



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/22/000076

To,

M/s IQVIA RDS (India) Private Limited,
Omega Embassy TechSquare Marathahalli-Sarjapur,
Outer Ring Road Kadubeesanahalli Bangalore (India) – 560103.

Sir,

With reference to your application No. GCT/CT04/FF/2022/33396 (GCT/76/22) dated 08-08-2022, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 3, multicenter, randomized, double-blind, 24-week study of the clinical and antiviral effect of S-217622 compared with placebo in non-hospitalized participants with COVID-19”, Protocol No.: ACTIV-2d/A5407 Version 3.0 dated 23/June/2022 with a total of up-to 416 subjects from the country** 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) 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;

File No. CT/76/22-DCG(I)

- (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 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 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;
- (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 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 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 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;
- (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 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;
- (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) 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;
- (xix) 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,

VENUGOPA
L G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL
ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA),
pseudonym=112046a34e21727bacb255748732c456d249073e
55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI,
serialNumber=e97f241aa0c08ba41522525fca0705074b4997e
6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.12.27 11:53:25 +05'30'

(Dr. V. G. Somani)

Drugs Controller General (India)
Central Licencing Authority
Stamp

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

1. The Central Licensing Authority hereby permits **M/s IQVIA RDS (India) Private Limited, Omega Embassy TechSquare, Marathahalli - Sarjapur Outer Ring Road Kadubeesanahalli Bangalore (India) – 560103** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: ACTIV-2d/A5407 Version 3.0 dated 23/June/2022** 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 _____

VENUGOPAL G SOMANI
L G SOMANI
(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
Stamp

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL
ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA),
pseudonym=112046a34e21727bacb255748732c456d24907
3e55e953d9cb5b58748ee3113c, postalCode=110002,
st=DELHI,
serialNumber=e97f241aa0c0bba41522525ffca0705074b499
7efb246b5c8d81c7282ad0c4c, cn=VENUGOPAL G SOMANI
Date: 2022.12.23 12:53:40 +05'30'

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	S-217622
Therapeutic class:	Antiviral
Dosage form:	Tablets
Composition:	S-217622B Drug Substance (as S-217622 free base) =125.0000 milligram (mg) In House Specification Active
Indications:	COVID-19

File No. CT/76/22-DCG(I)
Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Government Medical College and Hospital, Medical College Square Road, Nagpur-440003, Maharashtra, India	Institutional Ethics Committee GMC Nagpur, Government Medical College and Hospital, Nagpur, Government Medical College, Medical Square, Hanuman Nagar, Nagpur-440003, Maharashtra, India ECR/43/Inst/MH/2013/RR-19	Dr. Rashmi Nilesh Nagdeve
2.	Unity Trauma Center and ICU (Unity Hospital), Nr. D.R. World, Opp Raghuvir Business Empire, Aai Mata Rd, Parvat Patiya, Surat, Gujarat - 395010, India	UNITY HOSPITAL ETHICS COMMITTEE, UNITY TRAUMA CENTER AND ICU, N-4 Janki Park Society, Aai Mata Road, Paravat Patiya, Surat, Gujarat - 395010, India ECR/1226/Inst/GJ/2019	Dr. Mahesh Vithalbhai Sutariya
3.	BAJRR Hospital and Research Centre, P-14, M.I.D.C Phase 1, Milap Nagar, Dombivli East, Dist. Thane, Maharashtra – 421203, India.	Altezza Institutional Ethics Committee, Shree Ashirwad Hospital, C/3 Shree Complex, Opposite Mahavir Road, Manpada Road, Dombivli (E)-421201, Dist. Thane, Maharashtra, India ECR/1457/Inst/MH/2020	Dr. Varade Deepak Bhanudas
4.	Shetty's Hospital, Plot No 11&12, 12 th Main, Kaveri Nagar, Bommanahalli-560068, Bengaluru, Karnataka, India	Shettys Hospital Ethics Committee, Shetty Hospital, Plot No. 11 & 12, 12th Main Road, Kaveri Nagar, Kodichikkanahalli, Bommanahalli, 560068, Bengaluru, Karnataka, India ECR/918/Inst/KA/2017/RR-20	Dr. Poorna Prasad S
5.	VHS - Infectious Diseases Medical Centre, CART Clinical Research Site, Voluntary Health Services, Rajiv Gandhi Salai, Taramani, Chennai - 600113	Institutional Ethics Committee, The Voluntary Health Services, Multi-Specialty Hospital & Research Centre, Rajiv Gandhi Salai, Adyar, Chennai- 600113, Tamil Nadu, India ECR/752/Inst/TN/2015/RR-22	Dr. Poongulali Selvamuthu
6.	Grant Medical Foundation Ruby Hall Clinic, 40, Sassoon Road, Pune-411001, Maharashtra, India.	Institutional Ethics Committee, Poona Medical Research Foundation, E-4 C to E-4 F, 4th Floor, Fifth Avenue Condominium, Dhole Patil Road, Pune- 411001, Maharashtra, India ECR/24/Inst/MH/2013/RR-22	Dr. Zirpe Kapil Gangadhar

