48	159.80
49	156.47
50	153.09
51	149.67
52	146.20
53	142.68
54	139.13
55	135.56
56	131.95
57	128.33
58	124.70
59	121.05
60	117.41
61	113.77
62	110.14
63	106.52
64	102.93
65 or more	99.37

EIGHTH SCHEDULE

FORM CT-01

(*See rules 8, 10 and 17*)

APPLICATION FOR REGISTRATION/RENEWAL OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY OR BIOMEDICAL HEALTH RESEARCH

I/We, ...*(name, designation and full postal address of the applicant)* of ..... (*name and full address with contact details of the ethics committee*) hereby apply for grant of registration of ethics committee.

The details of the application are as under:

1. Name of applicant:
2. Nature and constitution of applicant: (proprietorship, company, society, trust, independent, institutional, other to be specified)
3. (i) Applicant address including telephone number, mobile number, fax number and e-mail id: (ii) Address for correspondence: corporate or registered office or clinical trial site or bioavailability and bioequivalence study centre or biomedical health research
4. Details of accreditation, if any (self-attested copy of certificate to be attached):
5. I have enclosed the documents as specified in the Table 1 of the Third Schedule of the New Drugs and Clinical Trials Rules, 2019.

6. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.

Place: _____ Digital Signature

Date: _____ (Name and designation)

FORM CT-02

(*See rules 8, 9, 10 and 14)*

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No._____

The Central Licencing Authority here by registers and permits___(Name and full address with contact details of the ethics committee) to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place: …… Central Licencing Authority

Date: ..... Stamp

FORM CT-03

(*See rules 17 and 18)*

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO BIOMEDICAL HEALTH RESEARCH

Registration No._____

The designated authority is hereby register and permit_____
(Name and full address with contact details of the ethics committee) to perform duties of ethics committee as specified in the Regulation of New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter IV of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

Place: …… Central Licencing Authority

Date: ..... Stamp

FORM CT-04

(*See rule 21*)

APPLICATION FOR GRANT OF PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

I/We, ...*(name and full postal address of the applicant)* of ..... hereby apply for grant of permission to conduct clinical trial on new drug or investigational new drug.

The details of the application are as under:

1.Name of Applicant:	
2. Nature and constitution: proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified.	
3. (i) Sponsor address, telephone number, mobile number, fax number and e-mail id: (ii) Clinical trials site address, telephone number, mobile number, fax number and e-mail id: (iii) Name and address of person responsible for payment of compensation, if any: (iv) Address for correspondence: [corporate or registered office or clinical trial site]	
4. Details of new drugs or investigational new drugs and clinical investigation site [As per Annexure].	
5. Phase of the Clinical Trial	
6. Clinical trial protocol number with date:	
7. Fee paid on _____ Rs. _____ Receipt or Challan or transaction ID_____.	
8. I have enclosed the documents as specified in the Second Schedule of the New Drugs and Clinical Trials Rules, 2019.	
9. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.	

Place:……. Digital Signature

Date:……..... (Name and designation)

Annexure:

Details of new drugs or investigational new drugs:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	

Composition:	
Indications:	

Details of clinical trial site:

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

FORM CT-4A

(*See rule 23*)

INFORMATION TO INITIATE CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG AS PART OF DISCOVERY, RESEARCH AND MANUFACTURE IN INDIA

I/We, ...*(name and full postal address of the applicant)* of ..... hereby inform to initiate the conduct clinical trial on new drug or investigational new drug.

The details of the application areas under:

1.Name of Applicant:	
2. Nature and constitution: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified)	
3. (i) Sponsor address, telephone number, mobile number, fax number and e-mail id: (ii) Clinical trials site address, telephone number, mobile number, fax number and e-mail id: (iii) Name and address of person responsible for payment of compensation, if any: (iv) Address for correspondence: [corporate or registered office or clinical trial site]	
4. Details of new drugs or investigational new drugs and clinical investigation site [As per Annexure].	
5. Phase of the Clinical Trial	
6. Clinical trial protocol number with date:	
8. I hereby declared that I have already submitted the application under rule 21 of these rules and granted automatic approval under rule 23(2) and enclosed the documents as specified in the Second Schedule of the New Drugs and Clinical Trials rules, 2019.	
9. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.	

