सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services) Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/25/000076

To,

M/s Abiogenesis Clinpharm Private Limited,
8-2-624/A/1 LEVEL 1 MB TOWERS, ROAD NO. 10,
BANJARA HILLS, Hyderabad (India) - 500034.

Sir,

With reference to your application No. GCT/CT04/FF/2025/50097 dated 09-Jun-2025, please find enclosed herewith the permission in Form CT-06 for conduct of **phase III** clinical trial titled, **"A Multi-Center, Double-Blind, Randomized, Parallel-Group, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Phenazopyridine Hydrochloride Tablets, USP 200mg as a Non-Prescription (OTC) Analgesic for Short-Term Treatment in Female Subjects Suffering from Moderate-to-Severe Pain and Burning upon Urination Associated with Uncomplicated Urinary Tract Infections (uUTI)" Protocol No.: PHN-301-25 Version No. 1.0 dated 06-JUN-2025 with a total of up-to 570 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

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

(i) That the firm shall submit the study CRF should also include specific adverse drug reactions during treatment and immediate follow-up of study patients, in addition to any other (new) ADRs.

(ii) 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;

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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 electronically in the SUGAM portal;

(x) 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;

(xi) 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;

(xii) 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 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;

(xiii) 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 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;

(xiv) 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 authorised 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;

(xv) 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;

(xvi) the laboratory owned by any person or a company or any other legal entity and utilised 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;

(xvii) 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;

(xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial;

(xix) Merely granting permission to conduct the **clinical trial** with the Investigational Drug Product does not convey or imply that, based on the **clinical trial study data** generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;

(xx) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.11.28 11:48:18 +05'30'

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

FORM CT-06

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

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

1. The Central Licensing Authority hereby permits **M/s Abiogenesis Clinpharm Private Limited, 8-2-624/A/1 LEVEL 1 MB TOWERS, ROAD NO. 10, BANJARA HILLS, Hyderabad (India) - 500034** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: PHN-301-25 Version No. 1.0 dated 06-JUN-2025** with in the below mentioned clinical trial sites [As per Annexure].

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 _____

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.11.28 11:48:25 +05'30'

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

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	phenazopyridine hydrochloride
Therapeutic class:	Analgesic
Dosage form:	Tablets
Composition:	phenazopyridine =200.0000 milligram (mg) U.S.P. Active
Indications:	uncomplicated Urinary tract infection

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	ACSR Govt College and Hospital, Nellore, Andhra Pradesh, 524004	Institutional Ethics Committee Nellore ACSR Government Medical College and Hospital, Dargamitta, Nellore-524004 ECR/961/Inst/AP/2017/RR-25	Dr. Mary snigdha
2.	Apollo Speciality Hospital, Lake view Road, K. K. Nagar, Madurai-625020	Institutional Ethics Committee-Clinical Studies Apollo Speciality Hospitals Lake View Road, K.K Nagar Madurai Madurai, Tamil Nadu -625020 India ECR/43/Inst/TN/2013/RR-24	Dr. Arun Kumar
3.	Pragya Mother and Child Care Pvt Ltd, Rashmi Nagar colony, Lanka, varanasi-221005	Shubham sudhbhawana super speciality Hospital Ethics committee, B-31/80-23B, Bhogabeer, Lanka, Varanasi-221005, Uttar Pradesh. ECR/667/Inst/UP/2014/RR-20	Dr. Pragya Pandey
4.	Nuha Hospitals, D.No.12-19-61 & 62,Old Bank Road, Kothapet-Guntur -522001	Institutional Ethics Committee of Nuha Hospitals Nuha Hospitals Dr No 12-19-61/62 , Old Bank Road Kothapet, Guntur, Andhra Pradesh -522001 India ECR/1593/Inst/AP/2021	Dr. Shabana Syed

