

Nil

File No. FDC/MA/21/000256
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No. : 011-23236965
Fax No. : 011-23236973

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

14 DEC 2021

To,
M/s. Exemed Pharmaceuticals,
133/1 & 133/2, GIDC Selvas Road,
Vapi-396195, Gujarat.

Subject: Permission to conduct Phase III clinical trial with the FDC of Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin 100mg + Dapagliflozin 10mg tablets (Vide protocol no. CT/2021/04, version no. 00, dated: 11.10.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 30.10.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-198/2021** 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 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;
- 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;

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-06-198/2021**

1. The Central Licencing Authority hereby permits **M/s. Exemed Pharmaceuticals, 133/1 & 133/2, GIDC Selves Road, Vapi-396195 Gujarat** (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. CT/2021/04, version no. 00, dated: 11.10.2021** 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:

Date:

14 DEC 2021

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin 100mg + Dapagliflozin 10mg tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin 100mg + Dapagliflozin 10mg tablets
Indications:	In patients with type 2 diabetes mellitus inadequately controlled on Metformin monotherapy

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. 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

*Permission no.: CT-06-198/2021

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, Ajmer-305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan. ECR/1156/Inst/RJ/2018
3	Dr. Shri Krishna Gautam	Post Graduate Department of Medicine, 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/RR-20
4	Dr. Mohan Kumar Singh	W Pratiksha Hospital, Golf Course Ext. Road, Sushant Lok II, Sector 56, Gurugram, Haryana-122011.	North East Healthcare Private Limited, Golf Course Ext. Road, Sushant Lok-II, Sector 56, Gurugram, Haryana-122011. ECR/1282/Inst/HR/2019
5	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
6	Dr. Arindam Naskar	Department of Endocrinology, 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
7	Dr. Sagar Vivek Redkar	CROM Clinical Research & Medical Tourism Pvt. Ltd. at 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/RR-21

8	Dr. Vijaykumar Bhagwan Barge	Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416002, Maharashtra.	Kolhapur Institutional Ethics Committee 2. (RCSMGMCI EC2), Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416002, Maharashtra. ECR/703/Inst/MH/2015/RR20
9	Dr. S. Vasant Kumar	Department of Medicine, In Patient Block, 3rd Floor, Gandhi Medical College / Hospital, Musheerabad, Secunderabad-500003, Telangana.	Institutional Ethics Committee, Gandhi Medical College/Gandhi Hospital, Musheerabad, Secunderabad-500003, Telangana. ECR/180/Inst/AP/2013/RR-19
10	Dr. A. Gopal Rao	Department of Medicine, OPD No. 13, 1st Floor, 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/RR-20
11	Dr. P. Shravan Kumar	Department of General Medicine, Osmania Medical College & General Hospital, Afzalgunj, Hyderabad, Telangana-500012.	Upgraded Department of Pathology, Osmania Medical College & General Hospital, Afzalgunj, Hyderabad, Telangana-500012, India. Or Ampath Central Reference Laboratory, Nallagandla, Serilingampally, Hyderabad- 500019, Telangana. ECR/300/Inst/AP/2013/RR-19

Place:

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Central Licencing Authority

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Dte. General of Health Services
Ministry of Health and Family Welfare
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