Place:…….

Date:…….....

Digital Signature

(Name and designation)

Annexure:

Details of new drugs or investigational new drugs:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

Details of clinical trial site:

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

FORM CT-05

(See rule 33)

APPLICATION FOR GRANT OF PERMISSION TO CONDUCT BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

I/We, ...*(name and full postal address of the applicant)* of ..... hereby apply for grant of permission to conduct bioavailability or bioequivalence study (*strike off whichever is not applicable*) of new drug or investigational new drug, the details of which are as under:

1.Name of applicant:	
2. Nature and constitution: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified)	
3. (i) Sponsor address, telephone number, mobile number, fax number and e-mail id: (ii) Study address, telephone number, mobile number, fax number and e-mail id: (iii) Address for correspondence: [corporate or registered office or bioavailability or bioequivalence study centre]	

4. Details of new drug or investigational new drug and study centre [As per Annexure].
5. Study protocol number with date:
6. Fee paid on _____ Rs. _____ Receipt or challan or transaction ID_____.
7. I have enclosed the documents as specified in the Fourth Schedule of the New Drugs and Clinical Trials Rules, 2019.
8. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.

Place:……. Digital Signature

Date:……..... (Name and designation)

Annexure:

Details of new drug or investigational new drugs:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

Details of study centre:

Names and address of study centre	
Ethics committee details:	

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits_____

(Name and full address with contact details of the applicant) to conduct clinical trial of the new drug or investigational new drug as per protocol number _____in the below mentioned clinical trial sites. dated

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: ……. Central Licencing Authority

Date: ..... Stamp

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

Details of clinical trial site:

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

FORM CT-07

(See Rules 34, 35, 36, 37 and 38)

PERMISSION TO CONDUCT BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits_____
(Name and full address with contact details of the applicant) to conduct bioavailability or bioequivalence study (*strike off whichever is not applicable*) of the new drug or investigational new drug as per protocol number_____dated___in the below mentioned study centre.

2. Details of new drug or investigational new drug and study centre [As per Annexure].

3. This permission is subject to the conditions prescribed in part B of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: …… Central Licencing Authority

Date: ..... Stamp

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

Details of study centre:

Names and address of study centre:	
Ethics committee details:	
Name of principal investigator:	

FORM CT-08

(*See rule45*)

APPLICATION FOR REGISTRATION/RENEWAL OF BIOAVAILABILITY OR BIOEQUIVALENCE STUDY CENTRE

I/We, ...*(name, designation and full postal address of the applicant)* of ..... hereby apply for grant of registration of bioavailability or bioequivalence study centre. The details of the application are as under:

1.Name of applicant:	
2. Nature and constitution of applicant: (proprietorship, company, society, trust, independent, institutional, other to be specified)	
3. (i) Applicant address including telephone number, mobile number, fax number and e-mail id: (ii) Address for correspondence: [corporate or registered office or bioavailability or bioequivalence study centre]	
4. Details of accreditation, if any (self-attested copy of certificate to be attached):	
5. Fee paid on _____ Rs. _____ Receipt or challan or transaction ID_____.	
6. I have enclosed the documents as specified in the Table 1 of Fourth Schedule of the New Drugs and Clinical Trials Rules, 2019.	
7. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 the New Drugs and Clinical Trials Rules, 2019.	

Place: ……..

