सत्यमेव जयते

Government of India
Central Drugs Standard Control Organisation (Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
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File No: IND/CT/25/000087 Dated

To,

M/s Hetero Labs Limited, Hetero Corporate,
7-2-A2 Industrial Estate, Sanath Nagar Hyderabad (India) - 500018
Telephone No.: 040-23704923 FAX: 040-23714250
E-Mail: b.mohanreddy@heterodrugs.com

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Subject: Application for grant of permission to conduct Phase-II clinical trial entitled "A phase-II, Multicenter, Partially Blinded, Randomized, Parallel Group, Active Controlled, Dose Ranging Study to Evaluate the Safety and Efficacy of HRF-10071 Compared to Lamivudine (3TC) each in combination with Tenofovir Alafenamide (TAF) & Dolutegravir (DTG) in Human Immunodeficiency Virus-1 (HIV-1) Infected Antiretroviral Treatment naive adults." Protocol Number: HCR/II/HRF10071HIV/05/2025, Version No: 1.0, dated 25-July-2025 - regarding.

.

Ref: Your Application No IND/CT04/FF/2025/52081 dated 23-09-2025.

Sir,

With reference to your Application No. IND/CT04/FF/2025/52081dated 23-09-2025, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

(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 Licensing 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 Licensing 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 Licensing 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 Licensing Authority electronically in the SUGAM portal;

(IX) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing 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 Licensing 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;

(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 Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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 apply 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 Licensing 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) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

(XIX) Clinical Study report (CSR) shall be submitted to this office after completion of the trial.

(XX) **The firm should abide by all applicable rules of the HIV/AIDS Prevention & Control Act 2017 and relevant Guidelines of NACO**.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.04.29 14:58:41 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

F.No. IND/CT/25/000087

FORM CT-06

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

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

The Central Licensing Authority hereby permits M/s Hetero Labs Limited, Hetero Corporate, 7-2-A2 Industrial Estate, Sanath Nagar Hyderabad (India) - 500018 Telephone No.: 040-23704923 FAX: 040-23714250 E-Mail: b.mohanreddy@heterodrugs.com to conduct Phase-II clinical trial entitled " A phase II, Multicenter, Partially Blinded, Randomized, Parallel Group, Active Controlled, Dose Ranging Study to Evaluate the Safety and Efficacy of HRF-10071 Compared to Lamivudine (3TC) each in combination with Tenofovir Alafenamide (TAF) & Dolutegravir (DTG) in Human Immunodeficiency Virus-1 (HIV-1) Infected Antiretroviral Treatment naive adults." Protocol Number: HCR/II/HRF10071HIV/05/2025, Version No: 1.0, dated 25-July-2025 in the below mentioned clinical trial sites.

2. Details of 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:

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.04.29 14:58:59 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

F.No. IND/CT/25/000087

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Therapeutic class	Dosage form	Composition	Indications
HRF -10071 Tablets10mg	Anti HIV1	Tablet	Each film coated tablet contains 10mg of HRF-10071 In House Specification Active	Human Immunodeficiency Virus-1 (HIV-1) Infected Antiretroviral Treatment naïve Adults
HRF -10071 Tablets20mg	Anti HIV1	Tablet	Each film coated tablet contains 20mg of HRF-10071 In House Specification Active	Human Immunodeficiency Virus-1 (HIV-1) Infected Antiretroviral Treatment naïve Adults
HRF -10071 Tablets40mg	Anti HIV1	Tablet	Each film coated tablet contains 40mg of HRF-10071 In House Specification Active	Human Immunodeficiency Virus-1 (HIV-1) Infected Antiretroviral Treatment naïve Adults
HRF -10071 Tablets100mg	Anti HIV1	Tablet	Each film coated tablet contains 100mg of HRF-10071 In House Specification Active	Human Immunodeficiency Virus-1 (HIV-1) Infected Antiretroviral Treatment naïve Adults

F.No. IND/CT/25/000087

Details of clinical trial site:

