


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*.



Central Drugs Standard Control Organisation
Director General Of Health Services
Ministry of Health & Family Welfare, Government of India

Online Forms Submission

Select Department:

Select

Select Form:

Select

☐ I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division.

Proceed


GENERAL INSTRUCTIONS

* User can proceed to Online Form Submission only if the User Profile is complete.

Please read the below instructions carefully before proceeding to Online Form Submission

1. Online Form Submission is divided into few simple steps like:

- Filling of Form
- Uploading Essential Documents in checklist
- Payment (if applicable) and
- Final Form Upload.

2. User is required to download  pdf in Full Preview step. After downloading, perform the following steps:

- Sign and Stamp the form
- Scan the Signed and Stamped Form
- Upload this form in the Upload Form step

3. Please ensure that you have all the required documents ready to upload them in checklist section. Please view the checklist from [here](#)

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*.

Step 1


Step 2


Step 3


Step 4


Step 5


Step 6














Fill Form

Preview

Checklist

Payment

Full Preview

Submit Form

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

Form44 (Part 1)

Form44 (Part 2)

Form44 (Part 3)

Purpose of Application

Purpose Of Application

To Undertake Clinical Trial

Category of new drug

Global Clinical Trial

Application applied for

Finished Formulation

Type of Drug

Single Ingredient

Do you have simultaneously applied for Form 12 ?

No

Select CT

Clinical Trials (phase 1)

Drug Detail

Generic/INN Name(s) of Drug(s)

1

Finished Formulation

Note:

1. User can enter multiple Strength, Indication and Package details.

2. Atleast one strength, indication and Package details must be entered.

3. It is mandatory for the User, to enter the Ingredient details for each strength.

4. At least one Active ingredient should be entered.

Propreitary, Commercial or Trade name of Drug Product

Mitomycin

Dosage Form

Vaccines (Liquid)

Route of Administration

Drinking Water

Pharmacological Classification of Drug

Anticancer

Indication for which proposed to be used

chemo

Click on the '+' sign to add Indication

Cancer

Pack Presentation

Presentation

Select

Packaging Material

Select

Dose



Select

Pack Size

0

Select

Click on the '+' sign to add Package details

Presentation	Packaging Material	Dose	No. of Dose	Pack Size	Delete
Injectors	Bottle	Single Dose	1	1 Blood & Blood Products (Liquid)	
Ampules	Bottle	Single Dose	1	03 Oral Powders	

Storage Condition

2°C - 8°C

Proposed Shelf Life

12

in months

Strength

Select

Field is required

Field is required

Click on the '+' sign to add Strength

50 ml

List of Ingredients/Impurities for Strength(50 ml)

Category

Active

Ingredient

rrgfgs

Pharmacopial Monograph

x I.P.

Strength

<

0

Unit of Strength

ml

Percentage of Claim of Quantity

5



%

5

%

Label Claim

+

Name of Ingredients	Pharmacopial Monograph	Strength	Category	Percentage of Claim	Label Claim	Source of Bulk Drug	Manufacturer Name	Edit
dafaf	I.P.	> 0 ml	Active	5% to 5%	true			 

Save and Continue

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*.

Step 1

Step 2

Step 3

Step 4

Step 5

Step 6

Fill Form

Preview

Checklist

Payment

Full Preview

Submit Form

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

Form44 (Part 1)

Form44 (Part 2)

Form44 (Part 3)

Note:

1 Click on the 'f' button to open the panels.

2 It is mandatory to fill the details in all the panels.

Stability Data

Batch

Batch 1

Duration(months)

6 Month

Batch No.

