Tele No.011-23236965
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F. No. ND/MA/25/000149
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-11 0002

To
M/s Exemed Pharmaceuticals,
Plot No. 133/1 & 133/2, G.I.D.C, Selvas Road
Vapi-396195, Gujarat Vapi (India)

Subject: Application for grant of permission to conduct Phase-III Clinical Trial of Linzagolix tablets titled- A Multicentric, Prospective, Active Controlled, Parallel Group, Randomized, Comparative, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Linzagolix Tablets Versus Leuprolide Acetate for Depot Suspension for Injection 3.75 mg in Adult Women of Reproductive Age for Treatment of Moderate to Severe Symptoms of Uterine Fibroids." Protocol ID CT/2025/25 Version no. 02, Date: Apr 07, 2026 - regarding.

Sir,

With reference to your application no. **ND/CT21/FF/2025/52183 dated 30.09.2025**; please find enclosed herewith the permission in **Form CT-06, vide No. CT/ND/17/2026** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions, as mentioned below.

Yours faithfully

RAJEEV SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
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:

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:

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;

(vi) Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;

(vii) Status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

(viii) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority;

(ix) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;

(x) Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI of the New Drugs and Clinical Trials Rules, 2019;

(xi) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with the Chapter VI of the said Rules and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;

(xii) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with the Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;

(xiii) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorized by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

(xiv) Where the New Drug or Investigational New Drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;

(xv) The Laboratory owned by any person or a company or any other legal entity and utilized by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

(xvi) The Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

(xvii) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xviii) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

(xix) The Informed Consent Document including ICF and Patient Information Sheet should clearly mention in understandable language about the details of the drug therapy that the patient may or may not receive.

(xx) The firm should submit Bioequivalence study report to CDSCO for review by the committee before initiating the Phase III Clinical Trial.

FORM CT-06

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

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

CT Permission No. CT/ND/17/2026

The Central Licensing Authority hereby permits **M/s Exemed Pharmaceuticals, Plot No. 133/1 & 133/2 G.I.D.C, Selvas Road, Vapi - 396195, Gujrat (India) Telephone No.: 2606617700 FAX: 2606617799, E-Mail: MANISH.UPADHYAY @EXEMEDPHARMA.COM** to conduct clinical trial of the new drug as per **Protocol ID. CT/2025/25 Version no. 02, Date: Apr 07, 2026** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial site:

Names of the new drug ~~or investigational new drug:~~	**Linzagolix tablets 100 mg / 200 mg**
Therapeutic class:	**GnRH receptor antagonist**
Dosage form:	Film coated tablet
Composition:	**Linzagolix tablets 100 mg** Each film coated tablet contains: Linzagolix choline eq. to Linzagolix …….100 mg Excipients .....q.s Colours: Ferric Oxide Yellow USP-NF, Titanium Dioxide IP **Linzagolix tablets 200 mg** Each film coated tablet contains: Linzagolix choline eq. to Linzagolix …….200 mg Excipients .....q.s Colours: Ferric Oxide Yellow USP-NF, Titanium Dioxide IP
Indications:	Indicated in adult women of reproductive age for treatment of moderate to severe symptoms of uterine fibroids & symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis.

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
1.	**Dr. Suchitra Narayan** Jawahar Lal Nehru 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/RR-22**
2	**Dr. Madhavender Jain** Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar	Institutional Ethics Committee, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar

