



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
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File No. CT/24/000028

To,

M/s PSI CRO Pharma India Pvt. Ltd,
2nd floor, Doddamane Building, 19/1 Vittal Mallya Road,
Bangalore, Karnataka (India) - 560001.

Sir,

With reference to your application No. GCT/CT04/FF/2024/42027 (GCT/28/24) dated 22/02/2024 please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of 2 Active Dose Regimens of MORF-057 in Adults with Moderately to Severely Active Crohn’s Disease (GARNET)” Protocol No: MORF-057-203, Version 2.0 dated 28/11/2023 with a total of up-to 60 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) **Equal No. of Govt. & private sites should be include in the study.**
- (ii) **Human biological samples i.e. serum, plasma, whole blood, biopsies, stool and urine related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.**
- (iii) 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;
- (iv) 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;
- (v) 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;

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- (vi)** 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;
- (vii)** 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;
- (viii)** 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;
- (ix)** 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;
- (x)** 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;
- (xi)** 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;
- (xii)** 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;
- (xiii)** 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;
- (xiv)** 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;
- (xv)** 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;
- (xvi)** 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;
- (xvii)** 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- (xviii)** 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;
- (xix)** the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial;
- (xx)** 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

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automatically be granted to you;

(xxi) 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,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing 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 PSI CRO Pharma India Pvt. Ltd, ,2nd floor, Doddamane Building, 19/1 Vittal Mallya Road, Bangalore, Karnataka (India) - 560001 Telephone No.: 9844058849 FAX: 9844058849 E-Mail: RADHIKA.BOBBA@PSI-CRO.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No: MORF-057-203, Version 2.0 dated 28/11/2023** 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 _____

(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	MORF-057
Therapeutic class:	inhibitor of alpha 4 beta 7 integrin
Dosage form:	Capsules
Composition:	MORF-057 =100.0000 milligram(mg) In House Specification Active
Indications:	Moderately to Severely Active Crohn's Disease

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	SMS Medical College and Attached Hospitals, Vivekananda Marg, C-Scheme Jaipur Rajasthan - 302004	Ethics Committee, S.M.S. Medical College and Attached Hospitals, J.L.N. Marg, Jaipur, Rajasthan – 302004, India ECR/26/Inst/RJ/2013/RR-19	Dr Gaurav Kumar Gupta
2.	Prime Institute of Digestive Sciences, panchvati main road, Atithi chownk corner, nanamava road, Beside chandreshvadi Rajkot Gujarat - 360001	Prime Hospital Institutional Ethics Committee, Prime Institute Of Digestive Science LLP, Plot Number 82 and 83, Atithi chowk, Nr. Chandresh Vadi, Panchvati Main Road, Rajkot, Gujarat – 360001, India ECR/1745/Inst/GJ/2022	Dr Krishnkant Rawal
3.	Shree Giriraj Multispeciality Hospital, Department of Gastroenterology, 27-Navjyot Park Corner, 150 Feet Ring Road Rajkot Gujarat - 360005	Shree Giriraj Hospital Research Ethics Committee, Shree Giriraj Multispeciality Hospital, 27-Navjyot Park Main Road, Amin Marg Cross Road, Rajkot, Gujarat – 360005, India ECR/74/Inst/GJ/2013/RR-19	Dr Chetan Mehta
4.	Samvedna Hospital, Department of Gastroenterology, B27_88G Ravindrapuri Varanasi Uttar Pradesh - 221005	Samvedna Hospital Ethics Committee, Samvedna Hospital, B-22/88 G, New Ravindra Puri Colony, Varanasi, Uttar Pradesh – 221005, India ECR/45/Inst/UP/2013/RR-20	Dr Hemant Gupta
5.	Navneet Memorial Hospital, Opp. Sardar Patel Seva Samaj Hall, In Lane, Opp. Navrangpura Telephone Exchange, Off C.G Road Ahmedabad Gujarat - 380009	Ethics Committee of Navneet Memorial Hospital, Navneet Memorial Hospital, Opp. Sardar Patel Seva Samaj Hall, Navrangpura, Ahmedabad, Gujarat – 380006, India ECR/1866/Inst/GJ/2023	Dr Kaivan Shah

