Form-44 to Undertake Clinical Trials

Form 44

1.Applicant can apply for "**FORM 44**" by choosing **Biological, Investigational New Drugs, Subsequent New Drug, Fixed Dose Combination, GCT Division, New Drug Division** from **select department** and **select form** from the drop down list ,as highlighted in ***Figure 1.1.***

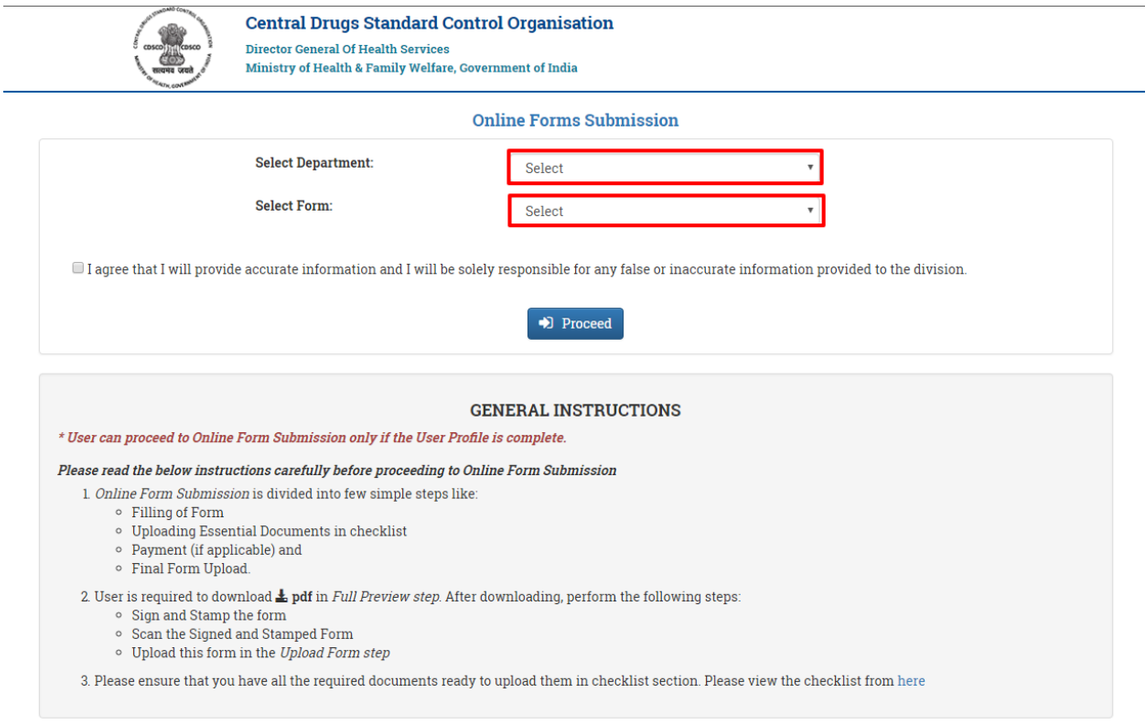


Figure 1.1.

Note:-

- Form44 is applied for the issue of Permission to import or manufacture a New Drug or to undertake clinical trial.

