



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/19/000038

To,

M/s. Excel Life Sciences Pvt. Ltd.,
Assotech Business Cresterra, Tower-02,
9th Floor, Unit 912, Plot No. 22, Sector-135
Noida-201301, Uttar Pradesh.

Sir,

With reference to your application No GCT/Form44/FF/2019/14669 (GCT/36/19) dated 10-05-2019, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Double-Masked, Placebo-Controlled, Randomized, Phase II Clinical Trial To Assess The Efficacy Of IVIEW-1201 In The Treatment Of Acute Adenoviral Conjunctivitis”, Protocol Number IVIEW-1201-01-AIC, version II dated 29/04/2019** 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) 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 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 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 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;
- (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 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 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) 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,

S ESWARA
REDDY

Digitally signed by S ESWARA REDDY
DN: cn=S ESWARA REDDY, o=CENTRAL LICENSING AUTHORITY,
c=IN, email=s.ESWARA.Reddy@nic.gov.in, serial=10502, version=1
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(Dr. S. Eswara Reddy)
Drugs Controller General (India)
Central Licensing Authority
Stamp

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

1. The Central Licensing Authority hereby permits **M/s. Excel Life Sciences Pvt. Ltd., Assotech Business Cresterra, Tower-02, 9th Floor, Unit-912, Plot No. 22, Sector-135, Noida-201301, Uttar Pradesh** to conduct clinical trial of the new drug or investigational new drug as per protocol number **IVIEW-1201-01-AIC, version II dated 29/04/2019** 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 ct, 1940.

Place: New Delhi

Date _____

**S ESWARA
REDDY**

Digitally signed by S ESWARA REDDY
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version=3

(Dr. S. Eswara Reddy)

Drugs Controller General (India)

Central Licensing 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	IVIEW-1201				
Therapeutic class:	Anti-Infective				
Dosage form:	Eye Drop				
Composition:	Component	Quantity (mg/g)	Percentage (w/w%)	Function	Reference to Standard
	Povidone-Iodine (Available Iodine)	10.0 (1.0)	1.0% (0.10%)	Active Ingredient: Antiseptic	USP
	Kelcogel (Deactylated gellan gum, Gelrite®)	2.5	0.25%	Gel-forming agent	NF

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	Sodium Chloride	2.5	0.25%	Osmolanty and gel-forming regulator	USP
	Mannitol	33.0	3.3%	Osmolanty regulator	USP
	Tromethamine	Q.S. to pH 5.5		pH regulator	USP
	Water for Injection	Q.S. to 1 g	100%	Diluent	USP
Indications:	Acute Adenoviral Conjunctivitis				

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
Charak Bhawan, Department of Ophthalmology, SMS Medical College and Hospital, JLN Marg, Jaipur-302004, Rajasthan, India.	Institution Ethics Committee, SMS Medical College and Attached Hospital, Jaipur Academic Department, 2 nd floor Room No. 209-10, S.M.S. Medical College, J.L.N. Marg, Jaipur-302004, Rajasthan ECR/26/Inst/RJ/2013/RR-16	Dr. Dharamveer Singh Choudhary
Department of Ophthalmology, Dr J.L Rohatgi Memorial Eye Hospital, 117/52, G.T Road, Sarvodaya Nagar, Kanpur-208005, Uttar Pradesh, India.	Institutional Ethics Committee, Kanpur Medical Ethics Committee J.L Rohatgi, Hospital, 117/52, G.T. Road, Sarvodaya Nagar, Kanpur-208005, Uttar Pradesh, India ECR/169/Inst/UP/2013/RR-16	Dr. Aparna Mahendru
Ophthalmology Dept, Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai-400022, Maharashtra, India.	Institutional Ethics Committee for Human Research Lokmanya Tilak Municipal Medical College (IEC+HR-LTMMC) Staff and Research Society, L.T.M. Medical College Building, 2nd Floor, Room No 17, Sion, Mumbai-400022, Maharashtra, India ECR/266/Lokmanya/Inst/MH/2013/RR-16	Dr. Chhaya Ashok Shinde

