



**GOVERNMENT OF INDIA**  
CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION(Headquarter)(Directorate General of Health Services) Ministry  
of Health & Family Welfare  
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ITO, Kotla Road  
New Delhi - 110002 (Delhi)  
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File No.CT/21/000091

To

M/s. Pfizer Limited,  
The Capital, 1802/1901 Plot No. C-70 G Block,  
Bandra Kurla Complex, Bandra (E), Mumbai- 400051, Maharashtra, India.

Sir,

With reference to your SUGAM application no.:GCT/CT04/FF/2021/27236 (GCT/91/21) dated 03-AUG-2021, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“An Interventional Efficacy and Safety, Phase 2/3, Double-Blind,2-Arm study to investigate orally administeredPF-07321332/Ritonavir compared with Placebo in Non-hospitalizedSymptomatic Adult Participants with COVID-19 who are at LowRisk of Progressing to Severe Illness” Protocol No.: C4671002, Amendment no. 3.0, dated 03-AUG-2021** 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, specifically:-

- 1) **Up to 100 subjects should be recruited in the study from India.**
- 2) **The firm should submit the final study data from the clinical Phase I study (FIH Study) to the CDSCO for review.**
- 3) **The firm should submit the completed non-clinical toxicological study data.**
- 4) 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;
- 5) 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;

- 6) 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 Licencing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;
- 7) 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;
- 8) 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;
- 9) 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;
- 10) 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;
- 11) 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;
- 12) 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;
- 13) 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;
- 14) 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;
- 15) 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;
- 16) 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;
- 17) 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;

- 18) 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;
- 19) 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;
- 20) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- 21) 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;
- 22) 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. V. G. Somani)  
Drugs Controller General (India) &  
Central Licensing Authority  
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**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. Pfizer Limited, The Capital, 1802/1901 Plot No. C-70 G Block, Bandra-Kurla Complex, Bandra (E), Mumbai- 400051, Maharashtra, India** to conduct clinical trial of the new drug or investigational new drug as per phase 2/3 study **Protocol No.: C4671002, Amendment no. 3.0, dated 03-AUG-2021** 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. V. G. Somani)  
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:

<b>Names of the new drug or investigational new drug:</b>	PF-07321332/Ritonavir
<b>Therapeutic class:</b>	Oral Protease Inhibitors
<b>Dosage form:</b>	Tablets/Capsules
<b>Composition:</b>	PF-07321332 tablet =150.0000milligram(mg) In HouseSpecification Active Ritonavir capsules =100.0000milligram(mg)In HouseSpecification Active
<b>Indication:</b>	Treatment in non-hospitalizedsymptomatic adult participantswith COVID-19 who are at low risk of progressing tosevere illness

**Annexure:**

Details of clinical trial site:

S. No.	Names and address of clinical trial site	Ethics Committee details	Name of Investigator
1.	Aakash Healthcare Private Limited, Hospital Plot, Road No. 201, Sector 3, Dwarka, New Delhi -110075	Aakash Healthcare Super Speciality Hospital Institutional Ethics Committee Department of Academic & Research Development, Basement 1, Near Ultrasound, Hospital Plot, Road No. 201, Sector 3, Dwarka, New Delhi - 75	Dr. Akshay Budhraj
2.	Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra	LPR Ethics Committee, Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra	Dr. Dange Amol Laxmanrao
3.	All India Institute of Medical Sciences (AIIMS), G.E. Road, Tatibandh, Raipur-492099 (C.G)	Institution Ethics Committee AIIMS, Raipur, Room No. 2103, 2 <sup>nd</sup> Floor, Medical College Complex, Gate no-5, AIIMS, Raipur-492099 (C.G)	Dr. Atul Jindal
4.	BGS Global Institute of Medical Sciences and Hospital, No. 67, BGS Health and Education City, Uttarahalli Main Road, Kengeri, Bengaluru-560060, Karnataka	Institution Ethics Committee, Room No. 01, Department of Community Medicine, BGS Global Institute of Medical Sciences and Hospital, No. 67, BGS Health and Education City, Uttarahalli Main Road, Kengeri, Bengaluru-560060, Karnataka	Dr. Balachandra G
5.	Dayanand Medical College & Hospital, Department of Medicine, Tagore Nagar, Civil Lines, Ludhiana, 141001, Punjab	Drug Trial Ethics Committee, Dayanand Medical College & Hospital, Tagore Nagar, Civil Lines, Ludhiana, 141001, Punjab	Dr. Dinesh Jain
6.	Department of Critical Care Medicine, MICU 3 <sup>rd</sup> Floor, Mazumdar Shaw Medical Center Narayana Hrudayalaya, 258/A, Bommasandra Industrial Area, Hosur Road, Anekal Taluk, Bangalore, Karnataka-560099	Narayana Health Medical Ethics Committee, 258/A, Bommasandra Industrial Area, Hosur Road, Anekal Taluk, Bangalore, Karnataka-560099	Dr. Harish Mallapura Maheshwarappa
7.	Medical College & S.S. G Hospital, Indira Avenue, Jail Road, Vadodara, Gujarat, India-390001	Institutional Ethics Committee for Human Research (IECHR) medical College Baroda, Room no. 2, First Floor, Department of Pharmacology, Medical College Baroda, Anandpura, Vadodara - 390001	Dr. Brahme Keyur Madan
8.	Research Cell, Dept. of Medicine, S.P. Medical College, Bikaner, Rajasthan-334003	Ethics Committee, S.P. Medical College, Bikaner, Rajasthan-334003	Dr. Sanjay Kumar Kochar