345235r

Batch Size

1

Presentation

Acid

Date of Initiation of Stability

06/01/2016

Manufacturing Date

06/05/2016

Proposed ShelfLife

1 in months

Storage Condition

Accelerated

Temperature/RH

10°C -20°C

Stability Condition

none

Parameters

Specification

Result(6 Months)

Remarks

Assay(adaf)

5% - 6%

success

good

Water Content

5

success

good

Others

Others

Others

Others

Others

Others

Others

Others

Others

Others

Others

Reset

Save Stability

Manufacturer of Drug Product (adfafasdf)

Site Type

Manufacturing Site

Formulation Site

Primary Packaging Site

Dispatch Site

Secondary Packaging Site

Batch Release Site

Testing Site

Manufacturing Unit

Select

Save

Clear

Manufacturer of Drug Substance (adaf)

Site Type

Manufacturing Site

Formulation Site

Primary Packaging Site

Dispatch Site

Secondary Packaging Site

Batch Release Site

Testing Site

Manufacturing Unit

Select

Save

Clear

Patent Details

Patent

Applicable

Not Applicable

Add Details

Regulatory Status in other countries(adfafasdf)

Regulatory Status in other countries, as appropriate

Add Details

Regulatory Status Form

Regulatory Status

Withdrawn

Date of Withdrawl

06/24/2016

Name of Country

Iceland

Reason

none

Save

Reset

Animal Toxicology Status

Item No.

Title

Status

1

Single-dose Toxicity Studies

Study Conducted

2

Repeated-dose Systemic Toxicity Studies

Study Conducted

3

Male Fertility Study

Study Conducted

4

Female Reproduction and Developmental Toxicity Studies

Study Conducted

5

Local Toxicity

Study Conducted

6

Allergenicity/Hypersensitivity

Study Conducted

7

Genotoxicity

Study Conducted

8

Carcinogenicity

Study Conducted

Animal Pharmacology Status

Item No.

Title

Status

1

Specific Pharmacological Actions

Study Not Requir

2

General Pharmacological Actions

Literature Survey

3

Follow-up and Supplemental Safety Pharmacology Studies

Study Conducted

4

Conditions under which Safety Pharmacology Studies are not necessary

Waiver

5

Timing of Safety Pharmacology Studies in relation to Clinical Development

Literature Survey

6

Application of Good Laboratory Practices (GLP)

Literature Survey

Save and Continue

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*.

Step 1

Step 2

Step 3

Step 4

Step 5

Step 6

Fill Form

Preview

Checklist

Payment

Full Preview

Submit Form

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

Form44 (Part 1)

Form44 (Part 2)

Form44 (Part 3)

Form44 (Part 4)

CT Study Details

Whether Global Clinical Trial

Scope/Objective of Trial

* Prophylaxis

Study Design

Single Arm Trial

Is Global Clinical Trial

Yes

No

Save

Sponsor Details

Sponsor

Self Sponsored

Sponsored by Others

Save

Comparator Drug Details

Add Details

S.No.	Comparator Drug Name	Brand Name	Dosage Form	Route of Administration	Name of Company	Name of Country	Edit
1	Mytocin	Mytocin	Blood & Blood Products (Liquid)	AURICULAR (OTIC)	Mytocin Pvt Ltd	Iceland	<div><div></div><div></div></div>

Disease Under Investigation

Add Details

S.No.	Disease Name	Rare Disease	Edit
1	Asthma	No	<div><div></div><div></div></div>

CT Site Details

Add Details

S.No.	Hospital	No. of Beds	Ethics Committee	Edit
1	Max hospital, Andheri, Sector 6, Mumbai City, Mumbai, MAHARASHTRA	200	Etetr	<div><div></div><div></div></div>

Protocol Details

Add Details

S.No.	Protocol No.	Version No.	Date of Protocol	Dosing	Subject Details	Age Group	Proposed Study Period	Edit
No Records Found								

Local Laboratory Details

Add Details

S.No.	Principal Investigator	Lab Name	Lab Address	Telephone No.	Fax	Email	Edit
No Records Found							

Centralized Laboratory Details

Add Details

S.No.	Lab Name	Lab Address	Telephone No.	Fax	Email	Edit
No Records Found						

Continue


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*.