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6.	S.R. Kalla Memorial Gastro and General Hospital, Department of Gastroenterology, 78-79 Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme Jaipur Rajasthan - 302006	SR Kalla Memorial Ethical Committee For Human Research, S.R. Kalla Memorial Gastro & General Hospital, 78-79 Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme, Jaipur, Rajasthan – 302001, India ECR/8/Inst/Raj/2013/RR-19	Dr Mukesh Kalla
7.	Yashoda Hospital, Behind Hari Hara Kala Bhavan, SP road, Secunderabad, Telangana, 500003, India Secunderabad Telangana - 500003	Yashoda Academy of Medical Education and Research, Yashoda Hospitals, Behind Hari Hara kala Bhawan SP Road, Secunderabad, Hyderabad, Telangana – 500003, India ECR/49/Inst/AP/2013/RR-22	Dr Ravi Shankar B
8.	Max Smart Super Speciality Hospital, Saket A unit of Gujarmal Modi Hospital and Research Centre for Medical Sciences - Gate No 6 , Press Enclave Road, Mandir Marg, Saket New Delhi Delhi -110017	Max Healthcare Ethics Committee, Ground Floor, Office of Ethics Committee, West block, Near MS Office, Max Super Speciality Hospital, Saket (A Unit of Max Healthcare Institute Limited), 1, Press enclave Road, Saket, New Delhi – 110017, India ECR/118/Inst/DL/2013/RR-19	Dr Kaushal Madan
9.	SIDS Hospital and Research Centre, Department of Gastroenterology, A unit of SIDS health care private limited, Off ring road, Near shell petrol pump, Ring road-sosyo circle lane, Surat Gujarat -395002	Surat Institute of Digestive Sciences EC, Surat Institute of Digestive Sciences, A Unit of SIDS healthcare Pvt Ltd, JJ Empire, Vijay Nager – 3, Beside Nirmal Bhavan, Majura Gate, Surat, Gujarat – 395002, India ECR/813/Inst/GJ/2016/RR-19	Dr Mayank Kabrawala
10.	Amrita Institute of Medical Sciences - AIMS, Ponekkara P.O., Kochi, Kerala, 682041, India Kochi Kerala - 682041	Institutional Ethics Committee, Amrita Institute of Medical Sciences, AIMS – Ponekkara Kochi Edappally, Ernakulam, Kerala – 682041, India ECR/129/Inst/KL/2013/RR-19	Dr Shine Sadasivan

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11.	Noble Hospital Pvt Ltd, 153, Magarpatta City Road, Hadapsar, Pune, Maharashtra, 411013, India Pune Maharashtra - 411013	Noble Hospital Institutional Ethics Committee, Noble Hospitals Pvt Ltd, Room No 5, Clinical Research Department, Noble Annex, 153 A, Magarpatta City Road, Hadapsar – 411013, India ECR/259/Inst/MH/2013/RR-19	Dr Pramod Katare
12.	Apollo Cancer Centre No. 320, Padma Complex, Anna Salai, Chennai Chennai Tamil Nadu- 600035	Institutional Ethics Committee – Clinical Studies Apollo Hospitals Enterprises Limited No-21 Greams Lane off Greams road, Chennai, Tamil Nadu – 600006, India ECR/37/Inst/TN/2013/RR-19	Dr Ganesh Subramanian
13.	King Georges Medical University, Shahmina Road, Chowk Lucknow Uttar Pradesh - 226003	Institutional Ethics Committee, King George’s Medical University, Shahmina Road, Chowk, Lucknow, Uttar Pradesh, 226003, India ECR/262/Inst/UP/2013/RR-19	Dr Ajay Kumar Patwa
14.	Lisie Hospital, North Kaloor Kaloor Kerala - 682018	Institutional Ethics Committee, Lisie Hospital, P.B No 3053, Ernakulam, Kerala, 682018, India ECR/40/Inst/KL/2013/RR-20	Dr Mathew Philip
15.	BGS Gleneagles Global Hospitals, 67, Uttarahalli mainroad, Kengeri, Bengaluru, Karnataka, 560060, India Bengaluru Karnataka - 66061	Institutional Ethics Committee, BGS Global Hospitals, BGS Health And Education City, 67 Uttarahalli Main Road, Kengeri, Bengaluru, Karnataka, 560060, India ECR/128/Inst/KA/2013/RR-19	Dr Adarsh CK
16.	All India Institute of Medical Sciences, Virbhadra Rd, Sturida Colony Rishikesh Uttarakhand - 249203	Ethics Committee relating to Clinical Trial, All India Institute of Medical Sciences Rishikesh, Virbhadra Marg, Pashulok, Rishikesh, Dehradun, Uttarakhand, 249203, India ECR/736/Inst/UK/2015/RR-21	Dr Rohit Gupta
