ND/CT21/FF/2021/26093
Dated 01.06.2021

F. No. ND/MA/21/000080

Tele No.011-23236965
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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated: 01 JUL 2021

To

M/s Pure & Cure Health Care Pvt. Ltd.
305, Mohan Place, L.S.C., Block-C
Saraswati Vihar Delhi (India) – 110034

Subject:- Permission to conduct clinical trial entitled "A Phase III, Randomized, Prospective, Open label, Parallel Group, Clinical study to evaluate theefficacy and safety of Molnupiravir Tablets in adult patients with Moderate COVID-19 infection." (Protocol No.:BRPL/CT/MOLCOV/05/21,Ver.2.0, Dated 01.06.2021) - reg.

Sir,

With reference to your application dated 01.06.2021, please find enclosed herewith the permission in **Form CT-06, No. CT/ND/70/2021** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019 granted based on evaluation in consultation with subject Expert Committee (SEC) as part of accelerated approval process in light of Covid-19 outbreak.

This permission is subject to the conditions, as mentioned below.

Yours faithfully

(Dr. V. G. Somani)
Central Licensing Authority

Condition of permission

(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;

(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;

(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 of the New Drugs and Clinical Trials Rules, 2019;

(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 the Chapter VI of the said Rules 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 the 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 authorized 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 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 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) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

(xix) Undertaking by Investigators along with all supportive documents as per New Drugs and Clinical Trials Rules, 2019 shall be submitted before initiation of clinical trial.

(xx) CMC data as per the requirement like characterization details, certificate of analysis, stability data etc. should be submitted to CDSCO for initiation of clinical trial.

(xxi) The study should be conducted in two parts and termed as Phase II/III Clinical trial.

a) In part I, the study should be conducted in 100 patients and submit interim Clinical trial data to CDSCO for further consideration.

b) RTPCR test should be done at 5, 10 and 15 days of the study.

c) Sample size should be atleast 1282 moderate COVID patients in randomized 1:1 ratio into Test: Reference arm.

Test Arm
Molnupiravir 800 mg (4 capsules of 200 mg) administered orally every 12 hours for 5 days (10 doses total) plus Standard of Care.

Reference Arm
Standard of Care

d) Patients age limit should be 18 to 60 years.

FORM CT-06

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

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

Number of the permission and date of issue **CT/ND/70/2021** dated 01 JUL 2021

The Central Licensing Authority hereby permits **M/s. Pure & Cure Health Care Pvt. Ltd. 305, Mohan Place, L.S.C., Block-C, Saraswati Vihar Delhi (India) – 110034, India** to conduct clinical trial of the new drug as per **Protocol No.: BRPL/CT/COVID 19/MOL/05/21, Ver.2.0, Dated 01.06.2021** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial sites: -

Names of the new drug or investigational new drug:	Molnupiravir Tablets 200mg, 800mg
Therapeutic class:	Antiviral
Dosage form:	Tablet
Composition:	Each tablet Contains Molnupiravir ..... 200 mg Each tablet Contains Molnupiravir ..... 800 mg
Indications	For the management of adults with Moderate COVID-19 Infection

Details of clinical trial site		
Sr. No.	**Name of Principal Investigator & Trial Sites**	**Name of Ethics Committee and address with Ethics Committee registration No**
01	Dr. Gouranga Sarkar Health Point hospital, 21, Prannath Pandit Street, Kolkata-700025.	HEALTHPOINT ETHICS COMMITTEE, Health Point Hospital, 21 Prannath Pandit Street, Opp Landsdown Padmapukur, Kolkta- 700025 **ECR/284/Inst/WB/2013/RR-19**
02	Dr. Rakhi Ludam IMS & SUM Hospital, K8 Lane 1, Kalinganagar, Bhubaneswar, Odisha 751003	IEC IMS and SUM HOSPITAL IMS and SUM Hospital K-8, Kalinga Nagar, Shampur Khurdha, Bhubaneswar-75l003 Odisha, India **EC.W 627 /Lnst/OR/2014/RR-20**
03	Dr. Sujata Devi AIIMS, Bhubaneswar SIJUA, PATRAPADA, ODISHA, PIN-751019	INSTITUTIONAL ETHICS COMMITTEE AIIMS, Bhubaneswar SIJUA, PATRAPADA, ODISHA, PIN-751019 **ECR/534/Inst/OD/2014/RR-20**
04	Dr. Sumit Poddar Poddar Nursing Home, Eqbal Mansion, Gulam Jilani Khan Rd, Topsia, Kolkata, West Bengal 700039	HEALTHPOINT ETHICS COMMITTEE, HealthPoint Hospital, 21 PrannathPandit Street, Opp Landsdown Padmapukur, Kolkta- 700025 **ECR/284/Inst/WB/2013/RR-19**

