Form D3 BRL-1: APPLICATION TO UNDERTAKE CONFINED FIELD TRIAL AND TO UNDERTAKE SAFETY STUDIES OF GENETICALLY ENGINEERED CROPS/ PLANTS FOR AGRICULTURAL AND ENVIRONMENTAL USE

Instructions to follow

Parent UAC:

- PART 1
- PART 2
- PART 3
- PART 4
- PART 5
- PART 6
- PART 7
- PART 8

PART 1

A. Applicant Details :

Organization Name :

Name of Applicant :

Designation :

Address/Line-1 :

Address/Line-2 :

State / UT :

District :

Village / Town / City :

Pin Code :

Office Phone Number :
With STD Code

Mobile No :

Email :

B. Application Type :

Biosafety Research Level-1 (BRL-1)

C. Application For :

D1. Product Code :

Choose/ generate the CODE, which explicitly conveys the essence of the proposed work. Kindly note that the same code might be used for generation of future references.

D2. Status of the project :

Revised Submission New Submission

E. Chronology of approval(s) accorded so far by the IBSC for the event(s) under investigation :

- Mention the date(s) of IBSC meeting wherein various considerations pertaining to the event(s) under investigation were deliberated and approved.
- Enclose color photocopy(ies) of the minutes of the relevant IBSC meeting(s)

Upload

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F. Chronology of approval(s) accorded so far by the RCGM for the event(s) under investigation:

- Mention the date of permission(s) issued previously by the GEAC for the event(s) under investigation.
- Enclose color photocopy(ies) of permit(s) issued earlier

Upload

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G. Chronology of approval(s) accorded so far by the GEAC for the event(s) under investigation :

- Mention the date of permission(s) issued previously by the GEAC for the event(s) under investigation.
- Enclose color photocopy(ies) of permit(s) issued earlier

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H. background about the event(s) under investigation :

H.1: Event(s) Identity :

Write self-explanatory name of the product

H.2: Country of Origin :

In Case,plant material to be used in the confined field trial is imported,
provide NBPGR import permit number with date of import/relevant approval letter.

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H.3: Trait(s) for which applied for :

To be submitted as bullet points

H.4: Status of approval & marketing history in country of origin and worldwide :

PART 2
Unmodified plant species

I. Unmodified plant species

Latin Name	Common Name	Biology Document for the Plant Species [?] Whether attached? or published by Regulatory Agency
		Upload Upload NMT 5 MB

I.1: Whether the unmodified plant species has an extended history of safe use in Food, Feed, and Agriculture?

Provide details.

Yes No

If no, provide details thereof

I.2: Is the plant species considered to be weedy or naturally invasive?

If yes, list any locations below

Yes No

I.3: Are there any member(s) of the family of plant species considered to be weedy or naturally invasive in India?

If yes, list any locations below

Yes No

I.4: Are there sexually compatible wild relatives of the plant species Globally?

If yes, list any locations below

Yes No

I.4.1 Are there significant free-living populations of the plant species in India?

If yes, list name of species and locations below.
Free-living plant populations are those which are able to survive,
without direct human assistance,over the long term in competition with the native flora.

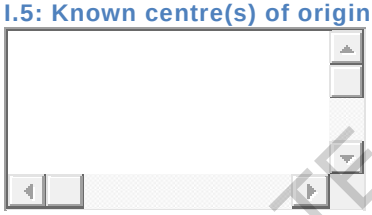
( ) Yes (•) No

I.4.2 Are there sexually compatible wild relatives of the plant species in the State (s) where trial(s) proposed to be conducted?

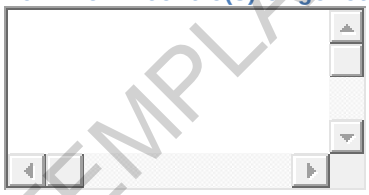
If yes, list name of species and locations below

