File No. SND/CT/20/000062
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 29.06.2021

To,

M/s. Ipca Laboratories Limited,
125, Kandivali Industrial estate, Kandivali west,
Mumbai, Maharashtra (India) – 400067.

Subject: **"Permission to conduct Phase III Clinical trial of Hydroxychloroquine Sulfate Tablets "Title- Evaluation of efficacy and safety of hydroxychloroquinee when used as an add-on therapy in Type 2 Diabetes Patients uncontrolled on Metformin Monotherapy: A randomized double blind, placebo-controlled study. (Protocol No. Ipca/HCQP/PIII-20, Version Number: 02, Amendment Number: 01, Date:-08-02-2021) - Reg.**

CT NOC No.: SND/CT/20/000062

Sir,

With reference to your Application No. SND/CT04/FF/2020/22042 dated 19.10.2020 please find enclosed herewith the permission in Form CT-06, CT NOC No. **SND/CT/20/000062** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

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

Yours faithfully,

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
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(Dr. V. G. Somani)
Central Licensing Authority

Conditions 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 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 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 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) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (lCF) 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.

FORM CT-06

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

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

CT NOC NO.: SND/CT/20/000062

The Central Licensing Authority hereby permits **M/s Ipca Laboratories Limited, 125, Kandivali Industrial estate, Kandivali west, Mumbai, Maharashtra (India) – 400067** to conduct clinical trial of the new drug ~~or investigational new drug~~ as per **Protocol No. Ipca/HCQP/PIII-20, Version Number: 02, Amendment Number: 01, Date:-08-02-2021** in the below mentioned clinical trial sites.

2. Details of new drug or ~~investigational new drug~~:

Names of the new drug:	Hydroxychloroquine Sulfate Tablets 200mg, 300mg and 400mg
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Each tablet contains: Hydroxychloroquine…….200mg, 300mg & 400mg
Indications:	Type 2 diabetes mellitus.

Details of clinical trial sites

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/Registration Number
1	Dr. C.L Nawal Senior Professor and former Head, Department of Medicine, S.M.S Medical College and Hospital, Jaipur- 302004, Rajasthan	Ethics Committee, S.M.S. Medical College And Attached Hospitals, J.L.N Marg Jaipur- 302004, Rajasthan. ECR/26/Inst /RJ/2013/RR- 19
2	Dr. Madhukar Mittal Additional Professor, Department of Endocrinology and Metabolism, All India Institute of Medical Sciences, Basni industrial Area, MIA 2nd Phase, Basni, Jodhpur, Rajasthan-342005.	Institutional Human Ethics Committee All India Institute of Medical Sciences, Basni, Jodhpur-342005, Rajasthan. India. ECR/866/Inst /RJ/2016/RR-19
3	Dr. Indira Pattnaik Senior Consultant Physician, Department of Medicine, Sparsh Hospital and Critical Care (P) Ltd, A-407, Saheed Nagar Bhubaneswar-751007, Orissa.	Institutional Ethics Committee, Sparsh Hospital, Sparsh Hospital and Critical Care Pvt. Ltd, Plot-A/407, Saheed Nagar, Bhubaneswar, Khordha, Orissa - 751007, India. ECR/68/Inst /OR/2013/RR-19
4	Dr. Ritesh Kumar Agrawala Consultant Endocrinologist, AMRI Hospitals Ltd., Plot No. 1, Near Satya Sai Enclave, Khandagiri, Bhubaneswar- 751030, Odisha, India.	Institutional Ethics Committee, AMR, Hospitals Ltd., Bhubaneswar, Plot No. 1, Khata No. 276, Satyasai Enclave, Beside Jaydev Vatika, Khandagiri, Bhubaneswar- 751030, Odisha, India. ECR/903/Inst/OR/2017/RR-20
5	Dr. Parul Bhatt Department of Medicine, GMERS Medical College and Hospital, Sola, Nr. Gujarat High Court S.G. Highway Sola Ahmedabad - 380060 India.	Institutional Ethics Committee, GMERS Medical College Sola Highway Nr. Gujarat High Court, Ahmedabad – Gujarat – 380061, India. ECR/404/Inst/GJ/2013/RR-20