Date: ……

Digital Signature

(Name and designation)

FORM CT-09

(*See rules 47, 48, 49, 50and 51*)

GRANT OF REGISTRATION OF BIOAVAILABILITY OR BIOEQUIVALENCE STUDY CENTRE

Registration No._____

The Central Licencing Authority hereby register_____
(Name and full address with contact details of the applicant) for conduct of bioavailability and bioequivalence studies of new drugs and investigational new drugs as specified in the New Drugs and Clinical Trials Rules, 2019.

2.This registration is subject to the conditions prescribed in Chapter VII of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: …….

Date: .....

Central Licencing Authority

Stamp

FORM CT-10

(*See rule 52)*

APPLICATION FOR GRANT OF PERMISSION

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

I/We, ...

(name and full postal address of the applicant) of ..... hereby apply for grant of permission to manufacture new drug or investigational new drug for clinical trial or bioavailability or bioequivalence study or for examination, test and analysis.

The details of the application are as under:

1. Name of applicant:	
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: (ii) Applicant's address, telephone number, mobile number, fax number and e-mail id: (iii) Address for correspondence:	
4. Details of new drugs and investigational new drugs to be manufactured [As per Annexure].	
5. Particulars of Manufacturer, Manufacturing sites [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 the Chapter VIII of New Drugs and Clinical Trials Rules, 2019. (ii) The new drug to be manufactured from M/s..... shall be used exclusively for the purpose of clinical trial and no part of it shall be diverted to the domestic market.

Place: …… Date:	Digital Signature (Name and designation)

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

Details of manufacturer and manufacturing site:

Name and address of Active Pharmaceutical Ingredient and formulation manufacturer (full address with telephone, fax and e-mail address of the manufacturer).	
Name and address of manufacturing sites of Active Pharmaceutical Ingredient and formulation (full address with telephone, fax and e-mail address of the manufacturing site).	

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:	

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: (ii) Formulation manufacturer's address including telephone number, mobile number, fax number and e-mail id: (iii) 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)

FORM CT-13

(*See rule 59 and 60)*

APPLICATION FOR GRANT OF PERMISSION TO MANUFACTURE UNAPPROVED ACTIVE PHARMACEUTICAL INGREDIENT FOR DEVELOPMENT OF FORMULATION 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 unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability or bioequivalence study.

The details of the application are as under:

1. Name of manufacture:	
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: (ii) Formulation manufacturer's address including telephone number, mobile number, fax number and e-mail id: (iii) Address for correspondence:	
4. Details of unapproved active pharmaceutical ingredient to be manufactured [As per Annexure].	
5. Details of formulation to be manufactured [As per Annexure].	
6. Fee paid on_____Rs_____ receipt or challan or transaction ID_____.	
(i) 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 unapproved active pharmaceutical ingredient to be manufactured shall be supplied to M/s ……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) to be obtained	Quantity	Name of the formulation or test batches to be developed for test/analysis or clinical trial	Quantity

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)

FORM CT-14

(*See rules 60, 61, 62, 63and64*)

PERMISSION TO MANUFACTURE FORMULATION OF UNAPPROVED ACTIVE PHARMACEUTICAL INGREDIENT 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 postal address with contact details of the formulation manufacturer) to manufacture the formulation of the unapproved active pharmaceutical ingredient specified below for test or analysis or for conduct of clinical trials bioavailability or bioequivalence study.

Name of the formulation or test batches to be developed for test or analysis or clinical trial	Quantity

2. Details of manufacturer, manufacturing site of formulation [As per Annexure].

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. This licence is subject to the conditions prescribed under Chapter VII of the New Drugs and Clinical Trials Rules,2019 under the Drugs and Cosmetics Act,1940.

4. Details of manufacturer and manufacturing site of active pharmaceutical ingredient to be supplied.

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. This licence shall, unless previously suspended or revoked, be in force fora period of ..... from the date of its issuance.

Place:…….

Date: .....