	Nagar, Jaipur-302039, Rajasthan.	Nagar, Jaipur-302039, Rajasthan. **ECR/1222/Inst/RJ/2019/RR-22**
3	**Dr. Amrita Chaurasia** Department of Obstetrics & Gynaecology, Motilal Nehru Medical College, Prayagraj (Allahabad)-211002, Uttar Pradesh.	Institutional Ethics Committee, Motilal Nehru Medical College, George Town, Prayagraj, Allahabad-211002, Uttar Pradesh. **ECR/922/Inst/UP/2017/RR-22**
4	**Dr. Manvi Gupta** Subharti Medical College and Hospital, Subharti Puram, NH-58, Delhi-Haridwar Bypass Road, Meerut-250005, Uttar Pradesh.	Institutional Ethics Committee, Subharti Medical College and Hospital, Subhartipuram, NH 58, Delhi-Haridwar Bypass Road, Meerut-250005, Uttar Pradesh. **ECR/256/Inst/UP/2013/RR-24**
5	**Dr. Ruchika Garg** Department of Obstetrics & Gynaecology, S. N. Medical College, Near Agra College, Central Library, Moti Katra, Mantola, Agra-282003, Uttar Pradesh.	Institutional Ethics Committee, S. N. Medical College, First Floor, Department of Clinical Research, New Surgical Building, Agra-282003 Uttar Pradesh. **ECR/1409/Inst/UP/2020/RR-2025**
6	**Dr. Bibek Mohan Rakshit** Department of Gynaecology & Obstetrics, Medical College and Hospital, Gynae Building, 1st Floor, 88 College Street, Kolkata-700073, West Bengal.	Institutional Ethics Committee for Human Research, Medical College, 88, College Street, Kolkata-700073, West Bengal. **ECR/287/Inst/WB/2013/RR-24**
7	**Dr. Swapnita Hota** Sunshine Hospital (A Unit of Sai Sidhi Swagat Health Services Pvt. Ltd.), Laxmi Sagar Square, Puri-Cuttack Road, Bhubaneswar-751006, Odisha.	CUTM-Independent Ethics Committee, Centurion University of Technology and Management, AT - Ramachandrapur, PO - Jatni Khordha, Bhubaneswar, Khordha-752050, Odisha. **ECR/349/Indt/OD/2021**
8	**Dr. Jadhav Jyotsna Sheetal** Supe Heart & Diabetes Hospital and Research Centre, Opp. Adhar Ashram, Near Rungtha School, Gharpure Ghat Road, Nashik-422002, Maharashtra.	Supe Hospital Ethics Committee, Supe Heart Diabetes Hospital and Research Centre, Opp. Adhar Ashram, Gharpure Ghat Near Rungtha School, Ashok Stambha, Nashik-422002, Maharashtra. **ECR/272/Inst/MH/2013/RR-24**
9	**Dr. Manjusha Prabhune** Dr. Prabhune's Sonography Centre and Clinic, Shop No. 6, Jeet Co. Op. Hsg. Society, Near Jeet Ground, Paud Road, Kothrud, Pune-411038, Maharashtra.	Central Independent Ethics Committee-CIEC, Gini Aria, A-703, S. No. 16/2/2A/1, Opposite to KJEIs-Trinity College, Kondhwa Annex, Pune-411048, Maharashtra. **ECR/390/Indt/MH/2024**
10	**Dr. Samipa Shah** Department of Obstetrics & Gynaecology, OPD No. B-26, Smt. Shardaben Chimanlal Lalbhai Municipal General Hospital, Saraspur, Ahmedabad-380018, Gujarat	Institutional Ethics Committee, NHLIEC, Smt. NHL Municipal Medical College, V S Hospital Campus, Ellisbridge, Ahmedabad-380006, Gujarat. **ECR/245/Inst/GJ/2013/RR-24**

11	**Dr. Shah Jayneel Vishal** HCC Happiness Care and Cure Multispeciality Hospital LLP, 302, 303, 305 & 407, Shital Varsha Mall-5, Shivranjani Cross Road, Satellite, Ahmedabad-380015, Gujarat.	Parth Hospital Ethics Committee, Parth Hospital, Galaxy Arcade, E/408-411, 4th Floor, Galaxy Road, Near Galaxy Cinema, Ahmedabad-382330, Gujarat. **ECR/1530/Inst/GJ/2021**
12	**Dr. Komal Agrawal** Jivan Gastro and Gynaec Hospital, Block-C, Ground Floor, SP Square, Besides Chroma Centre, New Maninagar, Vastral Road, Ahmedabad-382449, Gujarat.	Sangini Hospital Ethics Committee C/o Sangini Hospital, First Floor, Santorini Square, B/H Abhishree Complex, Opp. Star Bazar Lane, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015, Gujarat. **ECR/147/Inst/GJ/2013/RR-24**
13	**Dr. Mansuri Shafika Anisahmed** SAFA Women's Hospital and Sonography Centre, E-237, Sumel-8, Second Floor, Ajit Mil Near, Rakhial, Ahmedabad-380023, Gujarat.	Sangini Hospital Ethics Committee C/o Sangini Hospital, First Floor, Santorini Square, B/H Abhishree Complex, Opp. Star Bazar Lane, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015, Gujarat. **ECR/147/Inst/GJ/2013/RR-24**
14	**Dr. Isukapalli Vani** Department of Gynaecology and Obstetrics, King George Hospital, Andhra Medical College, Maharanipeta, Visakhapatnam-530002, Andhra Pradesh.	Institutional Ethics Committee, King George Hospital, Maharanipeta, Collector Office Junction, Visakhapatnam-530002, Andhra Pradesh. **ECR/197/Inst/KGH/2013/RR-20**
15	**Dr. Lakshmikantha G.** Department of Obstetrics & Gynaecology, Chaluvamba Hospital, Opposite Mysore Medical College and Research Institute, Irwin Road, Mysore-570001, Karnataka.	Institutional Ethics Committee-MMC and RI and Associated Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysuru (Mysore)-570001,Karnataka **ECR/134/Inst/KA/2013/RR-24**
16	**Dr. Yellayi. Aruna Subha Shree Rao** Department of Gynaecology, Maharani Mother and Child (Ghosha) Hospital, Government Medical College, Near Ambati Satram Area, Vizianagaram-535003, Andhra Pradesh	Institutional Ethics Committee - Government Medical College, Government Medical College, Contonment, Vizianagaram-535003, Andhra Pradesh. **ECR/1829/Inst/AP/2023**

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.

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

New Delhi