maharashtra, India ECR/234/Inst/MH/2013/RR-19	Dr. Ashwini Sonawane
4.	Narayana Nethralaya 121/C, Chord Road, Rajajinagar, Ist R Block Bangalore-560010 INDIA.	Narayana Nethralaya Ethics Committee, Narayana Nethralaya 121/C, Chord Road, Rajajinagar, Ist R Block Bangalore-560010 INDIA. ECR/187/Inst/KAR/2013/RR-16	Dr. Santosh Gopi Krishna G
5.	Advanced Eye Centre. PGIMER Sector - 12, Chandigarh, 160012	Institutional Ethics Committee Room No. 6006, 6th floor, Chuttani Block, Post Graduate Institute of Medical Education and Research, Sector-12 Chandigarh ECR/25/Inst/CH/2013/RR-16	Dr. Ramandeep Singh
6.	Dr. Rajendra Prasad Centre for Ophthalmic Sciences All India Institute of Medical Sciences Ansari Nagar, New Delhi-110029	Institute Ethics Committee, All India Institute of Medical Sciences Room No 102, I st Floor Old O.T. Block Ansari Nagar New Delhi- I I 0029 India ECR/538/Inst/DL/2014/RR-20	Dr. Rajpal
7.	Sankara Eye Hospital, Varthur Main Road, Kundalahalli gate, Banglaore-560037, Karnataka, India.	Institutional Ethics Committee, Sankara Eye Hospital, Varthur Main Road, Kundalahalli Gate, Bangalore- 56003 7, Karnataka, India. ECR/705/Inst/KA/2015/RR-18	Dr. Nidhi Tiwari

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8.	Indira Gandhi Institute of Medical Sciences Sheikhpura, Patna- 800014	Institutional Ethics Committee, IGIMS Sheikhpura, Patna-800014 ECR/640/Inst/BR/2014	Dr Bibhuti Prassan Sinha
9.	Dr. Naresh Babu Kannan Aravind Eye Hospital and Postgraduate Institute of Ophthalmology, No. 1, Anna Nagar, Madurai - 625020, Tamil Nadu, India	Institutional Ethics Committee, Aravind Eye Hospital, No. 1 Anna Nagar, Madurai - 625020 Tamil Nadu, India ECR/182/Inst/TN/2013/RR-19	Dr. Naresh Babu Kannan
10.	B. J. Govt. Medical College and Sassoon General Hospital Block No. 69, First Floor, Sassoon General Hospital, Jai Prakash Narayan Road, Near Pune Railway Station, Pune-411001, Maharashtra, India.	Institutional Ethics Committee - B.J. Govt. Medical College and Sassoon General Hospital, Department of Pharmacology, B.J. Govt. Medical College and Sassoon General Hospital, Jai Prakash Narayan Road, Near Pune Railway Station, Pune-411001, Maharashtra, India. ECR/280/Inst/Maha/2013/RR-19	Dr. Usha Subhash Nikumbh
11.	L V Prasad Eye Institute, GMRV Campus. Hanumanthwaka Junction, Visakhapatnam - 530040, Andhra Pradesh, India	Institutional Ethics Committee L V Prasad Eye Institute, GMRV Campus. Hanumanthwaka Junction. Visakhapatnam - 530040, Andhra Pradesh. India, India. ERC/888/Inst/AP/2016/RR-20	Dr. Bhavik Panchal
12.	Sankara Eye Hospital, Sathy Road, Sivanandhapuram, Coimbatore - 641035 Tamil Nadu, India.	Institutional Ethics Committee, Sankara Eye Hospital, Sathy Road, Sivanandhapuram, Coimbatore-641 035 Tamil Nadu, India ECR/1037/Sankara/Inst/TN/2013/RR-17	Dr. Prabhu Shanker Mahalingam
13.	St. Theresa's Hospital Sanathnagar, Hyderabad, Telangana 500018, India	Ethics Committee, St. Theresa's Hospital, St. Theersa's Hospital, Sanathnagar Hyderabad, Telangana-500038, India ECR/230/INST/AP/2013/RR-19	Dr. Mahajan Sheshadri Vishnu
14.	L V Prasad Eye Institute, MTC Campus, Patia, Bhubaneswar-751024, Odisha, India	Institutional Ethics Committee, L V Prasad Eye Institute, MTC campus, Bhubaneswar- 751024, Odisha, India ECR/496/Inst/OR/2013/RR-19.	Dr. Umesh Chandra Behera