Central Licencing Authority

Stamp

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.**

FORM CT-16

(*See rule 67*)

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

I/We, ...*(name and address of the applicant)* of M/s ..... hereby apply for grant of licence to import new drug or investigational new drug for clinical trial bioavailability or bioequivalence study or for examination, test and analysis.

The details of the application are as under:

1. Name of applicant:	
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 including telephone number, mobile number, fax number and e-mail id: (ii) Applicant's address including telephone number, mobile number, fax number and e- mail id: (iii) Address for correspondence:	
4. Details of new drugs to be imported [As per Annexure].	
5. Particulars of overseas Manufacturer, Manufacturing sites [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 IX of the New Drugs and Clinical Trials Rules, 2019. (ii) The new drug to be imported from M/s..... shall be used exclusively for the purpose of clinical trial and no part of it shall be diverted to the domestic market.	

Place: Digital Signature

Date: (Name and designation)

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	

Details of manufacturer and manufacturing site:

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)	

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:	

FORM CT-18

(*See rule 75*)

APPLICATION FOR GRANT OF PERMISSION TO IMPORT NEW DRUG FOR SALE OR FOR DISTRIBUTION

I/We, ... *(name and address of the applicant)* of M/s ..... hereby apply for grant of permission to import new drug for sale.

1. Name of applicant:	
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 including telephone number, mobile number, fax number and e-mail id: (ii) Manufacturer's address including telephone number, mobile number, fax number and e-mail id: (iii) Address for correspondence:	
4. Details of new drug to be imported (Active pharmaceutical Ingredient or Finished Formulation) [As per Annexure].	
5. Details of the manufacturer and manufacturing site [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 X of the New Drugs and Clinical Trials Rules, 2019.	

Place: Digital Signature

Date: (Name and designation)

Annexure:

Details of new drug:

Name of the new drug:	
Dosage form:	
Composition of the formulation:	
Therapeutic class of the new drug:	
Indications for which proposed to be used:	
Manufacturer of the raw material (active pharmaceutical ingredient):	

Details of manufacturer and manufacturing site of new drug:

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).

FORM CT-19

(*See rules 76, 77 and 78*)

PERMISSION TO IMPORT NEW ACTIVE PHARMCEUTICAL INGREDIENT FOR SALE OR FOR DISTRIBUTION

The Central Licencing Authority hereby grants permission to_____
(Name and full postal address of authorised agent with contact details of the organization) to import new active pharmaceutical ingredient manufactured by an overseas manufacturer specified below for sale.

2. Details of overseas manufacturer and its manufacturing site under this licence.

Serial number	Name and address of overseas manufacturer (full name and address with telephone and e-mail address of manufacturer)	Name and address of manufacturing site (full name and address with telephone and e-mail address of manufacturing site)

3. This permission is subject to the conditions prescribed in Chapter X of the New Drugs and Clinical Trials Rules,2019 under the Drugs and Cosmetics Act,1940.

4. Details of active pharmaceutical ingredient to be imported.

Name of the active pharmaceutical ingredient to be obtained.	Quantity.

Place: …….
Date: .....

Central Licencing Authority
Stamp

FORM CT-20

(*See rules 76, 77 and 78*)

PERMISSION TO IMPORT PHARMACEUTICAL FORMULATIONS OF NEW DRUG FOR SALE OR FOR DISTRIBUTION

The Central Licencing Authority hereby grant permission to_____
(Name and full postal address of authorised agent with contact details of the organisation) to import pharmaceutical formulation manufactured by an overseas manufacturer specified below for sale.

2. Details of overseas manufacturer and its manufacturing site under this licence.

Serial number	Name and address of overseas manufacturer (full name and address with telephone and e-mail address of manufacturer).	Name and address of manufacturing site (full name and address with telephone and e-mail address of manufacturing site)

3. Details of pharmaceutical formulation:

Name of the new drug to be imported:	
Dosage form:	
Composition:	
Indication:	

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

Place: ……. Central Licencing Authority

Date: ..... Stamp

FORM CT-21

(*See rule 80)*

APPLICATION FOR GRANT OF PERMISSION TO MANUFACTURE NEW DRUG FORMULATION FOR SALE OR FOR DISTRIBUTION

I/We, ... *(name and full postal address of the applicant)* of M/s ..... hereby apply for grant of permission to manufacture new drug for sale or distribution.