( ) Yes (•) No

I.5: Known centre(s) of origin of plant species

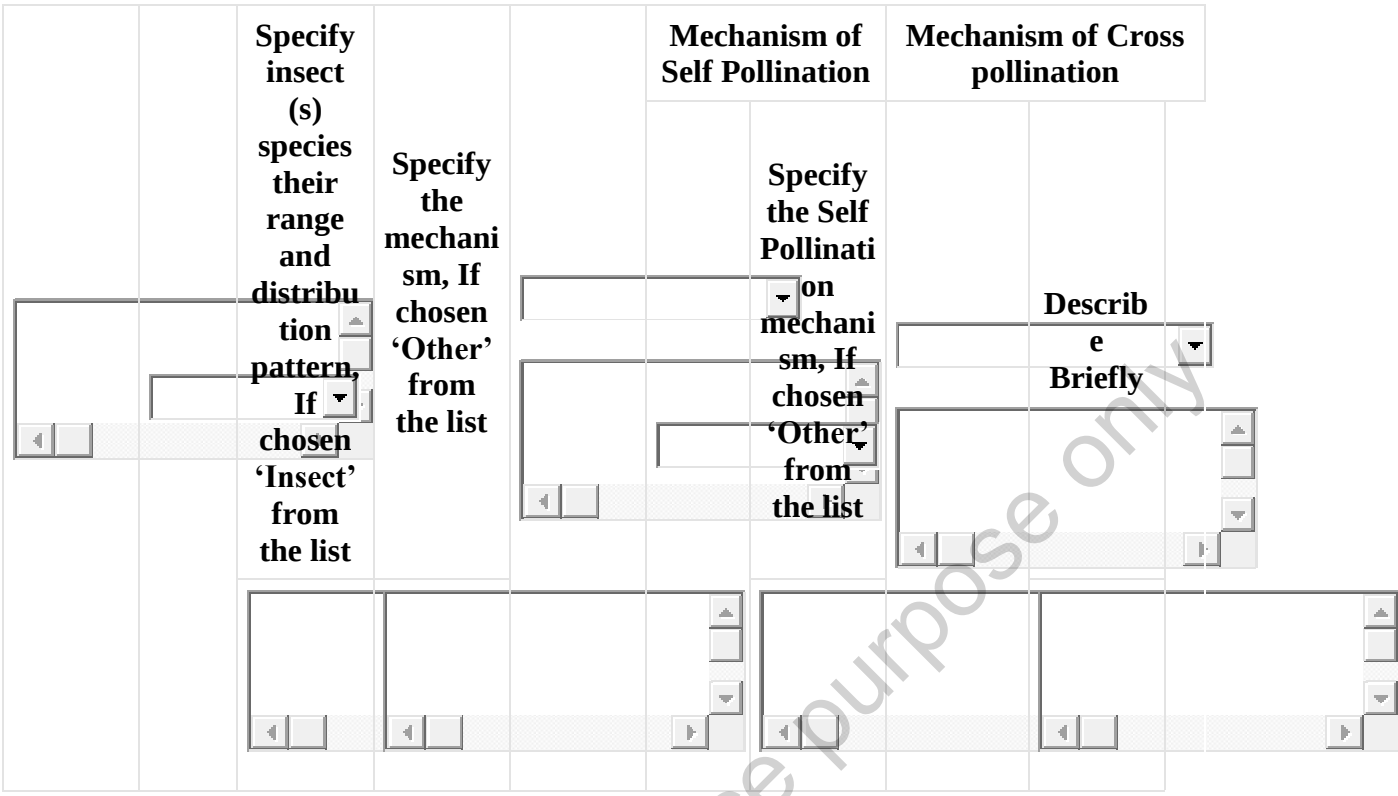


I.6: Known centre(s) of genetic diversity

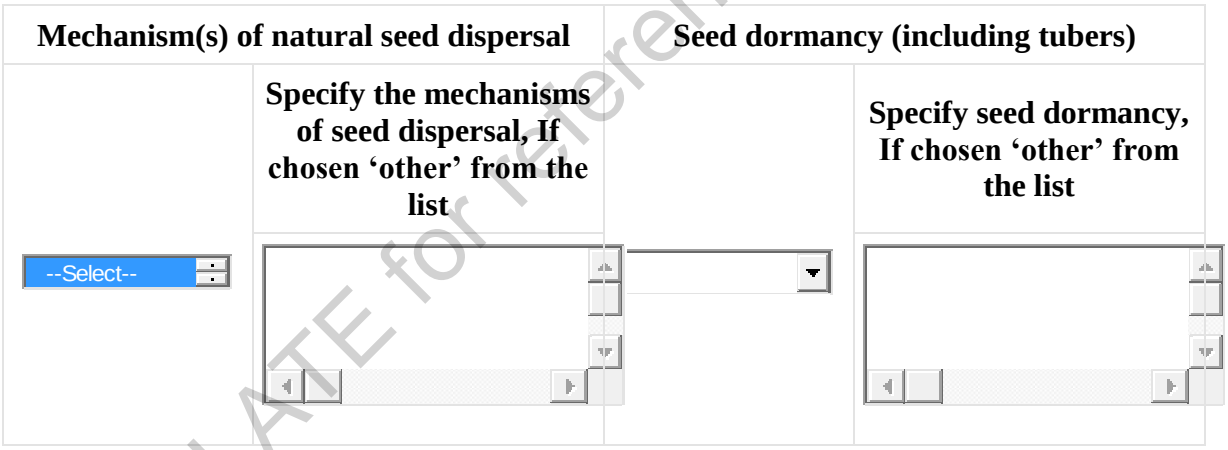


I.7: Pollen Behaviour

Details of pollen viability and physiology	Mechanism of pollen dispersal	Mode of Pollination

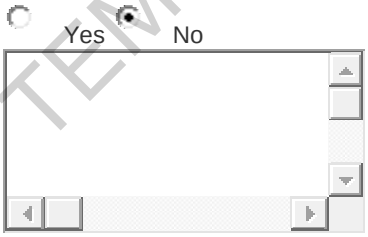


I.8: Seed Physiology



I.9: Is the plant species known to be allelopathic?

If yes, provide further details



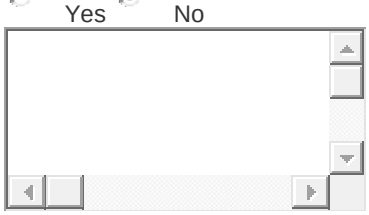
I.10: Is the plant species known to be a source of substances toxic to humans or animals?