2. After clicking on **Proceed** a new window will open ,as shown in ***Figure 1.2.***

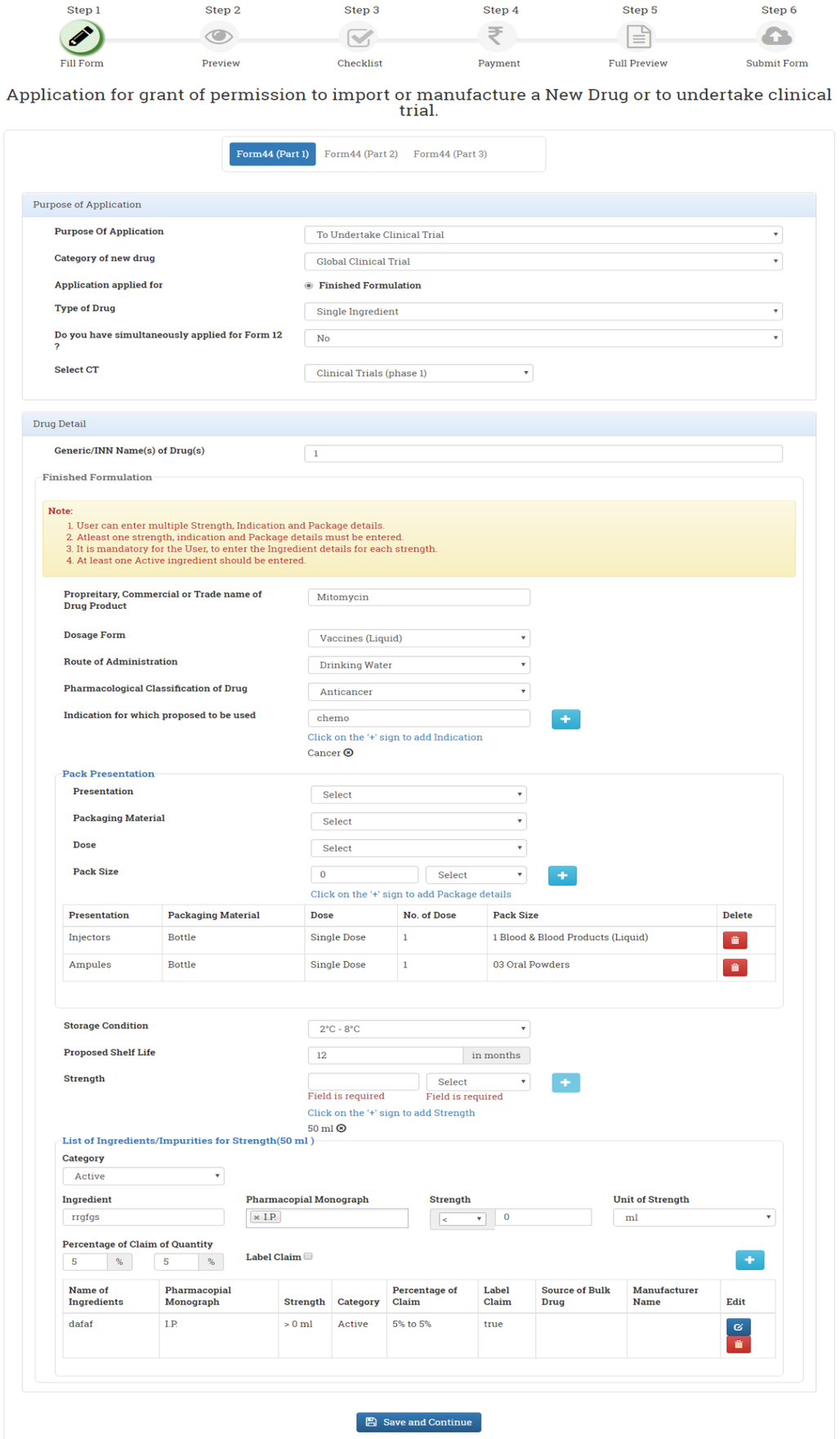


Figure 1.2.

Note:-

1. Applicant must add at least one strength, indication and Package details must be entered.
2. At least one Active ingredient should be entered.

3. After clicking on **Save and Continue** a new window will open, as shown in ***Figure 1.3.***

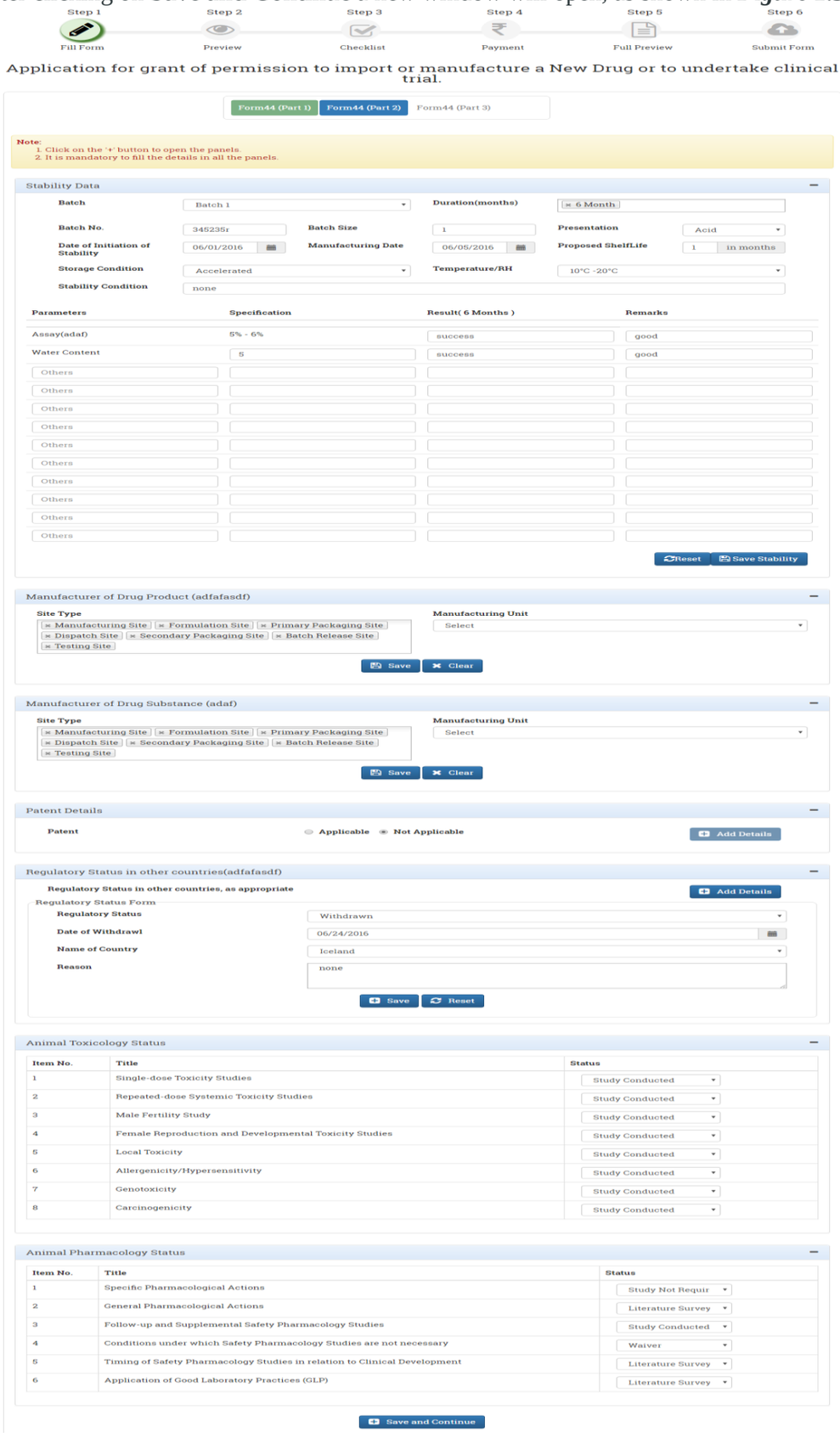


Figure 1.3.

Note:-

- Applicant must fill All the details along with Animal **Toxicology Status** and **Animal Pharmacology Status**

4.After clicking on **Save and Continue** a new window will as shown in ***Figure 1.4.***