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Kenia Eye Hospital,D-102, 1 st Floor, Rizvi Nagar, Corner of Milan Subway, Next to Milan Mall, S.V. Road, Santacruz (W),Mumbai-400054.	Institutional Ethics Committee, Kenia Medical & Research Foundation, Kenia Eye Hospital, C- 101, Rizvi Nagar, 1st Floor, Corner of Milan Subway, S.V. Road, Santacruz (W),Mumbai- 400054, Maharashtra, India ECR/1088/Inst/MH/2018	Dr. Arjun Sadharam Ahuja
Cornea Department, PBMA's H.V. Desai Eye Hospital, S.No. 93, Tarawade Vasti, Mohammadwadi Road, Hadapsar, Pune-411060, Maharashtra, India.	Institutional Ethics Committee, PBMA's H.V. Desai Eye Hospital, S.No. 93, Tarawade Vasti, Mohammadwadi Road, Hadapsar, Pune-411060, Maharashtra ECR/234/Inst/MH/2013/RR-16	Dr. Rasika Ramchandra Thakur
Eye Hospital, M & J Western Regional Institute of Ophthalmology, Manjushree Mill Compound, Opp. IOC Petrol Pump, Nr. Baliya Limbadi Temple, Asarwa, Ahmedabad-380016, Gujarat, India.	Institutional Ethics Committee, B.J. Medical College & Civil Hospital,Office of the Medical Superintendent, Civil Hospital, Ahmedabad-380016, Gujarat, India ECR/72/Inst/GJ/2013/RR-16	Dr. Bhatt Rupal Bipinchandra
Cornea Department, Sri Sankaradeva Nethralaya, 96, Basistha Road, Guwahati-781028, Assam, India.	Sri Sankaradeva Nethralaya Institutional Ethics Committee (SSNIEC) 96, Basistha Road, Guwahati-781028, Assam, India ECR/699/Inst/AS/2015/RR-18	Dr. Balmukund Agarwal
3 rd Floor, Ophthalmology Department, Regional Institute of Ophthalmology, Rajendra Institute of Medical Sciences, Ranchi, Jharkhand-834009.	Institutional Ethics Committee, Office of Research Cell, Administrative block Rajendra Institute of Medical Sciences, Ranchi - 834009, Jharkhand, India ECR/769/Inst/JH/2015/RR-18	Dr Vidya Bhushan Sinha
Disha Eye Hospitals Private Limited, Department of Cornea and Interior Segment, 88 (63A) Ghoshpara Road, Barrackpore, Kolkata - 700120, West Bengal	Disha Eye Hospitals Pvt. Ltd. Ethics Committee, 88 (63A) Ghoshpara Road, Barrackpore, Kolkata - 700120, West Bengal ECR/846/Inst/WB/2016	Dr. Samar Kumar Basak

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Sankara Eye hospital, Cornea Services, Sathy Road, Sivanandhapuram, Coimbatore – 641035, Tamil Nadu, India.	Ethics Committee, Sankara Eye Care Institutions, Sankara Eye Hospital, Sathy Road, Sivanandhapuram, Coimbatore – 641035, Tamil Nadu, India ECR/512/Inst/TN/2014-RR-17	Dr. Jagadeesh Kumar Reddy
Department of Ophthalmology, Room 1038, JSS Hospital M.G Road, Mysuru-570004, Karnataka, India.	Institutional Ethics Committee, 3rd floor, JSS Medical College, Mysuru-570015, Karnataka, ECR/387/Inst/KA/2013/RR-16	Dr. Premnath Raman
St. Theresa's Hospital, Sanathnagar, Hyderabad, 500018 Telangana State, India.	Ethics Committee, St. Theresa's Hospital, Sanathnagar, Hyderabad, Telangana- 500018, India ECR/230/INST/AP/2013/RR-19	Dr. Mahajan Sheshadri Vishnu