If YES, name the compounds, the levels that induce toxicity, and the affected species.

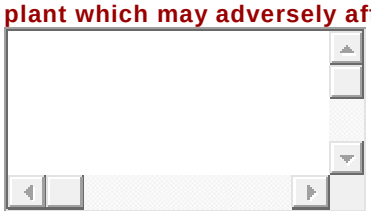
I.11: Is the plant species known to be a source of human allergens?

If yes, provide details thereof.

Yes No



I.12 Details of anti-nutrients and secondary metabolites inherently present in the recipient plant which may adversely affect human/animal health.

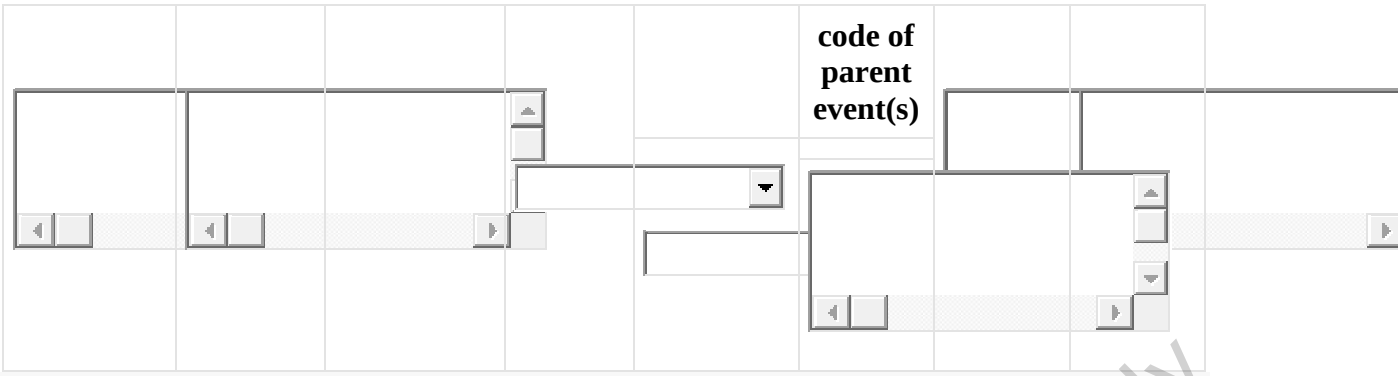


PART 3

J. Information on the genetically engineered plant

J.1 CATEGORY OF GENETIC MODIFICATION		
--Select--	Specify the category, If chosen 'Other' from the list	Specify seed dormancy, If chosen 'other' from the list

