

FORM CT-12*(See rule 59)***APPLICATION FOR GRANT OF PERMISSION TO MANUFACTURE FORMULATION OF UNAPPROVED ACTIVE PHARMACEUTICAL INGREDIENT FOR TEST OR ANALYSIS OR CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY**

I/We,.....(*name and full postal address of the applicant*)
of.....hereby apply for grant of permission to manufacture formulations of
unapproved active pharmaceutical ingredient for test or analysis or clinical trial or bioavailability or bioequivalence study.

The details of the application are as under:

1. Name of formulation manufacturer:	
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: (i) Formulation manufacturer's address including telephone number, mobile number, fax number and e-mail id: (ii) Address for correspondence:	
4. Details of unapproved Active pharmaceutical ingredient and its formulation [As per Annexure].	
5. Details of Manufacturer, Manufacturing sites of formulation [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 Chapter VIII of the New Drugs and Clinical Trials Rules, 2019. (ii) The formulation of the unapproved active pharmaceutical ingredient to be manufactured shall be used for the mentioned purpose only and no part of it shall be sold in the market.	

Place:

Digital Signature

Date:

(Name and designation)

Annexure:

Details of Active pharmaceutical ingredient and its formulation:

Name of the unapproved active pharmaceutical ingredient (API)	Quantity	Name of the formulation/test Batches to be developed for test/analysis or clinical trial	Quantity

Name of the formulation to be manufactured	
Quantity	
Composition	
Indication	

Details of manufacturer and manufacturing site of formulation:

Serial number	Name and address of manufacturer of formulation (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of manufacturing site of formulation (full address with telephone, fax and e-mail address of the manufacturing site)

Details of manufacturer and manufacturing site of Active pharmaceutical ingredient:

Serial number	Name and address of manufacturer of Active pharmaceutical ingredient (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of manufacturing site of Active pharmaceutical ingredient (full address with telephone, fax and e-mail address of the manufacturing site)