FORM CT-27

(See rules 92, 93, 94 and 95)

PERMISSION TO MANUFACTURE UNAPPROVED NEW DRUG BUT UNDER CLINICAL TRIAL FOR TREATMENT OF PATIENTS OF LIFE THREATENING DISEASE IN A GOVERNMENT HOSPITAL OR MEDICAL INSTITUTION

Licence Number ……

The Central Licencing Authority hereby grant permission to …… (Name and full postal address with contact details of the organization) to manufacture the unapproved new drug specified below on the premises situated at ……..……..... (full postal address with contact details of the manufacturing site) for supply to …… (name of the medical officer and address of the Government hospital or medical institution) for the treatment of the patient for the disease..... (Name of the disease).

2. This licence is subject to the conditions prescribed in Chapter XI of the 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 one year from the date specified below:–

4. Details of the new drug to be manufactured

Name:	
Quantity:	

Place: …… Central Licencing Authority and Stamp

Date: .....

Annexure:

Details of unapproved new drug manufactured:

Serial number	Date of manufacture	Licence number	Name of the unapproved new drug	Quantity manufactured	Manufactured for

Details of record of patient history:

Licence number	Name of the new drug	Patient name	Diagnosis detail with date	Disease name	Dosage schedule

Details of reconciliation of unapproved active pharmaceutical ingredient manufactured:

Date	Name of the unapproved new drug	Licence No.	Quantity manufactured	Quantity supplied	Quantity remained	Supplied to	Quantity – left over or remain unused or got damaged or expired or found of sub-	Action taken

							standard quality	

*** Write NA where not applicable.**