1. Application For Global Clinical Trial:

Sr. No.	Contents			YES, Indicate Annexure No.	No
MODULE I	1.0 ADMINISTRATIVE SECTION				
	1.1	Enclosure sheet			
	1.2	Cover letter			
	1.3	Name & address of the applicant			
	1.4	Name & address of the sponsor			
	1.5	Authorization letter from sponsor in favour of applicant			
	1.6	Forms & transaction receipts / challan			
		1.6.1	Application for grant of permission to conduct clinical trial of new drug or investigational new drug in Form CT-04		
		1.6.2	Receipt of fees deposited (Treasury Challan/ Transaction ID) for the application applied in Form CT-04		
		1.6.3	Application for grant of permission to manufacture new drug or investigational new drug to conduct clinical trial in Form CT-10		
		1.6.4	Receipt of fees deposited (Treasury Challan/ Transaction ID) for the application applied in Form		

			CT-10		
		1.6.5	Application for grant of permission to manufacture formulation of unapproved active pharmaceutical ingredient for clinical trial in Form CT-12		
		1.6.6	Receipt of fees deposited (Treasury Challan/ Transaction ID) for the application applied in Form CT-12		
		1.6.7	Application for grant of permission to manufacture of unapproved active pharmaceutical ingredient for development of formulation for clinical trial in Form CT-13		
		1.6.8	Receipt of fees deposited (Treasury Challan/ Transaction ID) for the application applied in Form CT-13		
		1.6.9	Application for grant of licence to import new drug or investigational new drug for clinical trial in Form CT-16		
		1.6.10	Receipt of fees deposited (Treasury Challan/ Transaction ID) for the application applied in Form CT-16		
	1.7	Details of the study drug			
		1.7.1	Name of the study drug		
		1.7.2	Dosage form & strength		
		1.7.3	Therapeutic class		

	1.8	Details of the study - Global			
		1.8.1	Name of the participating countries		
		1.8.2	Regulatory status of the study in other participating countries (if approved, attach approval letter along with the English translated copy)		
		1.8.3	Total number of patients to be enrolled globally		
		1.8.4	Affidavit declaring that the study has not been discontinued in any country. In case of discontinuation, submit the reason for such discontinuation.		
		1.8.5	If any clinical trial of the investigational product has been withdrawn/discontinued in any country or rejected/refused by any regulatory agency if so details of the same		
	1.9	Details of the study - India			
		1.9.1	Total number of patients to be enrolled in India		
		1.9.2	Undertaking by the sponsor for application of marketing authorization in India after successful completion of clinical trial		
MODULE II	**2.0 SUMMARIES**				
	2.1	Executive summary			
	2.2	Protocol synopsis			
	2.3	Clinical Development for proposed indication and any other indication			

MODULE III	**3.0 CMC DATA**				
	3.1	IMPD Part 1			
	3.2	IMPD Part 2 (Optional)			
	3.3	IMPD Part 3 (Optional)			
	3.4	IMPD Part 4 (Optional)			
	3.5	IMPD Part 5 (Optional)			
MODULE IV	**4.0 ANIMAL TOXICOLOGY DATA**				
	4.1	Systemic toxicity studies			
		4.1.1	Single dose toxicity		
		4.1.2	Repeated dose toxicity		
		4.1.3	Male fertility study		
		4.1.4	Female reproduction and developmental toxicity studies		
	4.2	Local toxicity studies			
		4.2.1	Dermal toxicity		
		4.2.2	Ocular toxicity		
		4.2.3	Inhalation toxicity		
		4.2.4	Vaginal toxicity		
		4.2.5	Photo allergy or dermal photo toxicity		
		4.2.6	Rectal tolerance test		
	4.3	Genotoxicity			
	4.4	Allergenicity/Hypersensitivity			
	4.5	Carcinogenicity			
	4.6	Name, address of the laboratory / laboratories with			

		accreditation certificate /Authorization certificates for all animal toxicological reports			
MODULE V	**5.0 ANIMAL PHARMACOLOGICAL DATA**				
	5.1	Summary			
	5.2	Specific pharmacological actions			
	5.3	General pharmacological actions			
	5.4	Follow-up and Supplemental Safety Pharmacology Studies			
	5.5	Pharmacokinetics: absorption, distribution; metabolism; Excretion			
MODULE VI	**6.0 CLINICAL DATA**				
	6.1	Human/Clinical pharmacology (Phase I data)			
		6.1.1	Summary		
		6.1.2	Specific Pharmacological effects		
		6.1.3	General Pharmacological effects		
		6.1.4	Pharmacokinetics, absorption, distribution, metabolism, excretion		
		6.1.5	Pharmacodynamics / early measurement of drug activity		
		6.1.6	Study report		
	6.2	Therapeutic exploratory trials (Phase II)			
		6.2.1	Summary		
		6.2.2	Study reports		
	6.3	Therapeutic confirmatory trials (Phase III)			
		6.3.1	Summary		
		6.3.2	Individual study reports with listing of sites and		

