FORM CT-11

(*See rules 53, 54, 55, 56, 57 and 58)*

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

Licence Number _____

The Central Licencing Authority hereby grant permission_____(Name and full postal address with contact details of the applicant) to manufacture the new drug or investigational new drug for conduct of clinical trial or bioavailability or bioequivalence study as per protocol number_____dated_____in the below mentioned clinical trial sites or bioavailability and bioequivalence study centre [As per Annexure] or for examination, test and analysis.

Serial Number	Name of the new drug or investigational new drug to be manufactured.	Class of new drug or investigational new drug.	Quantity to be manufactured.

2. This licence is subject to the conditions specified in the Chapter VIII of New Drugs and Clinical Trials Rules,2019 under the Drugs and Cosmetics Act, 1940.

3. This licence shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.

4. Details of manufacturer and manufacturing site under this licence.

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

Place: …….

Date: .....

Central Licencing Authority

Stamp

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	
Ethics committee details:	
Name of investigator:	