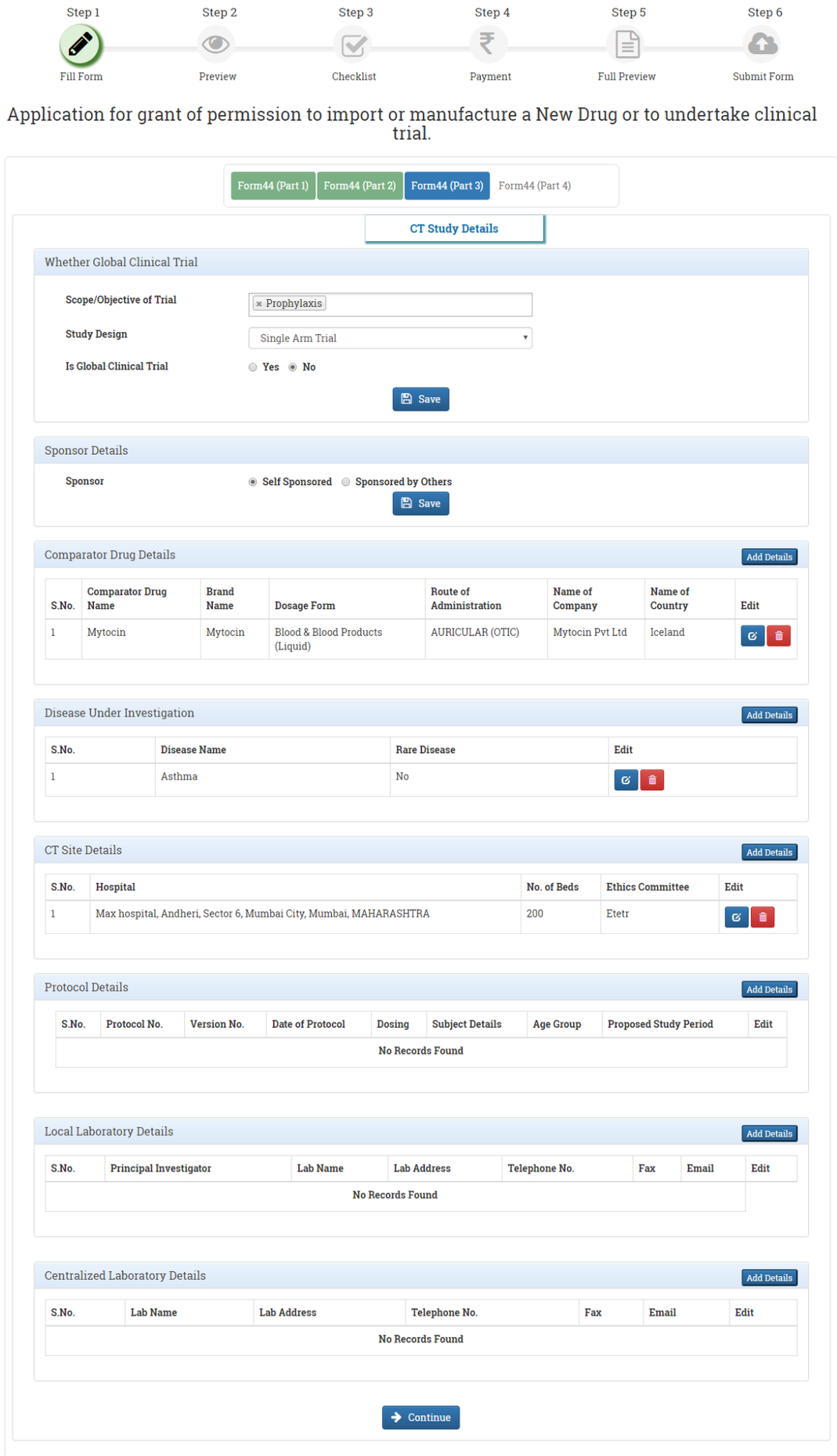


Figure 1.4.

Note:-

- Applicant must add all the **CT Study Details**.

