File No. SND/MA/20/000365
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. Dr.Reddy's Laboratories Limited,
Bachupally Village, Bachupally Mandal,
Hyderabad-500090, Telangana, India.

21 MAY 2021

Subject: A Randomized, Open Label, Balanced, Three-Treatment, Three-Period, Three-Sequence, Single Dose, Crossover, Oral Comparative Bioavailability Study of Test Batch (T) of Itraconazole Capsules 100 mg of Dr. Reddy"s Laboratories Limited, India Comparing with Two Individual Reference Products (R1 and R2) Sporanox® Capsules 100 mg (100 mg x 2 Capsules) of Johnson and Johnson Private Limited, India and Lozanac Capsules 50 mg (50 mg x 2 Capsules) of Mayne Pharma, Australia Respectively in Normal, Healthy, Adult Human Subjects Under Fed Conditions (Vide protocol no. ARL/20/248, Version no. 01, dated: 17/11/2020)-Reg.

Dear Sir,

With reference to your letter No. Nil dated 18-12-2020 please find enclosed herewith the "permission to conduct bioequivalence study of new drug" bearing no. **BE/SND/67/2021** under the provision of Drugs and Cosmetics Act and Rules. The permission is subject to the conditions mentioned below.
Kindly acknowledge receipt to this letter and its enclosures.

Yours faithfully,

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

CONDITIONS OF PERMISSION

1. Bioavailability or bioequivalence study at each site shall be initiated after approval of bioavailability or bioequivalence study protocol, as the case may be, and other related documents by the Ethics Committee of that site, registered under rule 8 of New Drugs and Clinical Trial Rules,2019.
2. Where a bioavailability or bioequivalence study Centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:
   I. Provided that the approving Ethics Committee shall in such case be responsible for the study at the Centre:
   II. Provided further that both the approving Ethics Committee and the Centre, shall be located .within the same city or within a radius of fifty kms of the bioavailability or bioequivalence study Centre;
3. In case an Ethics Committee of a bioavailability or bioequivalence study Centre rejects the approval of the protocol, the details of the same should be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the bioavailability or bioequivalence study at the same site;

4. The Central Licensing Authority shall be informed about the approval granted by the registered Ethics Committee within a period of 15 working days of the grant of such approval;
5. Bioavailability or bioequivalence study of new drug or investigational new drug shall be conducted only in the bioavailability or bioequivalence study Centre registered with the Central Licensing Authority under rule 47 of New Drugs and Clinical Trial Rules,2019;
6. Bioavailability or bioequivalence study of investigational new drug 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 study;
7. Bioavailability or bioequivalence study shall be conducted in accordance with the approved bioavailability or bioequivalence study protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and provisions of these rules;
8. In case of termination of any bioavailability or bioequivalence study, the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination;
9. Any report of serious adverse event occurring during bioavailability or bioequivalence study to a subject of such study, shall, after due analysis, be forwarded to the Central Licensing Authority, the chairperson of the Ethics Committee and the institute or the Centre where the bioavailability or bioequivalence study, as the case may be, 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 New Drugs and Clinical trial Rules,2019;
10. In case of an injury during bioavailability or bioequivalence study to the subject of such study, complete medical management and compensation shall be provided in accordance with the provisions of Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty days of the receipt of order issued in accordance with the provisions of said Chapter of New Drugs and Clinical Trial Rules,2019;
11. In case of bioavailability or bioequivalence study related death or permanent disability of any subject of such study during the study, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty days of receipt of the order issued in accordance with the provisions of said Chapter of New Drugs and Clinical Trial Rules,2019;
12. The premises of the sponsor including his representatives and bioavailability and bioequivalence study Centre shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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 bioavailability or bioequivalence study, as the case may be, and furnish reply to the queries raised by the said officer in relation to bioavailability or bioequivalence study;
13. The bioavailability or bioequivalence study shall be initiated by enrolling the first subject within a period of one year from the date of grant of permission, failing which prior permission from the Central Licensing Authority shall be required.
14. 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.

FORM CT-07

(*See rules 34, 35, 36, 37 and 38*)

PERMISSION TO CONDUCT BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OF NEW DRUG OR INVESTIGATION NEW DRUG

Permission Number: BE/SND/67/2021

1. The Central Licensing Authority hereby permits **Dr.Reddy's Laboratories Limited, Bachupally Village, Bachupally Mandal, Hyderabad-500090, Telangana, India** (Name and full address with contact details of the applicant) to conduct bioequivalence study of the new drug as per **protocol no. ARL/20/248, Version no. 01, dated: 17/11/2020** in the below mentioned study centre.
2. Details of new drug or investigational new drug and study centre [As per Annexure].
3. This permission is subject to the conditions prescribed in part B of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act,1940.

Place: New Delhi

Date:.....

21 MAY 2021

Central Licensing Authority

Stamp

Dr. 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

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Itraconazole Capsules 100mg
Therapeutic class:	Azole Anti-fungals
Dosage form:	Capsules
Composition:	Each hard gelatin capsule contains: Itraconazole.....100 mg
Indication:	Systemic aspergillosis and candidas cryptococcosis, sporotrichosis, paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or tropical mycoses.

Details of study centre:-

Names and address of study centre:	Accutest Research Laboratories (I) Pvt. Ltd.A-31, M.I.D.C, T.T.C Industrial Area, Khairane, Navi Mumbai –400709, Maharashtra, INDIA
Ethic committee details:	Ethicare Ethics Committee, Shop No. 9/ Ground Floor, Patidar Complex, Kannamwar Nagar-2, Vikhroli (E), Mumbai – 400083, Maharashtra, India.
Name of principal investigator:	Dr. Sainath Doiphode, MBBS, MD.