05	Dr. Arunansu Talukdar Medical College and Hospital, 88, College St, Calcutta Medical College, College Square, Kolkata, West Bengal - 700073	INSTITUTIONAL ETHICS COMMITTEE FOR HUMAN RESEARCH, Medical College & Hospital, 88, College Street, Kolkata-700073 **ECR/287/Inst/WB/2013/RR-19**
06	Dr. Dibyendu Patra Dum Dum Municipal Specialized Hospital, No. 4, Hari Mohan Dutta Road, Cantonment, Rajbari, Dum Dum, Kolkata, West Bengal -700028	HEALTHPOINT ETHICS COMMITTEE, Health Point Hospital, 21 Prannath Pandit Street, Opp Landsdown Padmapukur, Kolkta - 700025 **ECR/284/Inst/WB/2013/RR-19**
07	Dr Mulla Sadiq Yunus Jivan Rekha Hospital, Sr no 28, Prabhu Complex, Opp Republic School, Dehuroad, Pune - 412101	Narsimha Saraswati Medical Foundation Indrayani Hospital and Research Institute,alandi Chaken Road Alandi Devachi,Pune, Maharashtra- 412105. **ECR/1121/Inst/MH/20I8**
08	Dr. Rahul Babasaheb Jawale Shraddha Hospital and Critical Care Centre, Plot No 9, Gajanan Maharaj Mandir Road Aurangabad, Maharashtra - 431003.	Narsimha Saraswati Medical Foundation Indrayani Hospital and Research Institute, alandi Chaken Road Alandi Devachi, Pune, Maharashtra - 412105. **ECR/1121/Inst/MH/20I8**
09	Dr. Ashish Shankarrao Deshmukh ORIION Citicare Hospital, 5-5-70, opposite Kalash Mangal Karyalay, New Usmanpura, Aurangabad, Maharashtra 431005	AURANGABAD HEALTHCARE & RESEARCH LLP-INDEPENDENT ETHICS COMMITTEE Shop No.I26, CTS No.1248211 Chetan Trade Centre, Opp.S.F School, Jalna Road, Aurangabad, Pin 431 001, MH India **ECR/325/Inst/MH/2020**
10	Dr. Pandit Aravind Shridhar Moraya Multispeciality Hospital, Chinchwadgaon, Pune, Maharashtra 411033	Moraya Institutional Ethics Committee Ashwin Medical Foundation Moraya Multispeciality Hospital, Chinchwadgaon, Pune, Maharashtra 411033 **ECR/657/Inst/MH/2014/RR-20**
11	Dr. Sudhir Kumar Bhatnagar Abhinav Hospital, Kamal Chowk, Nagpur, Maharashtra 440017	JASLEEN HOSPITAL ETHICS COMMITTEE Panchasil square, Dhantoli, Nagpur, Maharashtra- 440012, India. **ECR/264/Inst/MH/2013/RR-2**
12	Dr. Krishna Madhukar Giri New Matrix Hospital, chowk, Sai nath Nagar, Nashik	Shree Institutional Ethics Committee Dhadiwal Hospital InCoalition with Shreeji HealthCare, Op. New CBS, Trimbak Road, Nashik-422002. **ECR/1149/Inst/MH/2018**
13	Dr. Varade Deepak Bhanudas BAJ RR Hospital, P 14 MIDC Phase 1, College Rd, Dombivli East, Dombivli, Maharashtra 421203	ALTEZZA INSTITUTIONAL ETHICS COMMITTEE C/3, Shree Complex, Manapada Road, Dombivli East-421201 **ECR/1457/Inst/MH/2020**

