FORM CT-10

(*See rule 52)*

APPLICATION FOR GRANT OF PERMISSION

TO MANUFACTURE NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR EXAMINATION, TEST AND ANALYSIS

I/We, ...

(name and full postal address of the applicant) of ..... hereby apply for grant of permission to manufacture new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis.

The details of the application are as under:

1. Name of applicant:	
2. Nature and constitution of applicant: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified)	
3.(i) Corporate or Registered office address, telephone number, mobile number, fax number and e-mail id: (ii) Applicant's address, telephone number, mobile number, fax number and e-mail id: (iii) Address for correspondence:	
4. Details of new drugs and investigational new drugs to be manufactured [As per Annexure].	
5. Particulars of Manufacturer, Manufacturing sites [As per Annexure].	
6. Fee paid on _____Rs_____receipt or challan or transaction ID___.	

7. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and the Chapter VIII of New Drugs and Clinical Trials Rules, 2019. (ii) The new drug to be manufactured from M/s..... shall be used exclusively for the purpose of clinical trial and no part of it shall be diverted to the domestic market.	
Place: ……. Date:	Digital Signature (Name and designation)

Annexure:

Details of new drug or investigational new drug:

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

Composition:	
Indications:	

Details of manufacturer and manufacturing site:

Name and address of Active Pharmaceutical Ingredient and formulation manufacturer (full address with telephone, fax and e-mail address of the manufacturer).	
Name and address of manufacturing sites of Active Pharmaceutical Ingredient and formulation (full address with telephone, fax and e-mail address of the manufacturing site).	