File No. CT/76/22-DCG(I)

7.	DEC-HEALTH CARE, OPD Room No. 04 16/2/219, Pogathota, Nellore, Andhra Pradesh-524001, India	Vijaya Ethics Committee, Vijaya Super Speciality Hospital, 16-II/41 A, Raghava Cini Complex Road, Poghatota, Nellore Andhra Pradesh-524001, India ECR/453/Inst/AP/2013/RR-19	Dr. M Manoj Kumar
8.	BGS Global Institute of Medical Sciences, No. 67, BGS Health and Education City, Uttarahalli Road, Kengeri, Bangalore-560060, Karnataka, India.	Institutional Ethics Committee, BGS Global Institute of Medical Sciences, No. 67 BGS Health and Education City, Uttarahalli Road, Kengeri, Bangaluru-560060 ECR/1307/Inst/KA/2019	Dr. M E Mohan
9.	Chopda Medicare & Research Centre Pvt. Ltd Magnum Heart Institute , 3/5 Patil Lane No. 1, Laxmi Nagar, Near K.B.H Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India Chopda Medicare & Research Centre Pvt. Ltd Magnum Heart Institute, Clinical Research Department, Flat No. 10, Laxmanrekha Apartment, Behind Magnum Heart Institute, Patil Lane No. 1, Canada Corner, Nashik-422005, Maharashtra, India	Magna-care Ethics Committee, C/o Chopda Medicare and Research Centre Pvt. Ltd., Magnum Heart Institute, Patil Lane No. 1, Near K.B.H Vidyalaya, Canada Corner, Nashik - 422005, Maharashtra, India ECR/79/Inst/MH/2013/RR-19	Dr. Swapnil Suresh Sakhala
10.	St. Theresa's Hospital, Sanathnagar, Hyderabad – 500018, Telangana State, India	Ethics Committee St Theresa's Hospital, Sanathnagar, Hyderabad, 500018, Telangana State, India ECR/230/Inst/AP/2013/RR-22	Dr. A Venkateshwar Rao
11.	KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India	Institutional Ethics Committee, KLE University, Dr. Prabhakar Kore Hospital and MRC Nehru Nagar, Belgavi-590010, Karnataka, India EC/RENEW/INST/2019/3323	Dr. Gautam Suresh
12.	Clinical Research Facility, (CRF), 1 st Floor Cooperate Building, Saveetha Medical College and Hospital, Saveetha Nagar, Thandalam, Chennai-602105, Tamil Nadu, India	Saveetha Medical College and Hospital - Institutional Ethics Committee (SMCH – IEC), Saveetha Nagar, Thandalam, Chennai – 602105, Tamil Nadu, India ECR/724/Inst/TN/2015/RR-19	Dr. Kannan Rajendran

File No. CT/76/22-DCG(I)