14	Dr. Shukla Dhaiwat Mrugeshbhai VS General Hospital, 605, Paldi Rd, Madalpur Gam, Paldi, Ahmedabad, Gujarat 380006	SHREY HOSPITAL INSTITUTIONAL ETHICS COMMITTEE Shrey Hospital Pvt Ltd, 270/B/5, Stadium Circle, Navrangpura, Ahmedabad, Gujarat - 380009. **EC/1302/INST/GJ/2019**
15	Dr. Ansari Rizwanahmed Nurulhasan GCS medical college & Hospital, Naroda Rd, nr. Chamunda Bridge, Ahmedabad, Gujarat 380025	INSTITUTIONAL ETHICS COMMITTEE, GCS MEDICAL COLLEGE, HOSPITAL and RESEARCH CENTRE, GCS medical college & Hospital, Naroda Rd, nr. Chamunda Bridge, Ahmedabad, Gujarat 380025 **ECR/339/Inst/GUJ/2013/RR-19**
16	Dr. Penurkar Sanjeevan Hospital, Pune, Maharashtra 411004	ETHICS COMMITTEE SANJEEVAN HOSPITAL Pune, Maharashtra 411004 ECR/54/INST/MAHA/2013/RR-16
17	Dr. Varun A. Bafna Star Superspeciality Hospital, Ruikar Colony, Near LIC Ground' Kolhapur' Maharashtra 416005	Om Sai Onco Institutional Ethics Committee' R.S.No. 457/10 c, Dr. Lad colony, Main road, Sugar Mill corner' Kasaba Bawada' Kolhapur' **ECR/1112/Inst/MH/2013/2018**
18	Dr. R S Raman Maharaja Agrasen Hospital, Block C, Shivaji Park, West Punjabi Bagh, Delhi, 110026	Maharaja Agrasen Hospital Institutional Ethics Committee, (MAH IEC), R. No -614, 6th Floor Maharaja Agrasen Hospital West Punjabi Bagh, New Delhi
19	Dr. Gursaran Sidhu Sidhu Hospital, G.T. Road, SBS Nagar, Doraha, Punjab 141421	Institutional Review Board, Sidhu Educational Research Inst and Hospital, Doraha Sidhu Hospital, G.T. Road, SBS Nagar, Doraha, Punjab 141421 **ECR/722/Inst/PB/2015/RR-18**
20	Dr. Surabhi Jindal Jindal Hospital, SPM Nagar, U.I.T Colony, Bharatpur, Rajasthan 321001	Jindal Superspeciality Hospital Institutional Ethics Committee, SPM Nagar, U.I.T Colony, Bharatpur, Rajasthan 321001 **ECR/992/Inst/RJ/2017/RR-20**
21	Dr. Vikas Sikri Mohandai Oswal Hospital, Grand Trunk Rd, BYE PASS, Sherpur, Ludhiana, Punjab 141009	MOHANDAI OSWAL CANCER TREATMENT AND RESEARCH FOUNDATION, R-7, Ground Floor, Mohandai Oswal Hospital, Ludhiana **ECR/365/INST/PB/2013/RR-20**
22	Dr. Prabath kumar Agrawal Care Hospital, 27/144, Panchkuiyan Rd, Ashok Nagar, Shahganj, Agra, Uttar Pradesh 282002	Care Hospital Ethics Committee 27/144, Ashok Nagar, Panchkuiyan Near Mathur Vaisya Seva sadan, Agra, UP-282001. **ECR/1447/INST/UP/2020**
23	Dr. Amit Kumar King George's medical University Chowk, Lucknow-226003, U.P India	Research Cell Administrative Block, King George's medical University Chowk, Lucknow-226003, U.P India **ECR/262/Inst/UP/2013/RR-19**

24	Dr. Zeba Siddiqi Department of Medicine Era's Lucknow Medical college & Hospital Sarfarajganj, Hardoi Road, Lucknow-226003	Institutional Ethics Committee, Era's Lucknow Medical college & Hospital Sarfarajganj, Hardoi Road, Lucknow-226003 ECR/717/InstUP/2015/RR-18
25	Dr. Abhishek Aggarwal Guru Nanak Hospital Shiv Colony Opposite old Palwal bus stand, Main Delhi- Mathura National Highway (NH 2) Palwal 121102	INCLEN Independent Ethies Committee The INCLEN Trust International F-1/5, SECOND FLOOR OKHLA INDUSTRIAL AREA PHASE 1NEW DELHI South Delhi, Delhi- 110020 **ECR/109/Indt/DL/2014/RR-20**
26	Dr. Jagadeesh S.G Gadag Institute of Medical Sciences, SH 6, Malasamudra, Karnataka 582103	INSTITUTIONAL ETHICS COMMITTEE (IEC), Gadag Institute of Medical Sciences, SH 6, Malasamudra, Karnataka 582103 **ECR/ 1173/Inst/KA/2019**
27	Dr. Rekha M.C Mandya Institute of Medical Sciences, Bangalore, Mysore Rd, Mandya, Karnataka 571401	IEC-MMC and RI and Associated Hospital Mysore Medical College and Research Institute, Irwin, Road Mysuru Mysuru (Mysore) Karnataka – 570001, India **ECR/134/Inst/KA/2013/RR-19**
28	Dr. Girish K Kempegowda Institute of Medical Sciences, Banashankari, Bengaluru, Karnataka 560070	KIMS Institutional Ethics Committee, Kempegowda Institute of Medical Sciences, Attimabbe Road Banashankari 2nd Stage Bangalore 560070 **ECR/216/Inst/Kar/2013/RR-19.**
29	Dr. Giridhar B.H Justice K S Hegde Hospital, Deralakatte, Mangalore – 575018, Karnataka, India	CENTRAL ETHICS COMMITTEE, NITTE (Deemed to be University) Central Ethics Committee, NITTE (Deemed to be University) University Enclave, Medical Science complex, Deralakatte, Mangalore,575018. **ECR/119/INST/KA/2013/RR-19**
30	Dr. Lakshmi Narasimhan R Columbia Asia Hospital, Siddique Nagar, Mandi Mohalla, Mysuru, Karnataka 570015	INSTITUTIONAL ETHICS COMMITTEE COLUMBIA ASIA HOSPITAL MYSORE Columbia Asia Hospital, Siddique Nagar, Mandi Mohalla, Mysuru, Karnataka 570015 **ECR/1106/INST/KA/2018**

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.

(Dr. V. G. Somani)
Central Licensing Authority

D.V.G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

Stamp

New Delhi
Date: 01 JUL 2021