5.Click on **Continue** ,a new window will as shown in ***Figure 1.5.***

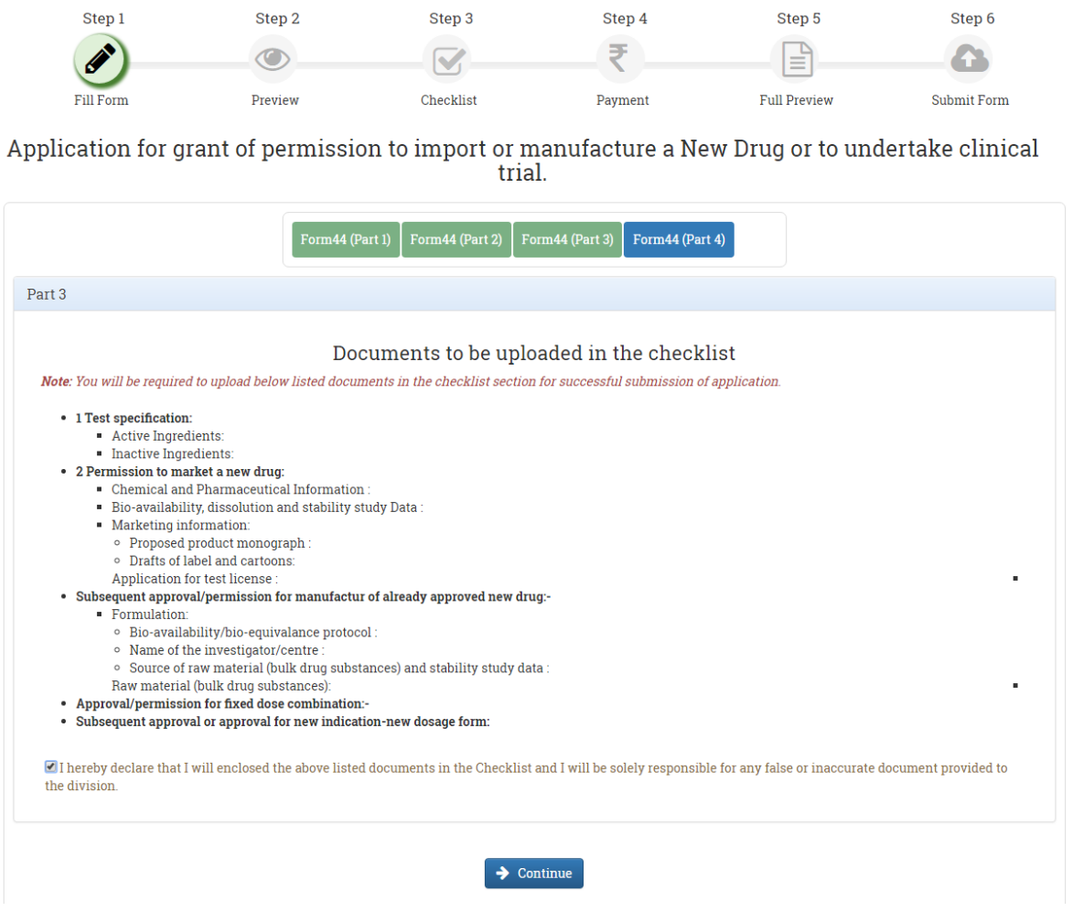
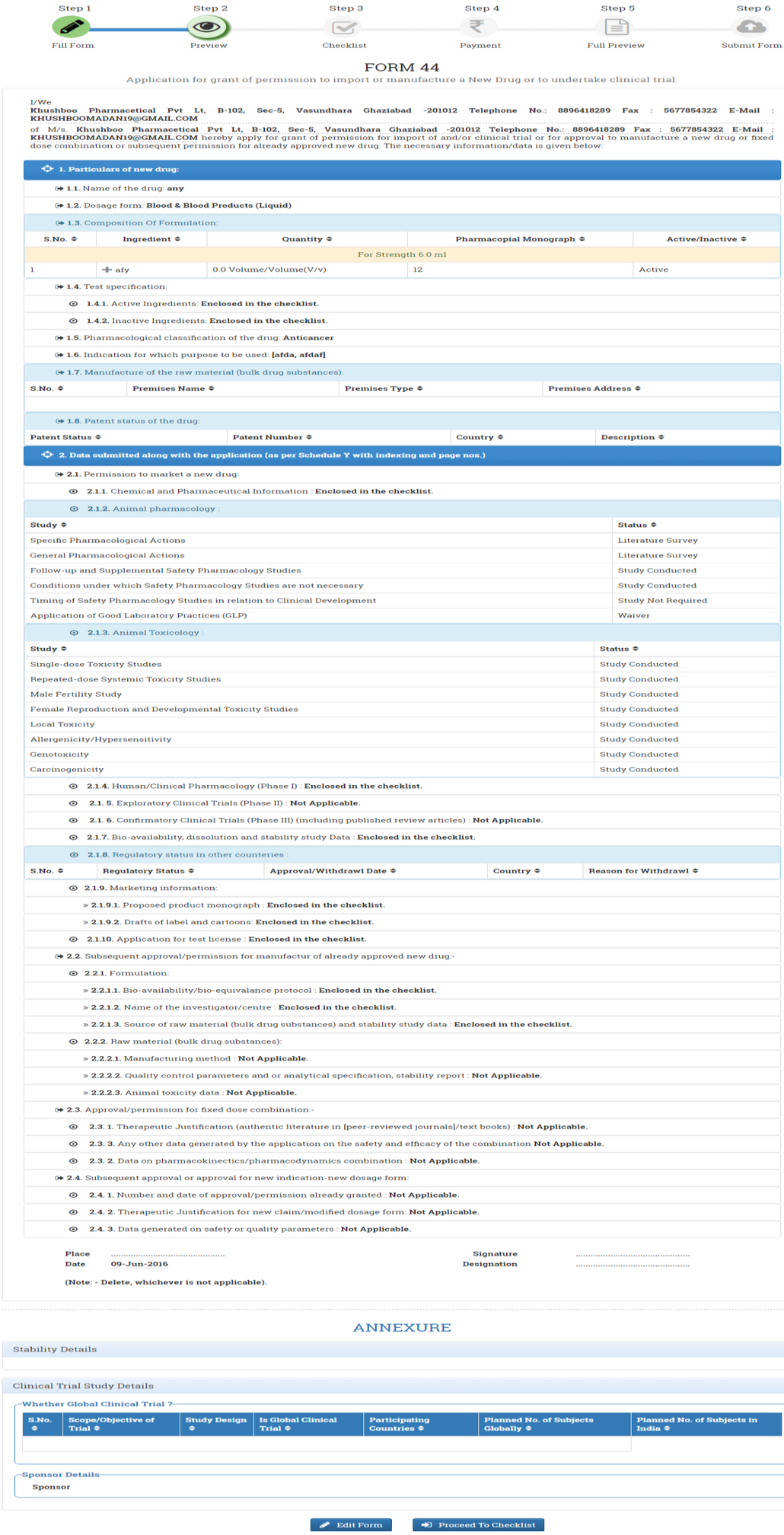


Figure 1.5.

6.On Clicking "**Continue**" Button. A new window will open ,as shown in ***Figure 1.6.***



Step 1 Fill Form | Step 2 Preview | Step 3 Checklist | Step 4 Payment | Step 5 Full Preview | Step 6 Submit Form

FORM 44

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

I/We
Khushboo Pharmacetical Pvt Lt, B-102, Sec-5, Vasundhara Ghaziabad -201012 Telephone No.: 8896418289 Fax : 5677854322 E-Mail : KHUSHBOOMADAN19@GMAIL.COM

of M/s. **Khushboo Pharmacetical Pvt Lt, B-102, Sec-5, Vasundhara Ghaziabad -201012 Telephone No.: 8896418289 Fax : 5677854322 E-Mail : KHUSHBOOMADAN19@GMAIL.COM** hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information/data is given below:

1. Particulars of new drug:

1.1. Name of the drug: **any**

1.2. Dosage form: **Blood & Blood Products (Liquid)**

1.3. Composition Of Formulation:

S.No.	Ingredient	Quantity	Pharmacopial Monograph	Active/Inactive
For Strength 6.0 ml				
1	afy	0.0 Volume/Volume(V/v)	12	Active

1.4. Test specification:

1.4.1. Active Ingredients: **Enclosed in the checklist.**

1.4.2. Inactive Ingredients: **Enclosed in the checklist.**

1.5. Pharmacological classification of the drug: **Anticancer**

1.6. Indication for which purpose to be used: **[afda, afdaf]**

1.7. Manufacture of the raw material (bulk drug substances):

S.No.	Premises Name	Premises Type	Premises Address

1.8. Patent status of the drug:

Patent Status	Patent Number	Country	Description

2. Data submitted along with the application (as per Schedule Y with indexing and page nos.)

2.1. Permission to market a new drug:

2.1.1. Chemical and Pharmaceutical Information : **Enclosed in the checklist.**

2.1.2. Animal pharmacology :

Study	Status
Specific Pharmacological Actions	Literature Survey
General Pharmacological Actions	Literature Survey
Follow-up and Supplemental Safety Pharmacology Studies	Study Conducted
Conditions under which Safety Pharmacology Studies are not necessary	Study Conducted
Timing of Safety Pharmacology Studies in relation to Clinical Development	Study Not Required
Application of Good Laboratory Practices (GLP)	Waiver

