

Diary No: 30126
Dated: 16.01.2022

F. No. ND/MA/22/000011
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

Tele No.011-23236965
Fax.No.011-23236973

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

31 MAY 2022

To

M/s Optimus Pharma Private Limited,
Sy. No. 37 /A & 37 /P, Plot No. 6P,
2nd Floor, Signature Towers, Kothaguda,
Kondapur, Hyderabad - 500 084, Telangana, India.

Subject: Grant of Permission to conduct "A Phase III, Double Blind, Randomized, Multi-center, two arm clinical Study to Evaluate the Efficacy and Safety of Bucillamine Tablets 100 mg in patients with Rheumatoid Arthritis." - regarding.

Sir/madam,

With reference to your application no. ND/MA/22/000011 dated 16.01.2022, please find enclosed herewith the permission in Form CT-06, No. **CT/ND/27/2022** 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



(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) It may kindly be noted that merely granting permission to conduct Clinical Trial study with the drug doesn't convey or imply that based Clinical Trial data generated with the drug, permission to market this drug will automatically be granted to you.
- (xx) **The firm should revise two arms study as Arm 1 (Intervention arm)- Methotrexate and Bucillamine and Arm 2 (Comparator arm)- Methotrexate**
- (xxi) **In both arms, the dose of Methotrexate should be as per standard treatment.**
- (xxii) **The firm should compare patient response & review after 8 weeks of the study.**
- (xxiii) **The firm should exclude patients who progress to systematic illness or who shows a flaring of disease activity before 8 weeks of therapy and should be discontinued from the study and drop out should be notified**
- (xxiv) **The firm should provide standard treatment to patients in case of failure of SOC / disease progression.**
- (xxv) **Accordingly the revised protocol shall be submitted to CDSCO.**

FORM CT-06

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

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUGNumber of the permission and date of issue **CT/ND/27/2022** dated **31 MAY 2022**

1. The Central Licensing Authority hereby permits M/s Optimus Pharma Private Limited, Sy. No. 37 /A & 37 /P, Plot No. 6P, 2nd Floor, Signature Towers, Kothaguda, Kondapur, Hyderabad - 500 084, Telangana, India to conduct clinical trial of the new drug as per **protocol number 003/CT/OP/BULM/2021, Version No. 2.0, Dated 23.02.2022** 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:	Bucillamine Tablets
Therapeutic class:	Anti – rheumatoid
Dosage form:	Tablet
Composition:	Each Sugar coated tablet contains Bucillamine..... 100 mg
Indications	For the treatment of Rheumatoid Arthritis

Details of Clinical trial Sites			
Sl No	Name of Investigator	Name and Address of Clinical trial Site	Ethics committee details
01	Dr. Satish Nesari MBBS, MS Orthopedics	Belagavi Institute Of Medical Sciences, Dr B R Ambedkar Rd, Sadashiv Nagar, Belagavi, Karnataka, 590019, India	Institutional Ethics Committee BIMS, Belagavi Institute of Medical Sciences, Dr. B R Ambedkar Rd, Sadashiv Nagar, Belagavi, Karnataka 590019, India. ECR/801/Inst/KA/2016/RR-20
02	Dr. Rahul Katta M.B.B.S, MS Orthopedics	SR Kalla Memorial Gastro and General Hospital, 78-79, Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C Scheme, Jaipur, Rajasthan 302001, India.	SR Kalla Memorial Ethical Committee for Human Research , 78-79 Dhuleshwar Garden Behind HSBC Bank, SPMarg C- scheme Jaipur, Rajasthan- 302001, India. ECR/8/Inst/RA/2013/RR-19
03	Dr. Girish Barttake M.B.B.S, MS Orthopedics	B.J. Govt. Medical College & Sassoon General Hospital, India Pune Maharashtra 411001.	IEC, B.J. Govt. Medical College & Sassoon General Hospital, India Pune Maharashtra 411001 ECR/280/Inst/Maha/2013/RR-19

04	Dr.Syamashish Bandyopadhyay M.B.B.S, MD Rheumatologist	Apollo Multispecialty Hospitals,58, Canal Circular Rd, Kadapara, Phool Bagan, Kankurgachi, Kolkata, WestBengal 700054	IEC Apollo Multispecialty Hospitals,58, Canal Circular Rd, Kadapara, Phool Bagan, Kankurgachi, Kolkata, West Bengal 700054. ECR/373/INST/WB/2013/RR-19
05	Dr. Sandeep Kharkar M.B.B.S, MD Rheumatology	CARE Hospital Pvt. Ltd, farmland Rd, Panchsheel Square, Nagpur, Maharashtra- 440012	CARE Hospital Nagpur Ethics Committee, farmland Rd, Panchsheel Square, Nagpur, Maharashtra- 440012. ECR/220/Inst/MH/2013/RR-19
06	Dr. Sunil Naik MBBS MD (gen. Med)	Govt. Medical college and Govt. General Hospital, Shrikakulam- 532001	Govt. Medical college and Govt. General Hospital - 532001. ECR/492/Inst/AP/2013/RR-20
07	Dr. Sivaram Naik MS, M. ch	Induss Hospital,13-23-93/1, Krishnaveni Nagar, Gaddiannaram, Near Municipal Office, Saroornagar,Hyderabad, Telangana- 500035.	Induss Hospital, 13-23-93/1, Krishnaveni Nagar, Gaddiannaram, Near Municipal Office, Saroornagar, Hyderabad 500035. ECR/1606/Inst/TG/2021

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.

New Delhi

Date:.....

31 MAY 2022

(Dr. V. G. Somani)

Central Licensing Authority

Stamp

डॉ. वी. जी. सोमानी
औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
एफ.डी.ए. भवन, कोटला रोड, आई.टी.ओ.
नई दिल्ली-110002