

Nil

File No. FDC/MA/21/000090 ✓
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:

07 JUL 2021

To,

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

Subject: Permission to conduct Phase III clinical trial with the FDC of Vildagliptin (as sustained release) + Dapagliflozin (100mg + 5mg & 100mg + 10mg) tablets (Vide protocol no. EP/DAP-VIL/CT/21/002, version no. 00, dated: 15.03.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 09.04.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-90/2021** 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;

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-06-90/2021**

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. EP/DAP-VIL/CT/21/002, version no. 00, dated: 15.03.2021** 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: **07 JUL 2021**

Central Licencing Authority

Dr. V. S. Chopra
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, New Delhi-110002.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Vildagliptin (as sustained release) + Dapagliflozin (100mg + 5mg & 100mg + 10mg) tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Vildagliptin (as sustained release) + Dapagliflozin (100mg + 5mg & 100mg + 10mg) tablets
Indications:	For the treatment of 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.: CT-06-90/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Vipul Khandelwal	Apex Hospitals Private Limited, SP-4 & 6, Malviya Industrial Area, Near Apex Circle, Malviya Nagar, Jaipur-302017, Rajasthan.	Institutional Ethics Committee, Apex Hospitals Private Limited, SP - 4 and 6, Malviya Industrial Area, Malviya Nagar, Jaipur-302017, Rajasthan. ECR/380/Inst/RJ/2013/RR-19
2	Dr. Richa Giri	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
3	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
4	Dr. Veer Bahadur Singh	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
5	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
6	Dr. Anirban Sinha	Medical College and Hospital, Kolkata, MCH Building, 4th 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/RR-19
7	Dr. Hrishikesh Bora	Down Town Hospital, Dispur, G.S. Road, Guwahati-781006, Assam.	Ethics Committee, Down Town Hospital, 6th Floor, 1st Building, G.S. Road, Dispur, Guwahati-781006, Assam. ECR/549/Inst/AS/2014/RR-20
8	Dr. Solanki Dipakkumar Becharlal	Department of Medicine, Dr. M. K. Shah Medical College & Research Centre & SMT S.M.S Multispecialty Hospital, Near Tapovan Circle, Visat – Gandhinagar Highway, Chandkheda, Ahmedabad-382424, Gujarat	Institutional Ethics Committee, Dr. M. K. Shah Medical College & Research Centre & SMT S.M.S Multispecialty Hospital, Opp. Akshar III Complex, Near Tapovan Circle, Visat Gandhinagar Highway, Chandkheda, Ahmedabad-382424, Gujarat. ECR/1383/Inst/GJ/2020

9	Dr. S. Vasanth Kumar	In Patient Block, 3 rd Floor, Department of Medicine, 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. S.S.V.V. Narasinga Rao	Department of Medicine, Government Medical College & Government General Hospital RIMS Government General (Old RIMSGGH), Srikakulam-532001.	Institutional Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital, Srikakulam-532001. ECR/492/Inst/AP/2013/RR-20
11	Dr. Vikas Reddy Maddali	Osmania Medical College & General Hospital, Afzalgunj, Hyderabad, Telangana-500012.	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500095, Telangana State. ECR/300/Inst/AP/2013/RR-19

Place: New Delhi

Date:

07 JUL 2021
Central Licencing Authority

Stamp

Dr. V. G. Srinivasan
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kailash Colony, New Delhi-110022