The details of the application are as under:

1. Name of applicant:	
2. Nature and constitution of applicant: (i.e. proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified)	
3.(i) Corporate or registered office address including telephone number, mobile number, fax number and e-mail id: (ii) Manufacturer's address including telephone number, mobile number, fax number and e-mail id: (iii) Address for correspondence:	
4. Details of new drug to be manufactured (Active pharmaceutical Ingredient or Finished Formulation or both) [As per Annexure].	
5. Details of the manufacturer and manufacturing site [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 X of the New Drugs and Clinical Trials Rules, 2019.

Place:…….. Digital Signature

Date: …… (Name and designation)

Annexure:

Details of new drug:

Name of the new drug:	
Dosage form:	
Composition of the formulation:	
Therapeutic class of the new drug:	
Indications for which proposed to be used:	

Details of manufacturer and manufacturing site of new drug:

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).

FORM CT-22

(*See rules 81, 82, 83 and 84*)

PERMISSION TO MANUFACTURE NEW ACTIVE PHARMACEUTICAL INGREDIENT FOR SALE OR FOR DISTRIBUTION

The Central Licencing Authority hereby grant permission to …… (Name and full address with contact details of the manufacturer) to manufacture for sale the new active pharmaceutical ingredient manufactured by manufacturer specified below.

2. Details of manufacturer and its manufacturing site under this permission.

Serial number	Name and address of manufacturer (full name and address with telephone and e-mail address of manufacturer)	Name and address of manufacturing site (full name and address with telephone and e-mail address of manufacturing site)

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

4. Details of the new active pharmaceutical ingredient to be manufactured------.

Place: ……. Central Licencing Authority

Date: ..... Stamp

FORM CT-23

(*See rules 81, 82, 83 and 84*)

PERMISSION TO MANUFACTURE PHARMACEUTICAL FORMULATION OF NEW DRUG FOR SALE OR FOR DISTRIBUTION

The Central Licencing Authority hereby grant permission to …… (Name and full address of authorised agent with contact details of the manufacturer) to manufacture for sale of pharmaceutical formulation manufactured by an manufacturer specified below.

2. Details of manufacturer and its manufacturing site under this licence.

Serial number	Name and address of manufacturer (full name and address with telephone and e-mail address of manufacturer).	Name and address of manufacturing site (full name and address with telephone and e-mail address of manufacturing site).

3. Details of pharmaceutical formulation:

Name of the new drug to be imported:	
Dosage form:	
Composition:	
Indication:	
Shelf life with storage condition:	

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

Place: ……. Central Licencing Authority

Date: ..... Stamp

FORM CT-24

(See rule 86)

APPLICATION FOR LICENCE TO IMPORT OF UNAPPROVED NEW DRUG FOR TREATMENT OF PATIENTS OF LIFE THREATENING DISEASE IN A GOVERNMENT HOSPITAL OR GOVERNMENT MEDICAL INSTITUTION

I/We, ...

(name and full postal address of the applicant) of M/s ..... hereby apply for grant of licence to import unapproved new drug but under clinical trial for treatment of patients of life threatening disease in a government hospital or medical institution.

The details of the application are as under:

1. Name of Medical officer:	
2. Nature and constitution of applicant: (Government Hospital or Medical Institution)	
3.(i) Aaddress including telephone number, mobile number, fax number and e-mail id of the Government Hospital or Medical Institution: (ii) Address for correspondence:	
4. Details of unapproved new drug pharmaceutical formulation to be imported [As per Annexure].	
5. Details of the manufacturer and manufacturing site [As per Annexure].	
6. Details of the patient and disease [As per Annexure].	
7. Fee paid on _____ Rs__ receipt or challan or transaction ID.	
8. A legal undertaking stating that the unapproved new drug to be imported shall be used for the treatment of the patient for the disease mentioned below only and no part of it shall be sold in the market is enclosed herewith.	