5.	King George Hospital, KGH Down Rd, Opp KGH OP Gate, Maharani Peta, Visakhapatnam, Andhra Pradesh 530002	IEC, King George Hospital, Maharanipeta Collect office junction, Visakhapatnam, Andhra Pradesh-530002 ECR/197/Inst/KGH/2013/RR-20	Dr. Syamala Kaitala
6.	Alliance Hospital, Pishach Mochan, Ramakanth Nagar, Chetganj, Varanasi, Uttar Pradesh 221001	Shubham sudhbhawana super speciality Hospital Ethics committee, B-31/80-23B, Bhogabeer, Lanka, Varanasi-221005, Uttar Pradesh ECR/667/Inst/UP/2014/RR-20	Dr.Javed Iqbal
7.	Sir Ganga Ram Hospital Ethics Committee Sir Ganga Ram Hospital Ethics Committee, Sir Ganga Ram Hospital Old Rajinder Nagar New Delhi New Delhi Delhi -110060 India	Sir Ganga Ram Hospital, Old Rajinder Nagar, Rajinder Nagar, New Delhi, Delhi, 110060 ECR/20/Inst/DL/2013/RR-24	Dr Shipra Gulati
8.	Kasturi Das Memorial Superspecialty Hospital, Block B, Mollar Gate, Santoshpur, Kolkata-700142	Institutional Ethics Committee Kasturi Das Memorial Superspecialty Hospital, Block B, Mollar Gate, Santoshpur, Kolkata-700142 ECR/1684/Inst/WB/2022	Dr Satya Narayan Sharma
9.	Calcutta National Medical College & Hospital, 32, Gorachand Rd, Beniapukur, Kolkata, West Bengal 700014	Institutional Ethics Committee Calcutta National Medical College & Hospital, 32, Gorachand Rd, Beniapukur, Kolkata, West Bengal 700014 ECR/771/Inst/WB/2015/RR-19	Dr. Pranab Kumar Biswas
10.	M. V. Hospital and Research Centre, 314/30, Mirza Mandi, Chowk, Lucknow-226003, Uttar Pradesh, India.	Inst. Ethics committee for MV Hospital and Research centre MV Hospital And Research Centre314/30, Mirza Mandi Chowk Lucknow-Uttar Pradesh Lucknow-226003 India ECR/13/Inst/UP/2013/RR-24	Dr. Sandeep Kumar Gupta
11.	Atharva Multispeciality Hospital & Research Centre, H-4/Comm-2, Construction Div-21, UP Avas Vikas Parishad, Sector-E Lucknow-226003, U.P.	Institutional Ethics Committee, Atharva Multispeciality Hospital and Research Centre Atharva Multispeciality Hospital and research CentreH-4/Comm-2, Constuction Div -21, , UP Avas Vikas Parishad, Sector E, Lucknow Lucknow Lucknow Uttar Pradesh - 226003 India ECR/1241/Inst/UP/2019/RR-24	Dr. Vinish Kumar Singh
12.	RISAA IVF Clinic Hauz Khas, Green Park, main market New Delhi,Delhi - 110016 India	Risaa IVF International Fertility Center H-6, Green Park, main market New Delhi -110016 India. ECR/330/Indt/DL/2020/RR-25	Dr. Rita Bakshi

13.	Rajiv Gaadhi Medical College & Chhatrapati Shivaji Maharaj Hospital, Thane-Belapur Road, Kalwa, Thane -400605	Institutional Clinical Ethics Committee RGMC and Chatrapati Shivaji Maharaj Hospital. Thane-Belapur Rd, Kalwa, Thane-400605 Thane-Belapur Rd, Kalwa, Thane-400605 Thane Thane Maharashtra -400605 India ECR/469/Inst/MH/2013/RR-20	Dr.Senapathi Jayanarayan
14.	MGM Institute of Health Sciences,MGM Medical College and & Hospital,Sector 1,Kamothe,Navi Mumbai,Maharashtra-410209,India.	Ethics Committee for Research on Human Subjects MGM Institute of Health Sciences Sector -1 Kamothe Navi Mumbai Raigad Maharashtra -410209 India EC/RENEW/INST/2025/18637	Dr. Sneha

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