Central Drug Standard Control Organization
Directorate General of Health Services
Office of Drugs Controller General (India)
(Biological Division)

Checklist for Permission for conducting clinical trial (Phase I,II,III) and Global clinical Trial

S.No.	Content	Closed response
1	Name of Applicant	☐ Yes ☐ No
2	Drug	☐ Yes ☐ No
3	Dosage Form , Composition and packing details	☐ Yes ☐ No
4	Form 44	☐ Yes ☐ No
5	TR challan	☐ Yes ☐ No
6	Sponsor's Name and Authorization letter	☐ Yes ☐ No
7	Chemical and Pharmaceutical /CMC Information	☐ Yes ☐ No
8	Pre-Clinical Data	☐ Yes ☐ No
	i. Animal Pharmacological data as per Appendix IV to Schedule Y	
	ii. Animal Toxicological data data as per Appendix III to Schedule Y	☐ Yes ☐ No
9	Study Protol	☐ Yes ☐ No
	i. Protocol Number:	☐ Yes ☐ No
	ii. Phase of the Study	☐ Yes ☐ No
10	. Study Rationale	☐ Yes ☐ No
	i. Undertaking by Investigators as per Appendix VII to Schedule Y	☐ Yes ☐ No
	ii. Name & No. of Centre's and Investigator's	☐ Yes ☐ No
11	No. of Patients to be enrolled	☐ Yes ☐ No
	i. Globally	☐ Yes ☐ No
	ii. India	☐ Yes ☐ No
12	. Names/Numbers of countries participating in study:	☐ Yes ☐ No
13	Regulatory status/Approval from Participating countries (Mention date in case of US IND)	☐ Yes ☐ No
14	Investigator's Brochure:	☐ Yes ☐ No
15	. Case Report Form:	☐ Yes ☐ No
16	Informed Concent of subject/volunteers as per appendix V to Schedule Y	☐ Yes ☐ No
17	Doc. As per CSCO Guidance doc.	☐ Yes ☐ No
18	Complete Phase I, II study report if Phase III permission is required	☐ Yes ☐ No
19	Phase I if Phase II permission is required	☐ Yes ☐ No