

FORM CT-05*(See rule 33)***APPLICATION FOR GRANT OF PERMISSION TO CONDUCT BIOAVAILABILITY OR BIOEQUIVALENCE STUDY**

I/We.....(*name and full postal address of the applicant*) of.....hereby apply for grant of permission to conduct bioavailability or bioequivalence study (*strike off whichever is not applicable*) of new drug or investigational new drug, the details of which are as under:

1.Name of applicant:	
2. Nature and constitution: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified)	
3. (i) Sponsor address, telephone number, mobile number, fax number and e-mail id: (ii) Study address, telephone number, mobile number, fax number and e-mail id: (iii) Address for correspondence: [corporate or registered office or bioavailability or bioequivalence study centre]	
4. Details of new drug or investigational new drug and study centre [As per Annexure].	
5. Study protocol number with date:	
6. Fee paid on _____ Rs. _____ Receipt or challan or transaction ID _____.	
7. I have enclosed the documents as specified in the Fourth Schedule of the New Drugs and Clinical Trials Rules, 2019.	
8. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.	

Place:.....

Date:.....

Digital Signature

(Name and designation)

Annexure:

Details of new drug or investigational new drugs:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	

Indications:	
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Details of study centre:

Names and address of study centre	
Ethics committee details:	