J.2 NUMBER OF EVENTS TO BE EVALUATED	J.3 IDENTIFICATION CODE(S) OR EVENT(S) NAME FOR EACH GE EVENT INCLUDED IN THE APPLICATION	J.4 THE EVENT(S) ARE			J.5 GENERATION OF THE EVENT (S)	J.6 PEDIGREE INFORMATION OF EVENT (S)
		--Select--	Stacked event(s) generated through			Upload Upload NMT 1 MB
			Feature of Molecular Stack	The identification		



J.7: Phenotype

J.7.1 Whether the genetic modification leads to change in the plant phenotype compared to the unmodified plants of the same genotype?

If Yes, describe the effects of genetic engineering of the plant phenotype (list the changes Such as difference in appearance of the plant like increased tillering or branching).

Yes No

J.7.1.1 If it is intended modification explain the mechanism of action:

J.8 A: Previous confined field trials

J.8.1 Whether the event(s) tested in India previously?

If YES, enter most recent trial authorization along with outcome of the trial.

Yes No

J.8.2 Event(s) previously approved for unconfined (general or commercial) release in other countries?

If YES, list countries and year of approval.

Yes No

J.8 B: MODIFICATION METHOD

	Specify the method, If chosen 'Other' from the list	Describe the transformation method(s) followed
--Select--		Upload Upload NMT 1 MB

J.9: Previous approval for unconfined release (for BRL only)

If YES, list countries and year of approval.

J.9.1 Whether the event(s) previously approved for unconfined (general or commercial) release in other countries?

If YES, list countries and year of approval.

Yes No

J.10: Selection agent(S) used to regenerate transformed cell / plant

	Specify the selection agent, If chosen 'Other' from the list	Provide more details of the selection agent
--Select--		

J.11: Introduced DNA

J.11.1 Gene Constructs

	Gene Construct Name	Size of the Gene Construct (kb)	GenBank Acce the vecto
--Select--			

J.11.1.1 Briefly describe changes introduced in the vector, if any

J.11.1.2 Mode of action of transgene(s)

J.11.1.3 Does the introduced DNA give rise to any infectious agent?

If Yes, provide details.

YES NO

J.11.1.4 Does the introduced DNA contain any sequences derived from Known human, animal or plant pathogens?

If Yes, provide details.

YES NO

J.12: Construct composition and expression

J.12.1 Gene Construct

J.12.1.1 Gene Cassettes

Provide information for each genetic element (or feature) of the construct and transformation vector, including coding and antisense sequences, promoters, enhancers, termination and polyadenylation signal sequences.

J.12.1.1.1 Trait Category

--Select--

Cassette

J.12.1.1.2 Genetic Elements

Name	Feature Type	Only if chosen feature type is "OO-Other"	GenBank Accession Number	Starting Position (bp)	End Position (bp)	Size (kb)
	--Select--					

J.12.1.1.2a Whether any modification(s) incorporated in native DNA sequence of the genetic element?

If yes, provide details thereof.

YES NO

J.12.1.1.2b Whether the genetic element is coding for a polypeptide/ protein?

If yes, provide below mentioned information.

YES NO

Coding Region Start position (bp)	Coding Region End position (bp)

J.12.1.1.2c Whether the genetic element is a promoter/ regulatory sequence?

If yes, choose relevant option from dropdown menu.

YES NO

--Select--

J.12.1.1.2d Source Organism

Common Name	Genus & Species Name

J.12.1.1.2da Whether the source organism is a source of known toxin(s) and/ or allergen(s)?

if yes, provide details thereof.

YES NO

J.12.1.1.2db Whether the source organism has history of use in consumption?

If YES, provide details of the use (e.g, country, types of uses, tissues used, including any approved food use by regulatory authorities etc.)

YES NO

J.12.1.1.2dc Whether the protein(s) encoded by the introduced DNA known for any post-translational modification in donor organism?

if yes, provide details thereof.

