

Nil

File No.FDC/MA/22/000143
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:

To,

M/s. Exemed Pharmaceuticals,
133/1 & 133/2, GIDC Selves Road,
Vapi-396195 Gujarat (India).

04 JUL 2022

Subject: Permission to conduct Phase III clinical trial with the FDC of Vildagliptin IP (as sustained release) + Pioglitazone Hydrochloride IP eq. to Pioglitazone (100mg + 15mg & 100mg + 30mg) tablets (Vide protocol no. CT/2022/07, version no. 00, dated 25.03.2022)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 10.05.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-54/2022** 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;

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

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**Permission no.: **FDC-CT-06-54/2022**

1. The Central Licencing Authority hereby permits **M/s. Exemed Pharmaceuticals, 133/1 & 133/2 GIDC Selvas Road, Vapi- 396195 Gujarat, Telephone No.: 912606617700 FAX: 912606617799** to conduct clinical trial of the new drug or investigational new drug as per protocol number (**Vide protocol no. CT/2022/07, version no. 00, dated 25.03.2022**) 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:

04 JUL 2022

Annexure:

Details of new drug or investigational new drug:

Central Licencing Authority**Stamp**

Dr. V. G. SOMANI
 Drugs Controller General (India)
 Dte. General Health Services
 Ministry of Health and Family Welfare
 FDA Bhawan, Kotla Road, I.T.O.
 New Delhi-110002

Names of the new drug or investigational new drug:	Vildagliptin IP (as sustained release) + Pioglitazone Hydrochloride IP eq. to Pioglitazone (100mg + 15mg & 100mg + 30mg) tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Each tablet contains: Vildagliptin IP (as sustained release) Pioglitazone Hydrochloride IP Eq. to Pioglitazone (100mg + 15mg & 100mg + 30mg)
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

Permission no.: FDC-CT-06-54/2022

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/RR22
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/RR22
3	Dr. Lalit Kumar	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
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. Arindam Ray	College of Medicine & Sagore Dutta Hospital, 578, B.T Road, Kamarhati, Kolkata-700058, West Bengal.	Institutional Ethics Committee, College of Medicine & Sagore Dutta Hospital, Office of Principal, 578, B.T Road, Kamarhati, Kolkata-700058, West Bengal. ECR/1210/Inst/WB/2019
6	Dr. Animesh Maiti	Medical College and Hospital, Kolkata, 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. Vijay kumar 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 (RCSMGMCIEC2), Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416002, Maharashtra. ECR/703/Inst/MH/2015/RR20
8	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
9	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
10	Dr. S. Vasanth Kumar	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: 04 JUL 2022

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