

FORM NO: 23 FORMAT FOR EC DOSSIERS-SUBMISSION

SL. NO.	ENCLOSURES:	PAGE NOS.
1.	Face-sheet	
2.	Study Synopsis	
3.	Summary of Changes if the Protocol is amended	
4.	Protocol signature page if any	
5.	Undertaking of Principal, Co-investigator	
6.	Brief Bio-data, MRC and GCP certificate of investigator and Co-Investigator	
7.	Conflict of interest, if applicable	
8.	Detailed protocol version and date	
9.	Placebo Justification – if applicable	
10.	Investigator Brochure version and date	
11.	Participant Information sheet version and date (All vernacular languages)	
12.	Informed Consent Document version and date (All vernacular languages)	
13.	Translation and Back translation certificates	
14.	Case reports forms if Any	
15.	Subject Dairies if Any	
16.	Funding Agency details or documents	
17.	Final CTA/Draft	
18.	Clinical trial registry-India	
19.	DCGI submission/Approval letter	
20.	Study/site Specific Insurance [Who it covers and validity]	
21.	Any other relevant documents	