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- (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 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,

VENUGOPAL
GIRDHARILA
L SOMANI

Digitally signed by VENUGOPAL GIRDHARILA SOMANI
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st=Maharashtra,
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(Dr. V. G. Somani)
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 Biocon Limited, 20th KM Hosur Road Electronics City, Bangalore (India) – 560100** to conduct clinical trial of the new drug or investigational new drug as **Protocol No: BIO-ITOLIZ-304 Protocol Version 2.0 dated 29/September/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 _____

VENUGOPAL
GIRDHARILAL
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(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:

Names of the new drug or investigational new drug	Itolizumab for Injection
Therapeutic class:	Immunomodulator
Dosage form:	Lyophilized Powder for solution for injection
Composition:	Itolizumab (r-DNA origin) = 100.0000 milligram (mg) In House Specification Active
Indications:	Hospitalised patients with COVID-19 requiring oxygen therapy

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Clinical Research Room, Department of General Medicine, Rajendra Prasad Ward, King George Hospital, Andhra Medical College, Maharanieta, Visakhapatnam-530002, Andhra Pradesh	Institutional Ethics Committee, King George Hospital, Maharanieta, Collector's Office Junction, Visakhapatnam_5 3 000 2, Andhra Pradesh, India. Visakhapatnam-530002, Andhra Pradesh, India ECR/197/Inst/KGH/2013/RR-20	Dr. Yandrapati Gnana Sundara Raju
2.	BGS Global Institute of Medical Sciences & Hospital, #67, BGS Health & Education City, Uttarahalli Road, Kengeri, Bangalore South-560060, Karnataka, India	Institutional Ethics Committee, No. 67, BGS Health & Education City, Uttarahalli Road, Kengeri, Bangalore-560060 ECR/1307/Inst/KA/2019	Dr. M.E. Mohan
3.	Raja Rajeshwari Medical College and Hospital, Kengeri Satellite Town, Bangalore-560074	Institutional Ethics Committee, Raja Rajeshwari Medical College and Hospital, Kengeri Satellite Town, Bangalore-560074 ECR/56/Inst/KA/2013/RR-19	Dr. Vivek G
4.	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. Nirhali Sonali Chandrakant
5.	Global Hospital & Research Institute, 577/2, Off Singhad Road, Near Dattawadi Police Chowki, Dattawadi, Pune-411030, Maharashtra, India	Saikrupa Hospital Institutional Ethics Committee, Saikrupa Hospital, Renuka Corner, Tapkir Chowk, Thergaon, Pune-411033, Maharashtra, India ECR/1350/Inst/MH/2020	Dr. Nischal V. Yalgi
6.	Yashwantrao Chavan Memorial Hospital, Dept. of Pulmonary Medicine, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra	Institutional Ethics Committee of Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra ECR/1236/Inst/MH/2019	Dr. Rakesh D. Waghmare

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7.	St. George Hospital, Grant Government Medical College and Sir J J Group of Hospitals, PD Mello Road, CST, Mumbai 400001, Maharashtra. India	Institutional Ethics Committee, Department of Pharmacology, Grant government Medical College & Sir J.J group of Hospitals, Byculla, Mumbai 400008, Maharashtra, India ECR/382/Inst/MH/2013/RR-19	Dr. Vinayak Maruti Swardekar
8.	Orchid Speciality Hospital, Second Floor, L-Square, Porwal Road, Sr. No. 282/3/3, Off Dhanori, Jakat Naka, Lohgaon, Pune-411047, Maharashtra, India	Orchid Speciality Hospital Ethics Committee, Orchid Speciality Hospital, L-Square, Porwal Road, Sr. No. 282/3/3, Lohgaon, Pune-411047, Maharashtra, India ECR/1089/Inst/MH/2018	Dr. Ashish Omprakash Goyal
9.	All India Institute of Medical Sciences, G. E. Road, Tatibandh, Raipur-492099 (C.G.)	Institutional Ethics Committee of All India Institute of Medical Sciences, Raipur, Room No. 2103, Department of Pharmacology, 2 nd Floor, South Wing, Medical College Complex, Gate No. 05, G.E. Road, Tatibandh, Raipur, Chhattisgarh-492099 ECR/714/Inst/CT/2015/RR-21	Dr. Atul Jindal
10.	Belagavi Institute of Medical Sciences, Dr. B R Ambedkar Road, Belagavi-590001, Karnataka, India	Institutional Ethics Committee, BIMS, 3 rd Floor, BIMS Building, Belagavi Institute of Medical Sciences, Dr. B R Ambedkar Road, Belagavi, Karnataka-590001 ECR/801/Inst/KA/2016/RR-20	Dr. Giridhar Patil
11.	Mahatma Gandhi Mission's (MGM), Medical College & Hospital, N-6, Cidco, Aurangabad, 431003, Maharashtra, India	MGM Ethics Committee For Research on Human Subject, MGM-ECRHS), Pharmacology Department, MGM Medical College, N-6, CIDCO, Aurangabad, 431003, Maharashtra ECR/581Inst/MH/2014/RR-20	Dr. Anand Marutirao Nikalje
12.	Victoria Hospital, Bangalore Medical College & Research Institute, K R Road, Fort, Bangalore Urban, Karnataka-560002, India	Ethics Committee of BMCRI, Bangalore Medical College & Research Institute, K R Road, Fort, Bangalore Urban, Karnataka-560002, India ECR/302/Inst/KA/2013/RR-20	Dr. Jayanthi C.R