FORM CT-17

(*See rules 68, 69, 70, 71 and 72*)

LICENCE TO IMPORT NEW DRUG OR INVESTIGATIONAL NEW DRUG FOR THE PURPOSE OF CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR EXAMINATION, TEST AND ANALYSIS

Licence Number:_____

The Central Licencing Authority hereby grants licence to_____(Name and full address with contact details of the applicant) to import new drug or investigational new drug for conduct of clinical trial or bioavailability or bioequivalence study as per protocol number dated

_____or for examination, test and analysis in the below mentioned clinical trial sites or bioavailability or bioequivalence study centre. [As per Annexure].

Serial number	Name of the new drug or investigational new drug to be imported	Therapeutic class of new drug or investigational new drug	Quantity to be imported

2. This licence is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.

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 overseas 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)

5. The licencee shall maintain the record of imported new drug or investigational new drugs [As per Annexure].

Place: …… Central Licencing Authority

Date: ..... Stamp

Annexure:

Details of clinical trial site or bioavailability or bioequivalence study centre:

Names and address:	
Ethics committee details:	
Name of investigator:	