

SOMANI HOSPITAL

277-278, Shri Gopal Nagar, 80 Ft. Road Gopalpura Bypass, Jaipur-302019
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SOMANI HOSPITAL

STANDARD OPERATING PROCEDURE

FOR CLINICAL TRIAL DEPARTMENT

VERSION 2.1

DATED: 19 JUL 2021

OFFICE ADDRESS:

Somani Hospital, 277-278, Shri Gopal Nagar, 80 ft. Road, Gopalpura Bypass, Jaipur-302019, Rajasthan, India

REVIEWED AND APPROVED BY:

Dr. Rajkumari Somani, Director, Somani Hospital

PREPARED BY:

Dr. Swati Guglani

Signature of Director

Date 19 July 2021

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Signature of Director

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I. ABBREVIATIONS

ADR- Adverse Drug Reaction
AE- Adverse Event
BA/BE- Bioavailability/ Bioequivalence
PI-Principal Investigator
IP-Investigational Product
IB- Investigator Brochure
CRF- Case Report Form
FDA- Food and Drug Administration
GCP-Good Clinical Practice
ICF- Informed Consent Form
ICH-International Conference on Harmonization
LAR- Legally Acceptable Representative
SAE-Serious Adverse Event
SC-Study Coordinator
SIV- Site Initiation Visit
SOP- Standard Operating Procedure
DCGI- Drug Controller General of India
DSMB-Data Safety Monitoring Board
GMP- Good Manufacturing Practice
NDA- New Drug Application
RCT- Randomized Controlled Trial
ICMR-Indian Council of Medical Research
IND- Investigational New Product
IRB- Institutional Review Board
CTA-Clinical Trial Agreement

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II. REFERENCES

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Signature of Director Rajkumar
Date 19 July 2021