

	PRINCIPAL INVESTIGATOR's SIGNATURE	
Study Code: ARL/20/248	Accutest Research Laboratories (I) Pvt. Ltd.	Page 1 of 1

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 100mg of Dr. Reddy's Laboratories Limited, India Comparing with Two Individual Reference Products (R1 and R2) Sporanox[®] Capsules 100mg (100mg x 2 Capsules) of Johnson and Johnson Private Limited, India and Lozanac Capsules 50 mg (50mg x 2 Capsules) of Mayne Pharma, Australia Respectively in Normal, Healthy, Adult Human Subjects Under Fed Conditions.

Clinical Site : Accutest Research Laboratories (I) Pvt. Ltd.,
A-31, M.I.D.C, T.T.C. Industrial Area,
Khairane, Navi Mumbai – 400 709,
Maharashtra, INDIA.
Tel: + 91 22 2778 0718/19/21,
Fax: + 91 22 2778 0720

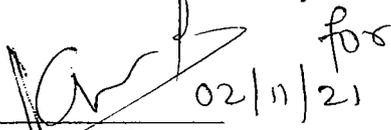
CSR Version No. : 00

Report Date : 02 November 2021

Study Report Author : Mr. Narayan Dudhate

The study was conducted in compliance with IEC approved protocol, relevant SOPs, GCP guideline, Declaration of Helsinki, applicable DCGI and national regulatory authorities' requirements.

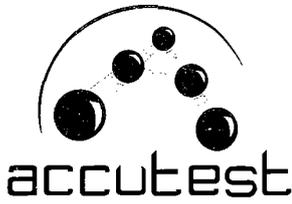
I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.


02/11/21 for
Signature with Date

Dr. Rashmi Shetty, MD (Pharmacology)

Principal Investigator

Accutest Research Lab. (I) Pvt. Ltd.



COMPLIANCE STATEMENT FOR RAW DATA & CHROMATOGRAMS

Date : 01/11/21

Sponsor : Dr. Reddy's Laboratories Ltd, Hyderabad, India.

Study Code : ARL/20/248 (Fed)

Product : Itraconazole Capsule 100 mg

This is to assure that the data provided in the electronic format (*.pdf) for the above mentioned study as Chromatograms from the system are verified and cross-checked with the hard copy. Hence, this electronic copy is system generated do not require any attestation.

Thus, the electronic copy provided is in compliance with the attested hard copy of raw data.

Checked by:

Lab Manager-Bio-Analytical
(Dr. Parikshit Champanerkar)

Approved by:

Bio-Analytical Investigator
(Dr. Varad Pradhan)

Signature of Principal or Coordinating Investigator or Sponsor's responsible personnel

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Accutest Research Laboratories (I) Pvt. Ltd.

A - 31, MIDC, TTC Industrial Area, Khairne, Navi Mumbai - 400 709. Maharashtra, India

Tel. : 91-22-2778 0718 / 19 / 21 Fax : 91-22-2778 0720 / E-mail : business@accutestglobal.com

Website : www.accutestglobal.com / CIN : U24239MH2001PTC131153.