

Nil

File No. FDC/MA/21/000127 ✓

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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

30 JUL 2021

To,

M/s. Synokem Pharmaceuticals Pvt. Ltd.,
Plot No. 35-36, Sec. 6A, Integrated Industrial Estate,
Ranipur (Bhel), Haridwar, Uttrakhand-249403.

Subject: Permission to conduct Phase III clinical trial with the FDC of Aspirin (EC) IP + Ticagrelor (SR) IP (75mg + 120mg & 75mg + 180mg) capsules (Vide protocol no. CRPL/CT/21/014, version no. 00, dated: 04.05.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 01.06.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-104/2021 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:
 - i. 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;
 - ii. 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;

(See rules 22, 25, 26, 29 and 30)

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

Permission no.: CT-06-104/2021

1. The Central Licencing Authority hereby permits **M/s. Synokem Pharmaceuticals Pvt. Ltd., Plot No. 35-36, Sec. 6A, Integrated Industrial Estate, Ranipur (Bhel), Haridwar, Uttrakhand-249403.** (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 (**Vide protocol no. CRPL/CT/21/014, version no. 00, dated: 04.05.2021** 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: New Delhi

Date:
30 JUL 2021

V-kr
Central Licencing 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

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Aspirin (EC) IP + Ticagrelor (SR) IP (75mg + 120mg & 75mg + 180mg) capsules
Therapeutic class:	Antihypertensive
Dosage form:	Capsules
Composition:	Aspirin (EC) IP + Ticagrelor (SR) IP (75mg + 120mg & 75mg + 180mg) capsules
Indications:	Patients with Acute coronary syndrome (ACS) who are already using Ticagrelor Tablets & Aspirin Tablets Concomitantly

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

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Prabhat Kumar Sharma	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan.	Institutional Ethics Committee, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan. ECR/1222/Inst/RJ/2019
2	Dr. Sanjiv Maheshwari	Department of Medicine, Jawahar Lal Nehru (J.L.N) Medical College, Kala Bagh, Ajmer305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan. ECR/1156/Inst/RJ/2018
3	Dr. Swapnav Borthakur	Down Town Hospital, Dispur, G.S. Road, Guwahati-781006, Assam.	Ethics Committee, Down Town Hospital, 6 th Floor, 1 st Building, G.S. Road, Dispur, Guwahati-781006, Assam. ECR/549/Inst/AS/2014/RR20
4	Dr. Raja Bhattacharya	Medical College and Hospital, Kolkata, MCH Building, 4 th Floor, 88 College Street, Kolkata-700073, West Bengal.	Institutional Ethics Committee for Human Research Medical College, Kolkata, 88, College Street, Kolkata-700073, West Bengal ECR/287/Inst/WB/2013/RR19
5	Dr. Vinayak Maruti Sawardekar	Grant Government Medical College and Sir J J Group of Hospital, J J Marg, Byculla, Mumbai-400008, Maharashtra.	Institutional Ethics Committee, Grant Government Medical College and Sir J J Group of Hospital, J J Road, J J Hospital Compound, Mumbai Central, Mumbai-400008, Maharashtra. ECR/382/Inst/MH/2013/RR19
6	Dr. A. Gopal Rao	Department of Medicine, Government Medical College & Government 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/RR20

Place: New Delhi

Date:

30 JUL 2021

VHL
Central Licencing Authority

Stamp
Dr. V. G. SOW
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bikaner, Kotla Road, I.T.O.
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