2.1.3. Animal Toxicology :

Study	Status
Single-dose Toxicity Studies	Study Conducted
Repeated-dose Systemic Toxicity Studies	Study Conducted
Male Fertility Study	Study Conducted
Female Reproduction and Developmental Toxicity Studies	Study Conducted
Local Toxicity	Study Conducted
Allergenicity/Hypersensitivity	Study Conducted
Genotoxicity	Study Conducted
Carcinogenicity	Study Conducted

2.1.4. Human/Clinical Pharmacology (Phase I) : **Enclosed in the checklist.**

2.1.5. Exploratory Clinical Trials (Phase II) : **Not Applicable.**

2.1.6. Confirmatory Clinical Trials (Phase III) (including published review articles) : **Not Applicable.**

2.1.7. Bio-availability, dissolution and stability study Data : **Enclosed in the checklist.**

2.1.8. Regulatory status in other counteries :

S.No.	Regulatory Status	Approval/Withdrawl Date	Country	Reason for Withdrawl

2.1.9. Marketing information:

» **2.1.9.1.** Proposed product monograph : **Enclosed in the checklist.**

» **2.1.9.2.** Drafts of label and cartoons: **Enclosed in the checklist.**

2.1.10. Application for test license : **Enclosed in the checklist.**

2.2. Subsequent approval/permission for manufactur of already approved new drug:-

2.2.1. Formulation:

» **2.2.1.1.** Bio-availability/bio-equivalance protocol : **Enclosed in the checklist.**

» **2.2.1.2.** Name of the investigator/centre : **Enclosed in the checklist.**

» **2.2.1.3.** Source of raw material (bulk drug substances) and stability study data : **Enclosed in the checklist.**

2.2.2. Raw material (bulk drug substances):

» **2.2.2.1.** Manufacturing method : **Not Applicable.**

» **2.2.2.2.** Quality control parameters and or analytical specification, stability report : **Not Applicable.**

» **2.2.2.3.** Animal toxicity data : **Not Applicable.**

2.3. Approval/permission for fixed dose combination:-

2.3.1. Therapeutic Justification (authentic literature in [peer-reviewed journals]/text books) : **Not Applicable.**

2.3.3. Any other data generated by the application on the safety and efficacy of the combination **Not Applicable.**

2.3.2. Data on pharmacokinectics/pharmacodynamics combination : **Not Applicable.**

2.4. Subsequent approval or approval for new indication-new dosage form:

2.4.1. Number and date of approval/permission already granted : **Not Applicable.**

2.4.2. Therapeutic Justification for new claim/modified dosage form: **Not Applicable.**

2.4.3. Data generated on safety or quality parameters : **Not Applicable.**

Place .....
Date 09-Jun-2016

Signature .....
Designation .....

(Note: - Delete, whichever is not applicable).

ANNEXURE

Stability Details

Clinical Trial Study Details

Whether Global Clinical Trial ?

S.No.	Scope/Objective of Trial	Study Design	Is Global Clinical Trial	Participating Countries	Planned No. of Subjects Globally	Planned No. of Subjects in India

Sponsor Details

Sponsor

Edit Form | Proceed To Checklist

Figure 1.6.

Note:-

- On this preview, Applicant has options to either **Edit Form** or **Proceed To Checklist**.

.

7: On clicking **Proceed to Checklist.** A new page will open , as shown in ***Figure 1.7***.