Step 1




Fill Form

Step 2




Preview

Step 3




Checklist

Step 4




Payment

Step 5



Full Preview

Step 6



Submit Form

Form44 (Part 1)

Form44 (Part 2)

Form44 (Part 3)

Form44 (Part 4)

Part 3

Documents to be uploaded in the checklist

Note: You will be required to upload below listed documents in the checklist section for successful submission of application.

- 1 Test specification:
 - Active Ingredients:
 - Inactive Ingredients:
- 2 Permission to market a new drug:
 - Chemical and Pharmaceutical Information :
 - Bio-availability, dissolution and stability study Data :
 - Marketing information:
 - Proposed product monograph :
 - Drafts of label and cartoons:
 - Application for test license :
- Subsequent approval/permission for manufactur of already approved new drug:-
 - Formulation:
 - Bio-availability/bio-equivalence protocol :
 - Name of the investigator/centre :
 - Source of raw material (bulk drug substances) and stability study data :
 - Raw material (bulk drug substances):
- Approval/permission for fixed dose combination:-
- Subsequent approval or approval for new indication-new dosage form:

☒ I hereby declare that I will enclosed the above listed documents in the Checklist and I will be solely responsible for any false or inaccurate document provided to the division.

Continue

Figure 1.5.

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

Step 1

Step 2

Step 3

Step 4

Step 5

Step 6

Fill Form

Preview

Checklist

Payment

Full Preview

Submit Form

FORM 44

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

I/We
Khushboo Pharmaceutical Pvt Lt, B-102, Sec-5, Vasundhara Ghaziabad -201012 Telephone No.: 8896418289 Fax : 5677854322 E-Mail : KHUSHBOOMADAN19@GMAIL.COM
of M/s Khushboo Pharmaceutical 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
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1.8. Patent status of the drug:

Patent Status	Patent Number	Country	Description
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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 countries :

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

Step 1




Fill Form

Step 2




Preview

Step 3




Checklist

Step 4




Payment

Step 5



Full Preview

Step 6



Submit Form







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/alterd under the Saved Application link available on the Dashboard

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

↑ Submit

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*.

Upload Certificate

Covering Letter

Browse...

No file selected.

Remarks

Enter Remarks

Submit

Reset

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*.

Upload Certificate

Covering Letter

Remarks

Thanks

Upload Certificate

Browse...

No file selected.

☒ Click to change File

Update

Reset

Figure 1.9.

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

Step 1


Step 2

Step 3

Step 4


Step 5

Step 6


Fill Form

Preview

Checklist

Payment

Full Preview

Submit Form

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/alterd 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 participating 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) Physiological Data)
	19. Data on Formulation
	20. Affidavit declaring that the information about study drug as mentioned in Investigators Brochure is correct and based on available 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 I 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*.

Step 1

Fill Form

Step 2

Preview

Step 3

Checklist

Step 4

Payment

Step 5

Full Preview

Step 6

Upload Form

Payment Details

Click here to view Fees Details

Mode of Payment

Challan

Purpose

submission fee

Challan Details

Challan No.

ABC123

Challan Date

06/09/2016

Amount (in ₹)

50000

Bank Name

Indian overseas bank

Branch Code

IOB01234

Upload Challan

Choose file

benchbook.pdf

Total Amount of Uploaded Challans

50000

Submit

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

Step 2

Step 3

Step 4

Step 5

Step 6

Fill Form

Preview

Checklist

Payment

Full Preview

Submit Form

FORM 44

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

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

S.No.	Regulatory Status	Approval/Withdrawal Date	Country	Reason for Withdrawal
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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-equivalence 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 pharmacokinetics/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
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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*.

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Fill Form Preview Checklist Payment Full Preview Upload Form

Application in Form 44

Choose file Form44_Report.pdf ✓

Submit

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*.

Your Application has been submitted successfully.
Kindly note your file no. **NA/Form44/NA/2016/2519** for future correspondence.

Figure 1.14.

Note:-

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