Names and address of clinicaltrial site	Ethics committee details	Name of Investigator
GVSM Medical College, Department of Medicine, Swaroop Nagar, Kanpur-208002, Utter Pradesh, India	Ethics Committee GSVM Medical College Room No. 125, First Floor, GSVM Medical College, Swaroop Nagar, Kanpur – 208002, Uttar Pradesh, India. ECR/680/Inst/UP/2014/RR-20	Dr Mahendra Pal Singh
North Bengal Medical College & Hospital, Department of Medicine, Sushrutnagar, Siliguri, Darjeeling – 734012, West Bengal, India	Institutional Ethics Committee, North Bengal Medical College & Hospital, Sushrutnagar, Siliguri, Darjeeling – 734012, West Bengal, India. ECR/1701/Inst/WB/2022	Dr Dipanjan Bandyopadhyay
Victoria Hospital, BMC & RI # 67/A Medicine "C" Block, Victoria Hospital, BMC & RI, Banglore-560002, Karnataka, India,	Ethics Committee of BMCRI Bangalore medical college and research institute, Fort, k r road, Bengaluru -560002, Karnataka, India. ECR/302/Inst/KA/2013/RR-25	Dr Diwakar TN
Sri Guru Ram Das Institute of Medical Sciences and Research, Mehta Road, VPO Vallah, Amritsar - 143501, Punjab, India.	Ethics Committee of Amandeep Hospital, Amandeep Hospital, GT Road, Model Town, Amritsar-143001, Punjab, India. ECR/692/Inst/PB/2014/RR20	Dr Parminder Singh
KLE Dr. Prabhakar Kore Hospital and MRC Nehru Nagar Belagavi - 590010, Karnataka, India.	Institutional Ethics Committee of KLE Academy of Higher Education and Research, JNMC Campus, Nehru Nagar, Belagavi-590010, Karnataka, India. ECR/211/Inst/KA/2013/RR-24	Dr. Dnyanesh N Morkar
Belagavi Institute of Medical Sciences, Belagavi Institute of Medical Sciences, Dr BR Ambedkar Road, Sadashiv Nagar, Belagavi -590001, Karnataka, India	Institutional Ethics Committee, Belagavi Institute of Medical Sciences, Dr. B.R. Ambedkar Road, Sadashiv Nagar, Belagavi - 590001, Karnataka, India. ECR/801/Inst/KA/2016/RR-20	Dr Prashantakumar Jaikar
Calcutta School of Tropical Medicine 108, Chittaranjan Avenue, College square	Clinical Research Ethics Committee, Calcutta School of Tropical Medicine 108, Chittaranjan Avenue, College square	Dr Dolanchampa Modak

Kolkata-700073 West Bengal, India	Kolkata-700073 West Bengal, India. ECR/194/Inst/WB/2013/RR-20	
S.N. Medical College and Hospital Near Moti Katra, Mantola, Agra-282003, Uttar Pradesh, India.	Institutional Ethics Committee, S.N. Medical College, Raja Mandi near Agra College, Agra Central Library, Moti Katra, Mantola, Agra-282003, Uttar Pradesh, India. ECR/1409/INST/UP/2020	Dr.Prabhat Agarwal
Aditya Multispecialty Hospital, D-no: 13-3-52, 3rd Line, Gunturivari Thota, Kothapet Beside Peoples Trauma Guntur - 522001, Andhra Pradesh, India	Institutional Ethics Committee – Aditya Multispecialty Hospital (IEC-AMSH), D-no: 13-3-52, 3rd Line, Gunturivari Thota, Kothapet Beside Peoples Trauma Guntur – 522001, Andhra Pradesh, India. ECR/1347/Inst/AP/2020/RR-25	Dr. Goli. M. Venkata Kasiram.
V.H.S. Infectious Diseases Medical Centre, Rajiv Gandhi Salai, Taramani, Chennai-600113, Tamil Nadu, India	The Voluntary Health Services Multi-Specialty Hospital and Research Centre Rajiv Gandhi Salai, Adayyar, Chennai, Tamil Nadu - 600113 India ECR/752/Inst/TN/2015/RR-22	Dr. N. Kumarasamy, MBBS, PhD

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