Place: …… Digital Signature

Date: ……. (Name and designation)

Annexure:

Details of unapproved new drug to be imported:

Name of the new drug:	
Dosage form:	
Quantity:	
Indications for which proposed to be used:	

Details of manufacturer and manufacturing site:

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).

Details of patient:

Name of the patient:	
Disease name:	

Certificate

Certified that the unapproved new drug specified above for import is urgently required for the treatment of patients suffering from…….. and that the said drug is not available in India.

Place..... Signature

Date..... Medical Superintendent of the Government Hospital or Head of Medical Institution

[Stamp]

FORM CT-25

(See rules 87, 88, 89 and 90)

LICENCE TO IMPORT UNAPPROVED NEW DRUG FOR TREATMENT OF PATIENTS OF LIFE THREATENING DISEASE IN A GOVERNMENT HOSPITAL OR MEDICAL INSTITUTION

Licence Number:_____

The Central Licencing Authority hereby grant license to_____(Name and full postal address with contact details of the Government Hospital or Government Medical Institution) to import the unapproved new drug specified below for the purpose of treatment of the patient for the disease …… (Name of the disease).

2. This permission 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 ..... from the date of its issuance.

4. Details of the new drug to be imported

Name of new drug:	
Quantity to be imported:	

Place: ……. Central Licencing Authority

Date: ..... Stamp

Annexure

Details of new drug imported:

Serial number	Date of import.	Licence number	Name of the new drug imported.	Imported through (Port office name).	Consignment number	Quantity imported.

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 new drug to be imported:

Date	Nam e of the new drug.	Licence number.	Initial quantity.	Quantity used.	Quantity remained.	Quantity – left over or remain unused or got damaged or expired or found of sub-standard quality	Action taken.

*Write NA where not applicable.

FORM CT-26

(See rule 91)

APPLICATION FOR GRANT OF 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

I/We, ... *(name and full postal address of the applicant)* of M/s ..... hereby apply for grant of 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.

The details of the application are as under:

1. Name of applicant:	
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 including telephone number, mobile number, fax number and e-mail id: (ii) Manufacturer's address including telephone number, mobile number, fax number and e-mail id: (iii) Address for correspondence:	
4. Details of unapproved new drug to be manufactured [As per Annexure].	
5. Details of the manufacturer and manufacturing site [As per Annexure].	
6. Details of the Medical officer and Government Hospital and Medical Institution	
7. Copy of recommendation of the ethics committee and consent from the patient in accordance with Rule 81 of the Regulation of New Drugs and Clinical Trials Rules 2019 are hereby enclosed.	

8. Fee paid on _____Rs_____ receipt or challan or transaction ID___.
9. A legal undertaking stating that the unapproved new drug to be manufactured shall be used for the treatment of the patient for the disease mentioned below only and no part of it shall be sold in the market is enclosed herewith.

Place:……. Digital Signature

Date: ……. (Name and designation)

Annexure:

Details of unapproved new drug to be manufactured:

Name of the new drug:	
Quantity:	
Indications:	

Details of manufacturer and manufacturing site:

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).

Details of the government hospital or government medical institution and patient:

Name of the government hospital or government medical institution:	
Address of the government hospital or government medical institution:	
Name and address of the patient:	
Disease name:	

Certificate

Certified that the unapproved new drug but under clinical trial specified above for manufacture is urgently required for the treatment of patients suffering from_____and that the said drug(s) is/are not available in India.

Place..... Signature

Date..... Medical Superintendent of the Government Hospital or Head of Medical Institution

[Stamp]

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.**

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