13.	Vijaya Super Speciality Hospital, OPD Room No. 07, 16-II/41 A, Raghava Cine Complex Road, Pogathota, Nellore-524001, Andhra Pradesh, India	Vijaya Ethics Committee, Vijaya Super Speciality Hospital, 16-II/41 A, Raghava Cini Complex Road, Poghatota, Nellore- 524001, Andhra Pradesh, India ECR/453//Inst/AP/2013/RR-19	Dr. Chandalva Premdeep MD
14.	Yenepoya Medical College Hospital, A Constituent College of Yenepoya (Deemed to be University), University Road, Deralakatte, Mangalore -575018, Karnataka, India	Yenepoya Ethics Committee-1 Yenepoya Deemed to be University, Academic Building, University Road, Deralakatte, Mangalore-575018, Karnataka, India ECR/521/Inst/KA/2014/RR-20	Dr. Prabha Adhikari M R
15.	Department of Medicine, Sir Sayajirao General Hospital, Medical College-Baroda, Jail Road (Indira Avenue), Vadodara- 390001, Gujarat, India	Institutional Ethics Committee for Human Research Medical College & SSG Hospital Baroda, Vadodara - 390001, Gujarat, India ECR/85/Inst/GJ/2013/RR-19	Dr. Keyur Madan Brahme
16.	Ruby General Hospital Ltd, 576, Anandapur, EM Bypass, Kasba, Kolkata - 700107, West Bengal, India	Institutional Ethics Committee, Ruby General Hospital Pvt. Ltd, 576, Anandapur, EM Bypass, Kasba, Kolkata - 700107, West Bengal, India ECR/1202/Inst/WB/2019/RR-22	Dr. Rimita Dey
17.	ESIC Medical College and Hospital, NH-3, NIT, Faridabad-121001, Haryana, India	Institutional Ethics Committee for ESIC Faridabad, Room No. 301, 3 rd Floor, Department of Physiology, Academic Building, ESIC Medical College And Hospital, NH-3 NIT Faridabad-121001, Haryana, India ECR/1539/Inst/HR/2021	Dr. Anil Kumar Pandey
18.	King George Hospital, Andhra Medical College, Clinical Research Room, Department of General Medicine, Rajendra Prasad Ward, King George Hospital, Andhra Medical College, Maharanipecta, Vishakhapatnam-530002, Andhra Pradesh, India	Institutional Ethics Committee, King George Hospital, Maharanipecta Collector's Office Junction, Visakhapatnam-530002, Andhra Pradesh, India ECR/197/Inst/KGH/2013/RR-20	Dr. Yandrapati Gnana Sundara Raju
19.	Jaipur National University Institute For Medical Sciences and Research Centre, Agra-Jaipur Road, Near new RTO Office, Agra Road,	Institutional Ethics Committee, JNU Institute for Medical Sciences and Research Centre, Jagatpura, Jaipur- 302017, Rajasthan, India	Dr. Madhumati Varma

File No. CT/76/22-DCG(I)

	Jagatpura, Jaipur-302017, Rajasthan, India	ECR/905/Inst/RJ/2017/RR-20	
20.	Sarvodaya Hospital and Research Centre, YMCA Road, Sector-08, Faridabad-121006, Haryana, India	Institutional Ethics Committee, Sarvodaya Hospital And Research Centre (A Unit Of Anshu Hospitals Limited) ,YMCA Road, Sector 08, Faridabad, Haryana-121006, India ECR/999/Inst/HR/2017/RR-20	Dr. Manisha Mendiratta
21.	Department of Medicine GSVM. Medical College, Swaroop Nagar, Kanpur-208002	Ethics Committee, GSVM Medical College, Room no 125 1st Floor, GSVM Medical College, Swaroop Nagar, Kanpur-208002 ECR/680/Inst/UP/2014/RR-20	Dr. Saurabh Agarwal
22.	HB Speciality Hospital and Research Institute, Kashipur Road, Rudrapur 263153, Uttarakhand, India	Ethics Committee HB Specialty Hospital, HB Specialty Hospital And Research Institute, Kashipur Road, Rudrapur, Udham Singh Nagar, Uttarakhand-263153, India ECR/1010/Inst/UK/2017/RR-20	Dr. Anupama Bansal
23.	Tagore Hospital & Research Institute, Tagore Lane, Sector-7, Shipra Path, Madhyam Marg, Mansarovar, Jaipur-302020, Rajasthan, India	TAGORE HOSPITAL ETHICS COMMITTEE, Tagore Hospital And Research Institute, Tagore Lane, Sector-7, Shipra Path, Madhyam Marg, Mansarovar, Jaipur, Rajasthan-302020, India ECR/1489/Inst/RJ/2021	Dr. Sandeep Jain
24.	Lifepoint Multispeciality Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra, India	LPR Ethics Committee, Lifepoint Multispeciality Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra, India ECR/751/Inst/MH/2015/RR- 21	Dr. Shivnitwar Sachin Kisan
25.	B.J. Govt. Medical College-John Hopkins University Clinical Research Site(BJGMC-JHU CRS), B J Medical Govt. College & Sassoon General Hospitals, 1st Floor, ENT Department, PGP Hall, Jai Prakash Narayan Road, Pune-411001, Maharashtra, India	Ethics Committee B J Medical College and Sassoon General Hospitals, Department of Physiology, 2 nd Floor, B J Govt Medical College and Sassoon General Hospital, Jai Prakash Narayan Road, Pune-411001, Maharashtra, India ECR/433/Inst/MH/2013/RR-19	Dr. Sonali Pankaj Salvi
26.	Calcutta School of Tropical Medicine, 108, Chittaranjan Avenue, Kolkata-700073, West Bengal, India	Clinical Research Ethics Committee, School of Tropical Medicine, 108, Chitta Ranjan Avenue, Kolkata - 700073, West Bengal - 700073, India	Dr. Santanu Munshi