6	Dr. Vijay Viswanathan Head & Chief Diabetologist M.V. Hospital for Diabetes (P) Ltd., # 4, West Madha Church Street, Royapuram, Chennai- 600013, Tamil Nadu, India.	Institutional Ethics Committee, Prof. M. Viswanathan Diabetes Research Centre, #4, West Madha Church Street, Royapuram, Chennai- 600013, Tamil Nadu, India. ECR/51/Inst/TN/2013/RR-19
7	Dr. Nihai Thomas, Professor & Head, Christian Medical College, 810, Dept. of Endocrinology Diabetes & Metabolism, Christian Medical College, Vellore – 632004, TN, India.	Institutional Review Board, Christian Medical College, Thorapadi Post Bagayam Vellore, Tamil Nadu – 632012, India. ECR/326/Inst/TN/2013/RR-19
8	Dr. Paramesh Shamanna Consultant Diabetologist, Bangalore Diabetes Centre, No. 426, 4th Cross, 2nd Block, Kammanahalli main road, Kalyan Nagar, Bangalore 560043.	Medisys Clinisearch Ethical Review Board, Bangalore Diabetes, Centre, No. 426, 4th Cross, 2nd Block, Kammanahalli main road, Kalyan Nagar, Bangalore 560043. ECR/33/Inst/KA/2013/R R-19
9	Dr. Damodara Shenoy Professor, Department of Medicine, Kasturba Medical College, N.G. Road, Attavar Mangalore.	MAHE Ethics Committee, Mezzanine floor, KMC Old library building, Madhya Nagar, Manipal 576104, Karnataka. ECR/191/Inst /KL/2013/RR-19
10	Dr. Neeraj Manikath Assistant Professor, Department of Medicine, Government Medical College, Kozhikode, Calicut - 673008, Kerala.	Institutional Ethics Committee, Govt. Medical College Kozhikode, 4th Floor, Golden Jubilee Annex Institute of Maternal and Child Health Kozhikode , Kerala - 673008 India. ECR/395/Inst/KLJ2013/RR-20.
11	Dr. Ramanathan Balamurugan Chief Diabetologist, Kovai Diabetes Speciality Centre & Hospital, 15, Vivekananda Road, Ram Nagar, Coimabtore-641009	Institutional Ethics Committee, Kovai Diabetes Speciality Centre and Hospital, 15, Vivekananda Road, Ramnagar, Coimbatore Tamil Nadu - 641009 India. ECR/233/Inst/TN/2013/RR-19
12	Dr. L. Sreenivasa Murthy Senior Consultant Physician & Diabetologist, Life Care Hospital & Research Center, #2748/2152 M.L.N. Enclave, 16th E-Cross road, 8th Main D Block, Next to Corporation Bank, Sahakarnagar, Bengaluru – 560092.	Life Care Hospital Institutional, Review Board, Life Care Hospital and Research Centre, 2748-2152, M.L.N Enclave, 16th, Cross Road, 8th Main, D-Block Next to Corportion Bank, Sahakarnagar, Bengaluru (Bangalore) Urban Karnataka -560092. ECR/883/Inst/KA/2017/RR-20
13	Dr. Ashu Rastogi Assistant Professor, Department of Endocrinology and Metabolism, PG1MER, Room no - 16, Ground floor, Nehru Extension Block, Chandigarh-160012, India	Institutional Ethics committee, Post Graduate institute of medical Education and Research Room No. 6006, IEC Office, 6th Floor P N Chuttani Block, Chandigarh — 160012 India. ECR/25/Inst/CH/2013/RR-20
14	Dr. Krishnamurthy HA Department of General Medicine, Mysore Medical College and Research Institute, K. R. Hospital, Mysore-570001.	IEC-MMC and RI and Associated Hospital Mysore Medical College and Research Institute Mysore Medical College and Research Institute Irwin Road Mysuru (Mysore) Karnataka - 570001, India. ECR/134/Inst/KA/2013/RR-19

15	Dr. Manish Agrawal Medilink Hospital Research Centre, Near Shyamal Char Rasta, 132ft. Ring Road, Satellite, Ahmedabad, Gujrat-380 015, India.	Medilink Ethics Committee, Medilink Hospital, Research Centre 132 feet ring road near shyamal cross road Ahmedabad Gujarat - 380015 India. ECR/344/Inst/GJ/2013/RR-19
16	Dr. Sujit Chandratreya, Vijan Hospital & Research Centre, College Road, Nashik – 422005, Maharashtra, India.	Vijan Hospital, Hospital Ethics Committee, Vijan Cardiac And Critical Care Centre Dr. Vijan Hospital Marg College, College Road, Nashik – 422005, Maharashtra, India. ECR/406/Inst/MH/2013/RR-19
17	Dr. Richa Girl Professor and Head, Department of Medicine, Ganesh Shankar Vidyarthi Memorial Medical College, Swaroop Nagar, Kanpur- 208002, Uttar Pradesh.	Ethics Committee GSVM Medical College Room no. 125, 1st floor, G.S.V.M. Medical college, Swaroop Nagar Kanpur -208002, Uttar Pradesh. ECR/680/Inst /UP/2014/RR -17
18	Dr. Md. Sabah Siddiqui, Associate Professor, Department of Medicine, All India Institute of Medical Sciences, Tatibandh, G E Road, Raipur -492099, Chhattisgarh.	Institutional Ethics Committee, All India Institute of Medical Sciences (AIIMS), Department of Pharmacology, 2nd Floor, South Wing, Medical College Complex, Gate No. 5, Tatibandh, GE Road Raipur - 492099, Chhattisgarh. ECR/714/Inst /CT/2015/RR-18
19	Dr. Dange Amol Laxmanrao, Consultant Diabetologiest & Physician, Lifepoint Multispeciality Hospital, Sr. No.145/1, Mumbai Bangalore Highway, near Hotel Sayaji, Wakad, Pune - 411057, Maharashtra, India.	LPR Ethics Committee, Lifepoint Multispeciality hospital, Sr No. 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra, India. ECR/751/Inst /MH/2015/RR -18

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.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
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(Dr. V. G. Somani)
Central Licensing Authority
Stamp

New Delhi
Date: 29.06.2021