			Investigators		
		6.3.3	Study reports		
	6.4	Special studies			
		6.4.1	Summary		
		6.4.2	Bio-availability / Bio-equivalence		
	6.5	Other studies			
		6.5.1	Geriatrics		
		6.5.2	Paediatrics		
		6.5.3	Pregnant or nursing women		
MODULE VII	**7.0 TRIAL RELATED DOCUMENTS**				
	7.1	Study protocol			
		7.1.1	Phase of the study		
		7.1.2	Declaration that as per the protocol, whether the subjects will receive the standard of care		
	7.2	Patient information sheet (PIS) and informed consent form (ICF) as per Table 3 of Third Schedule of the New Drugs and Clinical Trials Rules, 2019			
	7.3	Undertaking by the sponsor/sponsor representative/applicant to the Central Licencing authority to provide medical management and compensation in case of clinical trial related injury or death for which subjects are entitled to compensation as required under Chapter VI of the New Drugs and Clinical Trials Rules, 2019			
	7.4	Declaration regarding financial status of the applicant vis-à-			

		vis medical management and compensation to be paid to the trial participants (in case of injury or death in clinical trial)			
	7.5	Template of the CRF			
	7.6	Investigator's Brochure as per Table 7 of Third Schedule of the New Drugs and Clinical Trials Rules, 2019			
		7.6.1	Affidavit declaring that the information about study drug as mentioned in Investigator Brochure is correct and based on available facts		
	7.7	List of participating sites, along with name and contact details of the Principal Investigators and EC details			
		7.7.1	Details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any investigator/institution, plan for financial support fees, honorarium and payments in kind etc to be paid to the investigator		
		7.7.2	Undertaking by the investigators as per Table 4 of the Third Schedule of the New Drugs and Clinical Trials Rules, 2019 including list of investigators with qualification along with CV and MRC		
		7.7.3	Ethics committee approvals if any		
	7.8	Proposed draft of IMP label			
	7.9	Copy of the insurance certificate			

	7.10	Assessment of risk versus benefit to the patient (for this proposal)			
	7.11	Innovations versus existing therapeutic option (w.r.t this proposal)			
	7.12	Unmet medical need in the country (of IMP/trial proposal)			
	7.13	Any published literature on the development of the IMP			
	7.14	Details of the central lab			
	7.15	Rationale for conducting the study in India with the proposed drug and indication			
	7.16	Post Marketing (Phase IV)			
		7.16.1	Marketing approval status of the drug under study		
		7.16.2	Product prescribing information		
		7.16.3	Summary of Phase I, II & III studies		
	7.17	Any other information (optional)			
8.0	Reviewing Officre Report				

Checklist For (Site addition (GCT)

1	Covering Letter
2	Copy of CT permission letter
3	Copy of previous protocol amendment approval letter, if any
4	Trial Site Address
4.1	Undertaking by the Investigators as per Table 4 of third Schedule
4.2	CV including Statement of Qualification, CT Experience, GCP training and copy of MRC.
4.3	Name & Address of the study sites. (Private Clinic/Private hospital/Nursing home/ Govt. Hospital.)
4.4	Details of the medical facility /Hospitals: Number of beds, Whether it is equipped with super specialty or multispecialty facilities and emergency facilities.
4.5	Name, address and registration number of Institutional Ethics Committee
4.6	Copy of Ethics committee approval letter, if available
Checklist For (Site Closure or Deletion (GCT)	
1	Covering Letter
2	Copy of CT permission letter
3	Copy of previous protocol amendment approval letter, if any
4	Trial Site Addresss
4.1	Reason for closure
4.2	Subject enrolment status
4.3	Procedure for subject follow up at the given site
4.4	Copy of Ethics committee notification
4.5	Copy of Ethics committee approval letter, if available

4.6	Copy of summary report
4.7	Safety measures after discontinuation &/or premature closure/termination of the study/study site.
4.8	Ethic committee opinion for premature close-out of the study site vis-à-vis & rights of the subjects enrolled & exposed to the study drug
Checklist For (Change in Site Address (GCT)	
1	Covering Letter
2	Copy of CT permission letter
3	Copy of previous protocol amendment approval letter, if any
3	Present Site addrees (with approval from CDSCO)
4	New site address and EC notification
5	Reason of Change of Site address
6	Other documents
Checklist For (Change in Investigator (GCT)	
1	Covering Letter
2	Copy of CT permission letter
3	Copy of previous protocol amendment approval letter, if any
4	Trial Site and Reason for change

