



Subject Information Sheet and Informed Consent Form for Oral Comparative Bioavailability Study of Itraconazole Capsules 100 mg Under Fed Conditions
Study Code: ARL/20/248, Version No: 03

Registration No.: _____

Start of ICF obtaining time: ____:____ Recorded by and date: _____

Subject Information Sheet and Informed Consent Form

Subject Information Sheet (SIS) and Informed Consent Form (ICF) for Healthy Adult Human Subjects for Participation in Bioequivalence 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.

Study Code	ARL/20/248
Version No.	03
Date	10 June 2021
Superseded Version No.	02
Date	08 April 2021
Reference document	Protocol: ARL/20/248, version 02, dated 09 June 2021

STUDY CENTER	SPONSOR
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