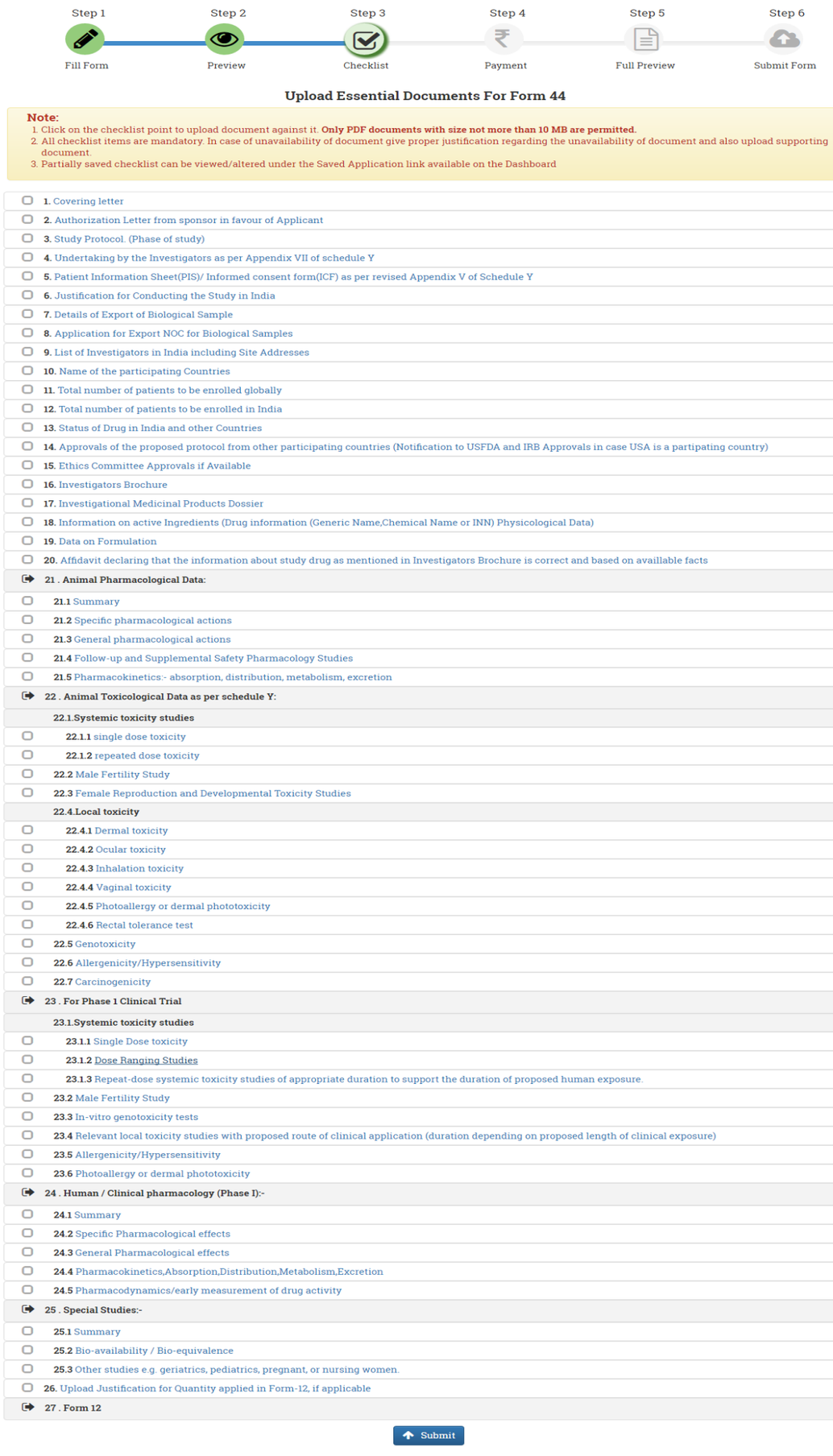


Figure 1.7.

Note:-

- Applicant must complete all the checklist and upload necessary documents.

➢ Clicking on Checklist , a new pop-up will open to upload the document ,as shown in ***Figure 1.8.***

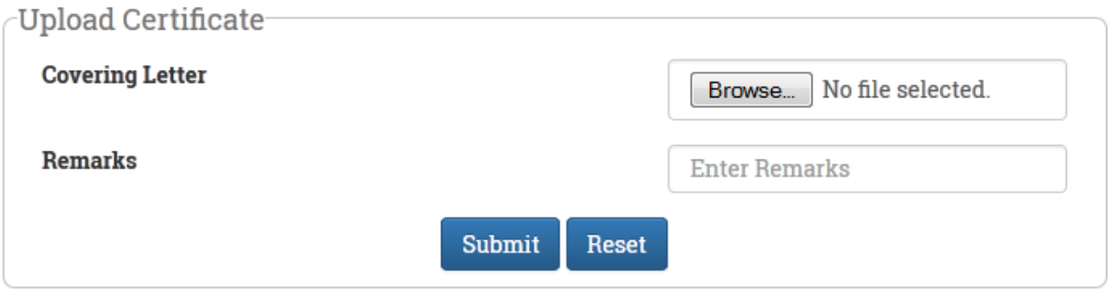


Figure 1.8.

Note:-

- On clicking **Submit** document will be uploaded .

➢ Applicant can replace/Update his document if he/she uploaded wrong document. As shown in ***Figure 1.9.***

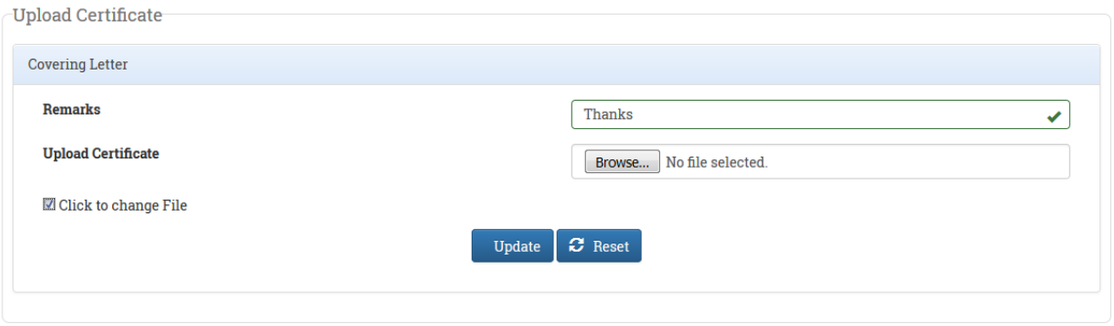


Figure 1.9.

Note:-

- After completing all the checklist page will look like, as shown in ***Figure 1.10.***

Upload Essential Documents For Form 44

Note:

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 10 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/altered under the Saved Application link available on the Dashboard

