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File No. FDC/MA/19/000048

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: 04 SEP 2019

To,

M/s. Synokem Pharmaceuticals Ltd.,  
Plot No. 35-36, Sector-6A, Integrated Industrial Estate,  
Ranipur (Bhel), Haridwar-245403, Uttarakhand.

**Subject:** Permission for conducting Phase III Clinical Trial with FDC of Montelukast Sodium eq. to Montelukast IP 10mg + Bilastine 20mg film coated bilayered tablet (Vide Protocol No. CRPL/CT/19/011, Version No. 00, dated 03.06.2019) -regarding.

Dear Sir,

With reference to your letter No. nil dated 24.04.2019 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-Drugs/71/2019 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,

V/G

(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:  
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 Licencing 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;

Sr. No.	Investigator & Trial site	Ethics Committee Name/Registration Number
1.	Dr. Raghumanda Sunil Kumar, Government Medical College & Govt. General Hospital (Old RIMSGGH), Srikakulam-532001, Andhra Pradesh.	Institutional Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital, Srikakulam-532001, Andhra Pradesh. ECR/492/Inst/AP/2013/RR-16
2.	Dr. Manish Kumar Jain, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan.	Sunrise Wellness Diagnostics, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur- 302039, Rajasthan. ECR/1222/Inst/RJ/2019
3.	Dr. Anand Kumar, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh	Ethics Committee, G.S.V.M Medical College, Principal Office, G.S.V.M Medical College, Swaroop Nagar, Kanpur-20800, Uttar Pradesh. ECR/680/Inst/UP/2014/RR-17
4.	Dr. Sagar Vivek Redkar, Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oshalbag, Village-Dhargal, Tal-pernem, Goa-403513,	Redkar Hospital Institutional Ethics Committee (RHIEC), Mumbai-Goa Highway, Oshalbag, Village-Dhargal, Tal-pernem, Goa-403513. ECR/902/Inst/GA/2018

Place: .....

Date: 04 SEP 2019

V/he  
Central Licencing Authority

डॉ. वी. जी. सोमानी  
औषधि महानियंत्रक (भारत)  
स्वास्थ्य सेवा महानिदेशालय  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
एफ.डी.ए. भवन, कोटला रोड, आई.टी.ओ.  
नई दिल्ली-110002



- 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;
- 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. 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;
- XV. 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;
- XVI. The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- XVII. 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.
- XVIII. In addition to the requirement of obtaining written informed consent, an audio-video recording of the informed consent process in case of vulnerable subjects in clinical trial of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record; provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record, as per Government of India, Gazette Notification vide G. S. R. no. 611(E) dated 31.07.2015;
- XIX. **Undertaking of principle investigators as per New and Clinical Trial Ruels-2019 should be submitted before initiation of the clinical 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-Drugs/71/2019

1. The Central Licencing Authority hereby permits **M/s. Synokem Pharmaceuticals Ltd., Plot No. 35-36, Sector-6A, Integrated Industrial Estate, Ranipur (Bhel), Haridwar-245403, Uttarakhand** (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 **CRPL/CT/19/011, Version No. 00, dated 03.06.2019** 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: **04 SEP. 2019**

Central Licencing Authority

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डॉ. वी. जी. सोमानी

औषधि महानियंत्रक (भारत)

स्वास्थ्य सेवा महानिदेशालय

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

एफ.डी.ए. भवन, कोटला रोड, आई.टी.ओ.

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**Annexure:**

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Montelukast Sodium eq. to Montelukast IP 10mg + Bilastine 20mg film coated bilayered tablet
Therapeutic class:	Anti histamines
Dosage form:	Film Coated Bilayered Tablet
Composition:	Montelukast Sodium eq. to Montelukast IP 10mg + Bilastine 20mg film coated bilayered tablet
Indications:	For the treatment of allergic Rhinoconjunctivitis.

**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

Sr. No.	Investigator & Trial site	Ethics Committee Name/Registration Number
1.	Dr. Raghumanda Sunil Kumar, Government Medical College & Govt. General Hospital (Old RIMSGGH), Srikakulam-532001, Andhra Pradesh.	Institutional Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital, Srikakulam-532001, Andhra Pradesh. ECR/492/Inst/AP/2013/RR-16
2.	Dr. Manish Kumar Jain, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan.	Sunrise Wellness Diagnostics, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur- 302039, Rajasthan. ECR/1222/Inst/RJ/2019
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4.	Dr. Sagar Vivek Redkar, Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oshalbag, Village-Dhargal, Tal-pernem, Goa-403513,	Redkar Hospital Institutional Ethics Committee (RHIEC), Mumbai-Goa Highway, Oshalbag, Village-Dhargal, Tal-pernem, Goa-403513. ECR/902/Inst/GA/2018

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