		ECR/194/Inst/WB/2013/RR- 20	
27.	Aakash Healthcare Pvt. Ltd, Hospital Plot, Road No. 201, Sector 3, Dwarka, New Delhi - 110075, India	Aakash Healthcare Super Speciality Hospital Institutional Ethic Committee, Department of Academic and Research Development, Basement 1, Near Ultrasound, Aakash Healthcare Pvt. Ltd, Hospital Plot, Road No 201, Sector 3, Dwarka, New Delhi 110075, India ECR/1265/Inst/DL/2019	Dr. Akshay Budhraj
28.	Sri Lakshmi Super Speciality Hospital, No. 301, 3rd Main Road, Near Indane Gas, V.B. Layout Old Extension, Krishnarajapura, Bengaluru-560036, Karnataka, India	Pranav Diabetes Center Ethics Committee, 57/1, Nanda Complex, Rammurthy Nagar Main road, Banaswadi, Bengaluru, Urban- 560043, Karnataka, India ECR/141/Inst/KA/2013/RR-19	Dr. SambashivaA C
29.	Sri Venkateshwara Hospitals, #27, 29 th Main Road Rashtra Kuvempu Nagara, BTM 2nd stage, BTM layout, Bengaluru-560076, Karnataka, India	Sri Venkateshwara Hospital Ethics Committee, Sri Venkateshwara Hospitals, #27, 29 th Main Road, Rashtra Kuvempu Nagara, BTM 2nd stage, BTM layout, Bengaluru-560076, Karnataka, India ECR/298/Inst/KA/2013/RR-19	Dr. Mantri Sumant Narayan
30.	Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi-110060, India	Sir Ganga Ram Hospital Ethics Committee, Sir Ganga Ram Hospital, Old Rajinder Nagar, New Delhi-110060, India ECR/20/Inst/DL/2013/RR-19	Dr. Pooja Khosla
31.	1 st & 7 th Floor (708) Sangini Hospital, Santorini Square, B/H Abhishree Complex, Opp. Star Bazar Lane, Near Jodhpur Cross Road, Ahmedabad City-380015, Ahmedabad, Gujarat, India	Sangini Hospital Ethics Committee, C/O Sangini Hospital, 1 st Floor, Santorini Square, B/H Abhishree Complex, Opp. Star Bazar Lane, Near Jodhpur Cross Road, Satellite, Ahmedabad-380015, Gujarat, India ECR/147/Inst/GJ/2013/RR-19	Dr. Shah Tapan Rohitbhai
32.	Mavens Hospital, N37, Opposite Reliance Fresh, Vaishali Nagar, Ajmer-305001, Rajasthan, India	Mavens Institutional Ethics Committee, Mavens Hospital, Lane Opp. Reliance Fresh, Vaishali Nagar, Ajmer-305001, Rajasthan, India ECR/157/Inst/RJ/2013/RR-20	Dr. Jai Prakash Kewlani

File No. CT/76/22-DCG(I)

33.	Aman Hospital and Research Center, 15, Shashwat, Opp ESI Hospital, Gotri Road, Vadodara - 390021, Gujarat, India	Institutional Ethics Committee, Aman Hospital and Research Centre, 15 Shashwat, Opp, ESI Hospital, Gotri Road, Vadodara-390021, Gujarat, India ECR/857/Inst/GJ/2016/RR-19	Dr. Khanna Aman Romesh
34.	Department of Surgical Gastroenterology & Liver Transplant, Room No. 168, 3 rd Floor, Polyclinic Building, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Raja Bazar, Patna-800014, Bihar, India	Institutional Ethics Committee, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Raja Bazar, Patna - 800014, Bihar, India ECR/640/Inst/BR/2014/RR-20	Dr. Manish Mandal