- **1.** Covering letter
- **2.** Authorization Letter from sponsor in favour of Applicant
- **3.** Study Protocol. (Phase of study)
- **4.** Undertaking by the Investigators as per Appendix VII of schedule Y
- **5.** Patient Information Sheet(PIS)/ Informed consent form(ICF) as per revised Appendix V of Schedule Y
- **6.** Justification for Conducting the Study in India
- **7.** Details of Export of Biological Sample
- **8.** Application for Export NOC for Biological Samples
- **9.** List of Investigators in India including Site Addresses
- **10.** Name of the participating Countries
- **11.** Total number of patients to be enrolled globally
- **12.** Total number of patients to be enrolled in India
- **13.** Status of Drug in India and other Countries
- **14.** Approvals of the proposed protocol from other participating countries (Notification to USFDA and IRB Approvals in case USA is a partipating country)
- **15.** Ethics Committee Approvals if Available
- **16.** Investigators Brochure
- **17.** Investigational Medicinal Products Dossier
- **18.** Information on active Ingredients (Drug information (Generic Name,Chemical Name or INN) Physicological Data)
- **19.** Data on Formulation
- **20.** Affidavit declaring that the information about study drug as mentioned in Investigators Brochure is correct and based on availlable facts
- **21 . Animal Pharmacological Data:**
  - **21.1** Summary
  - **21.2** Specific pharmacological actions
  - **21.3** General pharmacological actions
  - **21.4** Follow-up and Supplemental Safety Pharmacology Studies
  - **21.5** Pharmacokinetics:- absorption, distribution, metabolism, excretion
- **22 . Animal Toxicological Data as per schedule Y:**
  - **22.1.Systemic toxicity studies**
    - **22.1.1** single dose toxicity
    - **22.1.2** repeated dose toxicity
  - **22.2** Male Fertility Study
  - **22.3** Female Reproduction and Developmental Toxicity Studies
  - **22.4.Local toxicity**
    - **22.4.1** Dermal toxicity
    - **22.4.2** Ocular toxicity
    - **22.4.3** Inhalation toxicity
    - **22.4.4** Vaginal toxicity
    - **22.4.5** Photoallergy or dermal phototoxicity
    - **22.4.6** Rectal tolerance test
  - **22.5** Genotoxicity
  - **22.6** Allergenicity/Hypersensitivity
  - **22.7** Carcinogenicity
- **23 . For Phase 1 Clinical Trial**
  - **23.1.Systemic toxicity studies**
    - **23.1.1** Single Dose toxicity
    - **23.1.2** Dose Ranging Studies
    - **23.1.3** Repeat-dose systemic toxicity studies of appropriate duration to support the duration of proposed human exposure.
  - **23.2** Male Fertility Study
  - **23.3** In-vitro genotoxicity tests
  - **23.4** Relevant local toxicity studies with proposed route of clinical application (duration depending on proposed length of clinical exposure)
  - **23.5** Allergenicity/Hypersensitivity
  - **23.6** Photoallergy or dermal phototoxicity
- **24 . Human / Clinical pharmacology (Phase I):-**
  - **24.1** Summary
  - **24.2** Specific Pharmacological effects
  - **24.3** General Pharmacological effects
  - **24.4** Pharmacokinetics,Absorption,Distribution,Metabolism,Excretion
  - **24.5** Pharmacodynamics/early measurement of drug activity
- **25 . Special Studies:-**
  - **25.1** Summary
  - **25.2** Bio-availability / Bio-equivalence
  - **25.3** Other studies e.g. geriatrics, pediatrics, pregnant, or nursing women.
- **26.** Upload Justification for Quantity applied in Form-12, if applicable
- **27 . Form 12**

Submit

Figure 1.10.

8.On Clicking **Submit** on Checklist page , a new window will open as shown in ***Figure 1.11.***

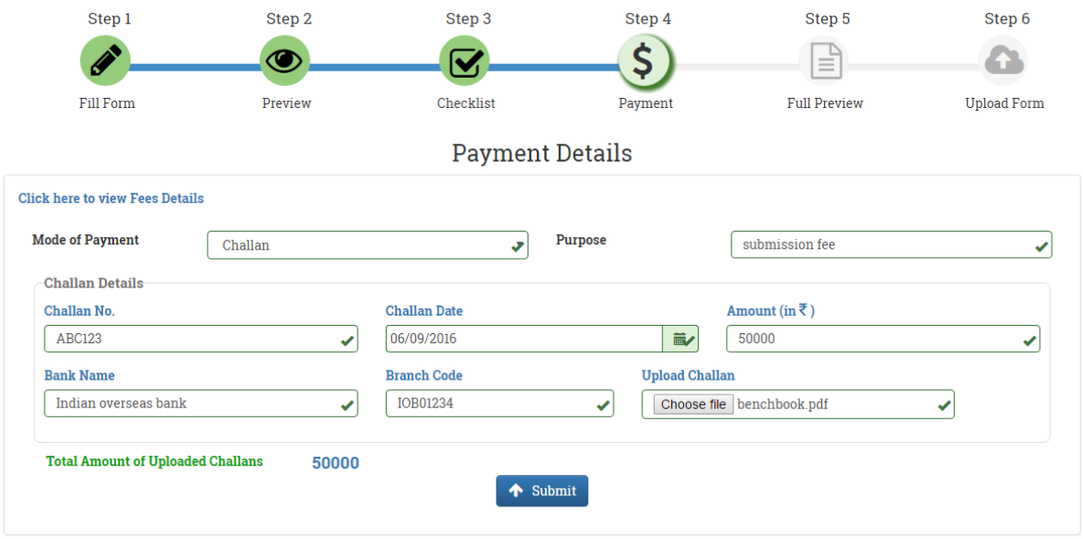


Figure 1.11.

Note:-

- Applicant must fill all the necessary **Payment Details**.

9. On Clicking **Submit ,** a new window will open ,as shown in ***Figure 1.12.***

Step 1 Fill Form | Step 2 Preview | Step 3 Checklist | Step 4 Payment | Step 5 Full Preview | Step 6 Submit Form

FORM 44

Application for grant of permission to import or manufacture a New Drug or to undertake clinical trial.

I/We
Khushboo Pharmacetical Pvt Lt, B-102, Sec-5, Vasundhara Ghaziabad -201012 Telephone No.: 8896418289 Fax : 5677854322 E-Mail : KHUSHBOOMADAN19@GMAIL.COM
of M/s. **Khushboo Pharmacetical Pvt Lt, B-102, Sec-5, Vasundhara Ghaziabad -201012 Telephone No.: 8896418289 Fax : 5677854322 E-Mail : KHUSHBOOMADAN19@GMAIL.COM** hereby apply for grant of permission for import of and/or clinical trial or for approval to manufacture a new drug or fixed dose combination or subsequent permission for already approved new drug. The necessary information/data is given below:

1. Particulars of new drug:

- **1.1.** Name of the drug: **any**
- **1.2.** Dosage form: **Blood & Blood Products (Liquid)**
- **1.3.** Composition Of Formulation:

S.No.	Ingredient	Quantity	Pharmacopial Monograph	Active/Inactive
For Strength 6.0 ml				
1	afy	0.0 Volume/Volume(V/v)	12	Active

- **1.4.** Test specification:
  - **1.4.1.** Active Ingredients: **Enclosed in the checklist.**
  - **1.4.2.** Inactive Ingredients: **Enclosed in the checklist.**
- **1.5.** Pharmacological classification of the drug: **Anticancer**
- **1.6.** Indication for which purpose to be used: **[afda, afdaf]**
- **1.7.** Manufacture of the raw material (bulk drug substances):