4.1	Undertaking by the Investigators as per Table 4 of third Schedule
4.2	CV including Statement of Qualification, CT Experience, GCP training and copy of MRC.
4.3	Name & Address of the study sites. (Private Clinic/Private hospital/Nursing home/ Govt. Hospital.)
4.4	Details of the medical facility /Hospitals: Number of beds, Whether it is equipped with super specialty or multispecialty facilities and emergency facilities.
4.5	Name, address and registration number of Institutional Ethics Committee
4.6	Copy of Ethics committee approval letter, if available
Checklist For (Change in Central Laboratory (GCT)	
1	Covering letter with overview of submission File Upload
2	Copy of CT permission letter
3	Justification / rationale for submission File Upload
4	Ethics committee notification letter, if available File Upload
5	Safety measures after discontinuation &/or premature closure/termination of the study/study site.
6	Ethic committee opinion for premature close-out of the study site vis-à-vis & rights of the subjects enrolled & exposed to the study drug
7	Other relevant document, if any
Checklist For (Notification for Annual Status Report (ASR))	
1	Covering letter with overview of submission
2	Copy of CT permission letter
3	Justification / rationale for submission
4	Ethics committee notification letter, if available

5	Safety measures after discontinuation &/or premature closure/termination of the study/study site.
6	Ethic committee opinion for premature close-out of the study site vis-à-vis & rights of the subjects enrolled & exposed to the study drug
7	Any other supportive document to be given with respect to ASR
7.1	Synopsis
7.2	Summary
7.3	Conclusion
Checklist For (Notification for end of Clinical Trial (GCT))	
1	Covering letter with overview of submission
2	Copy of CT permission letter
3	Justification / rationale for submission
4	Ethics committee notification letter, if available
5	Safety measures after discontinuation &/or premature closure/termination of the study/study site.
6	Ethic committee opinion for premature close-out of the study site vis-à-vis & rights of the subjects enrolled & exposed to the study drug
7	Other relevant document

Checklist For (Premature study withdrawal / study closure (GCT))	
1	Covering letter with overview of submission
2	Copy of CT permission letter
3	Justification / rationale for submission
4	Ethics committee notification letter, if available
5	Safety measures after discontinuation &/or premature closure/termination of the study/study site.
6	Ethic committee opinion for premature close-out of the study site vis-à-vis & rights of the subjects enrolled & exposed to the study drug
7	Other relevant document
Checklist For (Notify CDSCO (GCT))	
1	Covering Letter
2	Copy of CT permission letter
3	Relevant other documents
Checklist For (Notification for Clinical Study Report (CSR))	
1	Covering letter with overview of submission

2	Copy of CT permission letter
3	Clinical Study Report (CSR) reporting time frame
4	Ethics committee notification letter, if available
5	Safety measures after discontinuation &/or premature closure/termination of the study/study site.
6	Ethic committee opinion for premature close-out of the study site vis-à-vis & rights of the subjects enrolled & exposed to the study drug
7	Any other supportive document to be given with respect to CSR
7.1	Synopsis
7.2	Summary
7.3	Conclusion
Checklist For (Notification for Interim Analysis Report (IAR)	
1	Covering letter with overview of submission
2	Copy of CT permission letter
3	Interim Analysis Report (IAR) reporting time frame
4	Ethics committee notification letter, if available
5	Safety measures after discontinuation &/or premature closure/termination of the study/study site.

6	Ethic committee opinion for premature close-out of the study site vis-à-vis & rights of the subjects enrolled & exposed to the study drug
7	Any other supportive document to be given with respect to IAR
7.1	Synopsis
7.2	Summary
7.3	Conclusion
Checklist For (Notification for Periodic Safety Update Report (PSUR))	
1	Covering letter with overview of submission
2	Copy of CT permission letter
3	Periodic Safety Update Report (PSUR) reporting time frame
4	Ethics committee notification letter, if available
5	Safety measures after discontinuation &/or premature closure/termination of the study/study site.
6	Ethic committee opinion for premature close-out of the study site vis-à-vis & rights of the subjects enrolled & exposed to the study drug
7	Any other supportive document to be given with respect to PSUR
7.1	Synopsis
7.2	Summary

7.3	Conclusion
Checklist For (Notification for Development Safety Update Report (DSUR))	
1	Covering letter with overview of submission
2	Copy of CT permission letter
3	Development Safety Update Report (PSUR) reporting time frame
4	Ethics committee notification letter, if available
5	Safety measures after discontinuation &/or premature closure/termination of the study/study site.
6	Ethic committee opinion for premature close-out of the study site vis-à-vis & rights of the subjects enrolled & exposed to the study drug
7	Any other supportive document to be given with respect to DSUR
7.1	Synopsis
7.2	Summary
7.3	Conclusion
	Checklist For TL (GCT)
1	Covering letter
2	Earlier CT NOC issued / Existing test licence along with debit sheet and debit note
3	Justification of Quantity

4	Upload duly signed Form CT 16
5	TR-6 Challan of Fees paid