F. No. SND/CT/19/000037
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:

To,

M/s Ipca Laboratories Pvt Ltd.,
Plot 142AB, Kandivali Industrial Estate, Kandivali West,
Mumbai, Maharashtra, (India) – 400067.

Subject: "Grant of permission to undertake Phase III clinical trial of New Drug – Hydroxychloroquine Sulfate Tablets 200 mg & 300 mg" - Reg.

CT NOC No.: CT/SND/05/2020

Sir,

With reference to your Application No. SND/Form44/FF/2019/15499, please find enclosed herewith the permission in Form CT-06, CT NOC No. **CT/SND/05/2020** 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,

V G SOMANI

Digitally signed by V G SOMANI
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Date: 2020.01.28 15:03:00 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
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 (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) **The Firm should ensure recording of photographs of fundus examination of all the subjects.**

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.: CT/SND/05/2020

The Central Licensing Authority hereby permits **M/s Ipca Laboratories Pvt Ltd., Plot 142 AB, 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/HYQP/PIII-18, Version No: 02, Amendment No: 01, Dated 30/10/2019** in the below mentioned clinical trial sites.

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

Names of the new drug:	Hydroxychloroquine Sulfate Tablets 200 mg & 300 mg
Therapeutic class:	Disease Modifying Antirheumatic
Dosage form:	Tablets
Composition:	Each Tablet Contains Hydroxychloroquine Sulfate 200mg. Each Tablet Contains Hydroxychloroquine Sulfate 300mg.
Indications:	Type 2 Diabetic Mellitus Patients Uncontrolled on Metformin and Sulfonylurea Combination.

Details of clinical trial sites

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/Registration Number
1	**Dr. Kishore Kumar Behera,** Assistant Professor, Department of Endocrinology, Diabetes & Metabolism, All India Institute of Medical Sciences, P.O Patrapada, Bhubaneswar-751019, Odisha.	Institutional Ethics Committee All India Institute of Medical Sciences, Village Sijua, Patrapada, P.O DumDuma, Bhubaneshwar- 751019, Odisha. ECR/534/Inst/OD/2014/RR-17
2	**Dr. Richa Giri,** Professor and Head, Department of Medicine, Ganesh Shankar Vidyarthi Memorial Medical College, Swaroop Nagar, Kanpur, Uttar Pradesh 208002.	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
3	**Dr. Jugal V. Gada,** Assistant Professor, Department of Endocrinology, No.419, 4th Floor, College Building, Topiwala National Medical College & B. Y. L. Nair Charitable Hospital, Dr. A. L. Nair Road, Mumbai – 400008.	Institutional Ethics Committee TNMC NAIR HOSPITAL Topiwala National Medical College Nair Hospital, Dr. A. L. Nair Road, Mumbai Central, Mumbai Maharashtra- 400008. ECR/22/Inst/Maha/2013/RR-19

4	**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
5	**Dr. Hemant Ramsharan Gupta,** Associate Professor and HOU of Medicine, Department of Medicine, Grant Government Medical College & Sir J.J. Hospital, Byculla-400008.	Institutional Ethics Committee, GGMC, Grant Govt Medical College, JJ R oad, JJ Hospital compound Mumbai Central, Mumbai-400008 Maharashtra. ECR/382/Inst/MH/2013/RR-19
6	**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
7	**Dr. Krishnamurthy H A,** Assistant Professor, Department of General Medicine, Mysore Medical College and Research Institute, K. R Hospitals, Mysore – 570001.	Institutional Ethics Committee Mysore Medical College and Research Institute and Associated Hospitals, Department of Pathology, K..R. Hospital, Irwin Road, Mysore – 570021. ECR/134/Inst/KA/2013/RR-16
8	**Dr. Dipti Chand,** Associate Professor, Department of Medicine, Government Medical College and Hospital, Medical College Square, Near Hanuman Nagar, Nagpur-440003.	Institutional Ethics Committee, GMC, Nagpur Government Medical College and Hospital, Nagpur Government Medical College, Medical Square Hanuman Nagar Nagpur -440003, Maharashtra. ECR/43/Inst/MH/2013/RR-19
9	**Dr. Sudhir Bhandari,** Consultant Physician & Diabetologist, Bhandari Clinic & Research Centre, D-126, Krishna Marg, Bapu Nagar, Jaipur-302015, Rajasthan.	Institutional Ethics Committee (IEC) JNU Institute for Medical Sciences and Research Centre, Jagatpura, Jaipur 302017, Rajasthan. ECR/905/Inst/RJ/2017
10	**Dr. Siddharth Shah ,** Consulting Physician and Diabetologist, Bhatia Hospital Medical Research Society, Tardeo Road, Mumbai-400007, Maharashtra.	Bhatia Hospital Medical Research Society Ethics Committee Tardeo Road, Mumbai - 400007, Maharashtra. ECR/388/Inst/MH/2013/RR-19
11	**Dr. Srinath K M,** Professor, Department of General Medicine, JSS Hospital. Mahatma Gandhi Road, Mysuru - 570004, Karnataka	Institutional Ethics Committee JSS Medical College and Hospital, Sri Shivarathreeshwara Nagar, Mysore - 570015, Karnataka. ECR/387/Inst/KA/2013/RR-19

12	**Dr. C. S Anjaneyulu,** Consultant, Neelima Hospitals, 7-2-1735, Sanath Nagar, Hyderabad-500018, Telangana.	Institutional Ethics Committee Neelima Hospitals, Neelima Hospitals Private Limited, 7-2-1735, Czech Colony Sanath Nagar, Hyderabad-500018, Telangana. ECR/807/Inst/TG/2016/RR-19
13	**Dr. Manish Agarwal,** Diabetologist & Metabolic Physician, Medilink Hospital Research Center, Near Shyamal Char Rasta, 132ft. Ring Road, Satellite, Ahmedabad, Gujrat-380015.	Medilink Ethics Committee Basement Medilink Hospital Research Centre, Opp. Someshwara Jain Temple132 Ft. Ring Road, Satellite, Ahmedabad-380015, Gujarat. ECR/344/Inst/GJ/2013/RR-16
14	**Dr. Indira Pattnaik,** Senior Consultant, Department of Medicine, Sparsh Hospital and Critical Care (P) Ltd, Bhubaneswar.	Institutional Ethics Committee, Sparsh Hospital Sparsh Hospitals And Critical Care Private Limited, Plot No-A/407, Saheed Nagar, Bhubaneswar Khorda Orissa -751007. ECR/68/Inst/OR/2013/RR-19
15	**Dr. Amol Dange,** Consultant Diabetologist and Physician, Lifepoint Multispeciality hospital, Sr No. 145/1, Mum bai Pune Bypass Rd, Near Hotel Sayaji, Wakad, Pune- 411057, Maharashtra.	LPR Ethics Committee Lifepoint Multispeciality Hospital Pvt Ltd, 145/1, Mumbai-Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra. ECR/751/Inst/MH/2015/RR-18
16	**Dr. Sandeep Kumar Gupta,** Director and Consultant Physician, M.V. Hospital & Research Centre, 314/30, Mirza Mandi Chok, Lucknow-226003 Uttar Pradesh, India**.**	Institutional Ethics Committee for MV Hospital And Research Centre 314/30, Mirza Mandi Chowk, Lucknow-226003, Uttar Pradesh. ECR/13/Inst/UP/2013/RR-19

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.

V G SOMANI

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

New Delhi
Date: