ETHICARE
ETHICS COMMITTEE

IORG No.: IORG0009526 **DCGI Reg. No. ECR/224/Indt/MH/2015/RR-18**

Decision Letter

Date: 16/06/2021

To,
Dr. Rashmi Shetty,
Principal Investigator,
Accutest Research Laboratories (I) Pvt. Ltd.,
A-31, MIDC, TTC Industrial Area, Khairne,
Navi Mumbai – 400 709
Maharashtra, India

Subject: Decision for below mentioned research project submitted to the Ethicare Ethics Committee.

Protocol No.: ARL/20/248
Product Description: Itraconazole Capsules 100 mg
Study Title: 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.
Version No.: 02
Dated: 09/06/2021

Dear Sir/Madam,
The above mentioned project entitled "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" was previously reviewed and discussed by Ethicare Ethics Committee during the meeting held on 25/11/2020 & 11/04/2021. The following documents were reviewed and discussed on 16/06/2021;

1. Study Protocol (Version No.: 02, Dated: 09/06/2021).
2. Subject Information Sheet and Informed Consent Form (In English, Hindi and Marathi) (Version No.: 03, Dated: 10/06/2021).
3. Notice For Subject Accrual (In English, Hindi and Marathi) (Version No.: 03, Dated: 10/06/2021).
4. Principal Investigator's current CV.
5. Undertaking by Investigator.
6. Reference Literature.

Office Address: Shop No. 9, Ground Flr. Patidar Complex, Kannamwar Nagar-2, Vikhroli (E), Mumbai – 400083
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Email Id: contactethicare@yahoo.com

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The following members of ethics committee were present at the meeting which was conducted virtually (telephonically) on 16/06/2021 at 10:00 hours.

Sr. No.	Name	IEC – Designation
1.	Dr. Vanita Kanase	Chairperson
2.	Ms. Priti Gotpagar	Member Secretary
3.	Dr. Nilesh More	Clinician
4.	Dr. Urwashi Parmar	Basic Medical Scientist
5.	Adv. Mukesh Sirwal	Legal Expert
6.	Ms. Priyanka Kale	Social Scientist
7.	Mr. Rahul Jadhav	Lay Person

Ethicare Ethics Committee is constituted and functions as per the ICH-GCP, Good Clinical Practices guidelines issued by Central Drugs Standard Control Organisation (CDSCO) and New Drugs and Clinical Trials Rules 2019 G.S.R. 227(E) issued by Ministry of Health and Family Welfare (Department of Health and Family Welfare) under official gazette / notification (New Delhi), the 19th March, 2019, National guidelines for ethics committees reviewing biomedical Health Research during COVID-19 Pandemic, DCGI notice released on 30/03/2020 (Subject: Conduct of clinical trial in present situation due to outbreak of COVID-19-Reg), The Ethics guidelines for Biomedical research on Human Subjects, issued by Indian Council of Research and Declaration of Helsinki, 1964 as modified by World Medical Association, Brazil 2013, updated/amended from time to time.

Decision of Ethicare Ethics Committee

On reviewing the documents send by the Investigator, vide letter dated 10/06/2021 for Protocol No.: ARL/20/248, Version No.: 02. The Ethicare Ethics Committee concluded the decision that the research project submitted is Approved as presented. The Investigator has to update Ethicare Ethics Committee about;

1. Commencement date in advance and subsequent progress of the research project on regular basis.
2. Report serious and unexpected adverse events within 24 hours of their occurrence and subsequent follow up report after due analysis within 14 calendar days of occurrence of event.
3. Any changes in the protocol, subject information sheet / ICF.
4. Immediately report the significant protocol deviation.
5. Submit the copy of final report on completion of the research project.

Note:

1. Appropriate regulatory permission to be obtained prior to commencement of the research project wherever applicable.
2. Researcher should follow the National guidelines for ethics committees reviewing biomedical Health Research during COVID-19 Pandemic and DCGI

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notice released on 30/03/2020 (Subject: Conduct of clinical trial in present situation due to outbreak of COVID-19-Reg).

3. The validity of this decision is till the completion of the research project or one year from the date of decision, whichever is earlier.
4. Insurance policy for volunteer is already reviewed.

Yours sincerely,

16/06/21

For Ethicare Ethics Committee
Member Secretary

ETHICS COMMITTEE ETHICARE

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