FORM CT-15

(*See rules 60, 61, 62, 63 and 64*)

PERMISSION TO MANUFACTURE UNAPPROVED ACTIVE PHARMACEUTICAL INGREDIENT FOR THE DEVELOPEMNT OF FORMULATION FOR TEST OR ANALYSIS OR CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

Licence Number:_____

The Central Licencing Authority hereby grant permission to_____
(Name and full address of the active ingredient manufacturer) to manufacture the unapproved active pharmaceutical ingredient specified below to manufacture its formulation for test or analysis or for conduct of clinical trials or bioavailability or bioequivalence study.

Name of the unapproved active pharmaceutical ingredient (API) to be manufactured	Quantity

2. Details of Manufacturer, Manufacturing site of active pharmaceutical ingredient.

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)

3. Details of Manufacturer, Manufacturing site of formulation manufacturer to be supplied.

Serial. number	Name and address of formulator (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of site where the manufactured unapproved active pharmaceutical ingredient to be used (full address with telephone, fax and e-mail address of the manufacturing site)

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

5. This permission shall, unless previously suspended or revoked, be in force for a period of .....from the date of its issuance.

Place:……. Central Licencing Authority

Date: ..... Stamp

Annexure

Details of record of unapproved active pharmaceutical ingredient manufactured:

Serial number	Date of manufacture	Licence number	Name of the unapproved active pharmaceutical ingredient	Quantity manufactured	Manufactured for

Details of reconciliation of unapproved active pharmaceutical ingredient manufactured:

Date	Name of the unapproved active pharmaceutical ingredient	Licence number	Quantity manufactured	Quantity supplied	Quantity remained	Supplied to	Quantity – left over or remain unused or got damaged or expired or found of sub-standard quality	Action taken

*** Write NA where not applicable.**