

Nil

File No. FDC/MA/22/000106

Tele. No. : 011-23236965

Government of India

Fax No. : 011-23236973

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

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

To,

M/s. Ravenbhel Healthcare Pvt. Ltd.,
16-17, EPIP, SIDCO Bari Brahmana,
Jammu & Kashmir-181133.

23 JUL 2022

Subject: Permission to conduct Phase III clinical trial with the FDC of Telmisartan IP 40mg + Bisoprolol Fumarate IP 5mg tablets (Vide protocol no. CT/2022/05, version no. 01, dated: 14.06.2022)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 13.04.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-58/2022** 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 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;

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.: **FDC-CT-06-58/2022**

1. The Central Licencing Authority hereby permits **M/s. Ravenbhel Healthcare Pvt. Ltd., 16-17, EPIP, SIDCO Bari Brahmana, Jammu & Kashmir-181133, Telephone no. 01923221875, Fax: 01923222022** to conduct clinical trial of the new drug or investigational new drug as per protocol number (**Vide protocol no. CT/2022/05, version no. 01, dated: 14.06.2022**) 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:

23 JUL 2022

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Telmisartan IP 40mg + Bisoprolol Fumarate IP 5mg tablets
Therapeutic class:	Antihypertensive
Dosage form:	Tablet
Composition:	Each tablet contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg
Indications:	In patients with stage 2 hypertension

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

Central Licencing Authority

Stamp

Dr. V. C. J. MANI
Drugs Controller General (India)
Dte. General Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kirti Road, LPO.
New Delhi-110002

Permission no.: FDC-CT-06-58/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1	Dr. Sanjiv Maheshwari	Department of Medicine, Jawahar Lal Nehru (J.L.N) Medical College, Kala Bagh, Ajmer-305001, Rajasthan.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan. ECR/1156/Inst/RJ/2018/RR22
2	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/RR22
3	Dr. Mohan Kumar Singh	W Pratiksha Hospital, Golf Course Ext. Road, Sushant Lok II, Sector 56, Gurugram-122011, Haryana.	North East Healthcare Private Limited, Golf Course Ext. Road, Sushant Lok-II, Sector 56, Gurugram-122011, Haryana. ECR/1282/Inst/HR/2019
4	Dr. Richa Giri	Post Graduate Department of Medicine, LLR Hospital, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh	Ethics Committee, GSVM Medical College, Room No-125, 1st Floor, Swaroop Nagar, Kanpur-208002, Uttar Pradesh. ECR/680/Inst/UP/2014/RR20
5	Dr. Maghavendra Kumar	Vidhya Hospitals & Trauma Centre, Harikansgadi, Mohanlalganj, Raebareli Road, Lucknow-226301, Uttar Pradesh.	Vidhya Hospital and Trauma Centre Ethics Committee, Vidhya Hospitals & Trauma Centre, Harikansgadi, Mohanlalganj, Raebareli Road, Lucknow-226301, Uttar Pradesh. ECR/1579/Inst/UP/2021
6	Dr. Raja Bhattacharya	Department of Medicine, Medical College and Hospital, Kolkata, MCH Building, 4th Floor, 88 College Street, Kolkata-700073, West Bengal.	Institutional Ethics Committee for Human Research, Medical College and Hospital, Kolkata, 88, College Street, Kolkata-700073, West Bengal. ECR/287/Inst/WB/2013/RR19
7	Dr. Arindam Naskar	Calcutta School of Tropical Medicine, Government of West Bengal, 108, Chittranjan Avenue, Calcutta-700073, West Bengal.	Clinical Research Ethics Committee, Department of Clinical and Experimental Pharmacology, Calcutta School of Tropical Medicine, 108, C R Avenue, Kolkata-700073, West Bengal. ECR/194/Inst/WB/2013/RR19
8	Dr. Vijaykumar Bhagwan Barge	Department of Medicine, Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416002, Maharashtra.	Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Kolhapur Institutional Ethics Committee 2 (RCSMGMCI EC2), Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416002, Maharashtra. ECR/703/Inst/MH/2015/RR20

9	Dr. Vivek Eknath Redkar	Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oxelbag, Dhargal, Tal-Pernem, Goa-403513.	Redkar Hospital Institutional Ethics Committee (RHIEC), Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oxelbag, Dhargal, Pernem, Goa-403513. ECR/902/Inst/GA/2018/RR21
10	Dr. Vijaykumar Shivajirao Patil	Prakash Institute of Medical Sciences & Research (PIMS&R), Urun-Islampur, Islampur-Sangali Road, Islampur, Tal-Walwa, Dist-Sangali-415409, Maharashtra	Prakash Medical College Institutional Ethics Committee, Prakash Institute of Medical Sciences & Research (PIMS&R), Urun-Islampur, Islampur-Sangali Road, Islampur, Tal-Walwa, Dist-Sangali-415409, Maharashtra. ECR/1052/Inst/MH/2018/RR21
11	Dr. S.S.V.V. Narasinga Rao	Department of Medicine, Government Medical College & Government General Hospital (Old RIMSGGH), Srikakulam-532001, Andhra Pradesh.	Institutional Ethics Committee, Government Medical College & Government General Hospital (Old RIMSGGH), Srikakulam-532001, Andhra Pradesh. ECR/492/Inst/AP/2013/RR20
12	Dr. Jilla Naganna	In Patient Block, 3rd Floor, Department of General Medicine, Gandhi Hospital, Musheerabad, Secunderabad-500003, Telangana.	Institutional Ethics Committee, Gandhi Medical College/Gandhi Hospital, Musheerabad, Secunderabad-500003, Telangana. ECR/180/Inst/AP/2013/RR19

Place: New Delhi

Date:

23 JUL 2022

Central Licencing Authority

Stamp
Dr. J. S. D. MANI
Drugs Controller General (India)
Dir. General Health Services
Ministry of Health & Family Welfare
FDA Building, Connaught Road, LEO,
New Delhi-110002