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<b>9.</b>	Sri Ramachandra Hospital, Clinical Research Division, Dental College Basement, No. 1, Ramachandra Nagar, Porur, Chennai-600116, Tamil Nadu	Institutional Ethics Committee SRIHER, Sri Ramachandra, 1, Ramachandra Nagar, Porur, Chennai, Tiruvallur, Tamil Nadu-600116	Dr. Vengadkrishnan Krishnamoorthy
<b>10.</b>	DY Patil Medical College and Hospital, Plot-2, Sector 5, Nerul, Navi Mumbai-400706, Maharashtra	Institutional Ethics Committee, DY Patil Medical College Navi Mumbai-400706	Dr. AbhayGangadhar Uppe
<b>11.</b>	Sahyadri Super Speciality Hospital, 30 C Erandwane, Karve Road, Pune-411004, Maharashtra, India Sahyadri Clinical Research and Development Center (Unit of Sahyadri Hospital), 33/34B Makaranda, Bhave Path, Karve Road, Pune-411004, Maharashtra	Sahyadri Hospital Pvt. Ltd., Ethics Committee, Sahyadri Clinical Research and Development Center, 33/34B Makaranda, Bhave Path, Karve Road, Pune - 411004, Maharashtra	Dr. AmolBansode
<b>12.</b>	Department of Critical Care Medicine, 2 <sup>nd</sup> Floor, Bharati Hospital and Research Centre, BharatiVidyapeeth (deemed to be) University Medical College, Dhankawadi, Katraj, Pune-411043	Institutional Ethics Committee, BharatiVidyapeeth Deemed University, 4 <sup>th</sup> Floor Bharati Hospital and Research Centre, BharatiVidyapeeth (deemed to be) University Medical College, Dhankawadi, Katraj, Pune-411043	Dr. Shah JigneshNavinchandra
<b>13.</b>	Unity Trauma Center and ICU (Unity Hospital), Nr. D.R. World, OppRaghuvir Business Empire, Aai Mata Rd, ParvatPatiya, Surat-395010, Gujarat	Unity Hospital Ethics Committee, Unity Trauma Center And ICU, N-4 Janki Park Society, Aai Mata Road, ParavatPatiya, Surat - 395010, Gujarat, India	Dr. MaheshkumarVithalbhaiSutariya
<b>14.</b>	Jehangir Clinical Development Centre Pvt. Ltd. Jehangir Hospital Premises, 32 Sassoon Road, Pune-411 00 1	Ethics Committee Jehangir Clinical Development Centre, Jehangir Clinical Development Centre Pvt. Ltd, Jehangir Hospital Premises, 32 Sassoon Road, Pune-411001.	Dr. ChaudhariPiyush Ashok
<b>15.</b>	Apollo Hospitals, No. 21, Greams Lane, Off Greams Road, Chennai-600006, Tamil Nadu	Institutional Ethics Committee – Clinical Studies, Apollo Hospitals Enterprise Limited , #21, Greams Lane, Off Greams Road, Thousand Lights, Chennai-600006, Tamil Nadu, India	Dr. V. Ramasubramanian
<b>16.</b>	St. George Hospital, Grant Government Medical College and Sir J J Group of Hospitals, PD'Mello Road, CST, Mumbai-400001, Maharashtra	Institutional Ethics Committee, Department of Pharmacology, Grant Government Medical College and Sir J J Group of Hospitals, Byculla, Mumbai 400008, Maharashtra, India	Dr. SawardekarVinayakMaruti

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