INSTITUTIONAL ETHICS COMMITTEE (IEC) Seth GS Medical College and KEM Hospital

Established in 1986
IEC-I Re-registration No. ECR/229/Inst./MH/2013/RR-16,IEC-II registration No. ECR/417/Inst./MH/2013 Issued under rule 122DD of Drugs & Cosmetic rule 1945.



Date: _____

Recognized by:

The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER),
Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP)
for its compliance with international and local standards in ethical review.

Annexure 3

AX 03/SOP 05/V5

Delegation of Responsibilities of Study team

Role	No.
Principal Investigator	1
Co-Investigator	2
Co-Investigator	3
Co-investigator	4
Co-Investigator	5
Co-investigator	6
Study co-ordinator *	7
Study co-ordinator *	7
Laboratory Technician	8
	9
	10
	Principal Investigator Co-Investigator Co-Investigator Co-investigator Co-Investigator Co-investigator Study co-ordinator * Study co-ordinator *

(Please place tick marks against assigned duties for each member in the following table).

Code	TASKS	Role									
		1		3	4	3	6	,	8	9	10
Α	All relevant documents pertaining to										
	protect blinding.										
В	Research participants selection/										
	Screening.										ļ
С	Obtain informed consent.										
D	Evaluate inclusion/ exclusion criteria.										

^{*} Study coordinator may preferably be a person specifically appointed for coordinating the clinical trial; other than the staff member (assistant / associate professor).

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					,	
E	Conduct the visit assessments.					
F	Physical examination.					
G	Complete the source documents.					
Н	Complete Case Record Form .					
I	Final review and sign Case Record Form .					
J	Collect laboratory safety test samples.					
K	Processing of blood samples.					
L	Preparing aliquots & keeping a track of the samples sent.					
M	Review & sign of the lab reports.					
N	Receive the study drug, , document drug dispensing, storage & accountability.					
0	Person to whom research participants should contact in case of adverse event.					
Р	Report all serious adverse events					
Q	Follow up of Serious Adverse Event					
R	Maintaining study site master file					
S	In-charge of inventory & supplies					
Т	Archiving of study documents					
U	Resolution of queries					
V	Overall coordination and supervision					
						
						

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Signature with date of Principal Investigator	:
0	