S.No.	Premises Name	Premises Type	Premises Address

- **1.8.** Patent status of the drug:

Patent Status	Patent Number	Country	Description

2. Data submitted along with the application (as per Schedule Y with indexing and page nos.)

- **2.1.** Permission to market a new drug:
  - **2.1.1.** Chemical and Pharmaceutical Information : **Enclosed in the checklist.**
  - **2.1.2.** Animal pharmacology :

Study	Status
Specific Pharmacological Actions	Literature Survey
General Pharmacological Actions	Literature Survey
Follow-up and Supplemental Safety Pharmacology Studies	Study Conducted
Conditions under which Safety Pharmacology Studies are not necessary	Study Conducted
Timing of Safety Pharmacology Studies in relation to Clinical Development	Study Not Required
Application of Good Laboratory Practices (GLP)	Waiver

  - **2.1.3.** Animal Toxicology :

Study	Status
Single-dose Toxicity Studies	Study Conducted
Repeated-dose Systemic Toxicity Studies	Study Conducted
Male Fertility Study	Study Conducted
Female Reproduction and Developmental Toxicity Studies	Study Conducted
Local Toxicity	Study Conducted
Allergenicity/Hypersensitivity	Study Conducted
Genotoxicity	Study Conducted
Carcinogenicity	Study Conducted

  - **2.1.4.** Human/Clinical Pharmacology (Phase I) : **Enclosed in the checklist.**
  - **2.1. 5.** Exploratory Clinical Trials (Phase II) : **Not Applicable.**
  - **2.1. 6.** Confirmatory Clinical Trials (Phase III) (including published review articles) : **Not Applicable.**
  - **2.1.7.** Bio-availability, dissolution and stability study Data : **Enclosed in the checklist.**
  - **2.1.8.** Regulatory status in other counteries :

S.No.	Regulatory Status	Approval/Withdrawl Date	Country	Reason for Withdrawl

  - **2.1.9.** Marketing information:
    - » **2.1.9.1.** Proposed product monograph : **Enclosed in the checklist.**
    - » **2.1.9.2.** Drafts of label and cartoons: **Enclosed in the checklist.**
  - **2.1.10.** Application for test license : **Enclosed in the checklist.**
- **2.2.** Subsequent approval/permission for manufactur of already approved new drug:-
  - **2.2.1.** Formulation:
    - » **2.2.1.1.** Bio-availability/bio-equivalance protocol : **Enclosed in the checklist.**
    - » **2.2.1.2.** Name of the investigator/centre : **Enclosed in the checklist.**
    - » **2.2.1.3.** Source of raw material (bulk drug substances) and stability study data : **Enclosed in the checklist.**
  - **2.2.2.** Raw material (bulk drug substances):
    - » **2.2.2.1.** Manufacturing method : **Enclosed in the checklist.**
    - » **2.2.2.2.** Quality control parameters and or analytical specification, stability report : **Enclosed in the checklist.**
    - » **2.2.2.3.** Animal toxicity data : **Enclosed in the checklist.**
- **2.3.** Approval/permission for fixed dose combination:-
  - **2.3.1.** Therapeutic Justification (authentic literature in [peer-reviewed journals]/text books) : **Enclosed in the checklist.**
  - **2.3.3.** Any other data generated by the application on the safety and efficacy of the combination **Enclosed in the checklist.**
  - **2.3.2.** Data on pharmacokinectics/pharmacodynamics combination : **Enclosed in the checklist.**
- **2.4.** Subsequent approval or approval for new indication-new dosage form:
  - **2.4. 1.** Number and date of approval/permission already granted : **Not Applicable.**
  - **2.4. 2.** Therapeutic Justification for new claim/modified dosage form: **Not Applicable.**
  - **2.4. 3.** Data generated on safety or quality parameters : **Not Applicable.**

3. A total fee of rupees **0(in words)** has been credited to the government under the Head of Account .

Place .....
Date 09-Jun-2016

Signature .....
Designation .....

(Note: - Delete, whichever is not applicable).

ANNEXURE

Stability Details

Clinical Trial Study Details

Whether Global Clinical Trial ?

S.No.	Scope/Objective of Trial	Study Design	Is Global Clinical Trial	Participating Countries	Planned No. of Subjects Globally	Planned No. of Subjects in India

Sponsor Details

Sponsor

Download PDF | Continue

Figure 1.12.

Note:-

- Before clicking on **Continue**, Applicant must **Download PDF** and fill required details.

10.On clicking **"Continue",** a new window will open, as shown in ***Figure 1.13.***

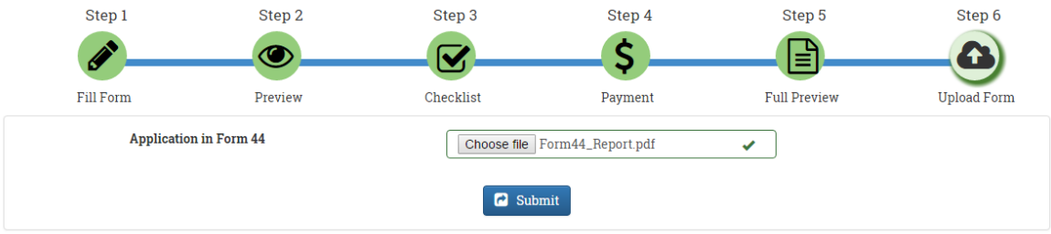


Figure 1.13.

Note:-

- Applicant must upload the Form44 after filling required details.

11.After clicking on **Submit** a new window will open ,as shown in ***Figure 1.14.***

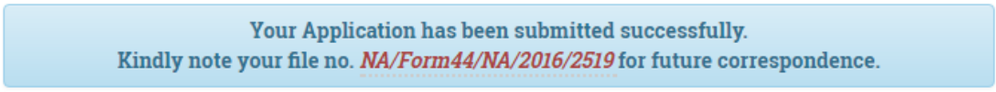


Figure 1.14.

Note:-

- Now the application has been submitted successfully.
- Applicant must note his/her File no. for future correspondence.