YES NO

J.12.1.1.2e Whether the genetic element share homology with gene(s)/ regulatory sequence(s) of the host plant used for genetically engineering?

If YES, list below mentioned details (provided that DNA sequence of the homologous/ orthologous genetic element/ or genome of the host plant is known)

YES NO

	S.No.	Name of homologous/ orthologous genetic element(s) in the GE host plant	GenBank Accession Number(s), if available and nucleic acid sequence in FASTA format	Extent (%) of homology between the nucleic acids
☐	01			

J.12.1.1.3 RNA Expression

Provide information for each expressed RNA (mRNA, antisense RNA, miRNA, siRNA etc.) from the gene cassette.

J.12.1.1.3a RNA

Type of RNA Expressed	Provide relevant details, if, type of RNA expressed other than the mentioned list	Name of the Gene Transcribed	Size of the Expressed RNA (base)	Whether RNA Expression is	If the expression is other than the Constitutive, provide information whichever is relevant			
					Specific Tissue(s)	Inducer(s)	Developmental Stage(s)	Other
--Select--				--Select--				

J.12.1.1.3aa Relative Expression Level (BRL-1 only)

S.No.	Reference gene(s) used to determine relative expression level	GenBank accession number of the reference gene(s)	Method of qRT-PCR followed e.g., SYBR green, Taqman, Molecular Beacon etc.

J.12.1.1.3ab Provide information for the expressed RNA in each tissue of GE plant

Tissue No.	Plant part/tissue used to determine the relative expression level	Details of inducers of the gene expression, if any [?] e.g. stress induction, pathogen inoculation etc. of the sampled plant part/tissue used to determine relative expression level	Relative Expression Level

J.12.1.1.4 Protein Expression

Provide information for expressed protein product(s) from the gene cassette

J.12.1.1.4a Proteins

Sr. No.	Name of the Protein	Molecular weight (kDa) of the protein	Amino acid sequence of the expresses protein in FASTA format.	Whether Protein Expression is	If the expression is other than the Constitutive, provide information whichever is relevant			
					Specific Tissue(s)	Inducer(s)	Developmental Stage(s)	Other
				--Select--				

J.12.1.1.4aa Level of expression in all parts of the GE Plant.

Sr.No.	Plant Part	Specify the Plant part, If chosen 'Other' from the list	Range of Expression and Mean Expression Level (µg/g DW)
☐	--Select--		

J.12.1.1.4ab Protein detection procedure

Details of the procedure followed for protein detection	Detection Limit of the method followed (ng)
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J.12.1.1.4ac Is the protein a known human allergen?

If yes, Provide details thereof.

○ YES ◉ NO

J.12.1.1.4ad Is the protein known to be toxic to humans or non-target organisms?

If yes, Provide details thereof.

○ YES ◉ NO

J.12.1.1.4ae Background information on history of use, allergenicity, and toxicity of the introduced transgene protein

J.12.1.1.4af Bioinformatics analysis of the expressed protein, to detect homology with allergens, anti nutrients and toxic proteins

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J.13: Characterization of event(S) (For BRL-1)

J.13.1 Gene Construct

J.13.1.1: Confirmation of the genetic engineering to show the presence of transgenes in the event (e.g. PCR Analysis)

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J.13.1.2: Determination of copy number of the inserted gene construct (e.g. Southern Blot Analysis)

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J.13.1.3: Annotated nucleic acid sequence of the integrated gene construct (from RB to LB) along with the flanking region in FASTA format.

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J.13.1.4: Sequence of the event specific primers

Forward (5'-3') :

Reverse (5'-3') :

J.13.1.5: Size of the amplicon generated using the event specific primers (kb)

J.13.1.6: Genomic location (Chromosome number) and site of integration

J.13.1.7: Name of flanking region endogenous gene(s) of the host plant

J.13.1.8: Percent similarity of the flanking region DNA sequence to known genome sequences of the host plant species

J.13.1.9: ORF analysis of integrated gene construct and flanking DNA sequence after joining right and left border flanking sequences. If new or chimeric ORF(s) detected,bioinformatics analysis of such ORF(s) to find out homology with known allergens,toxins, and anti-nutrient factors.

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J.13.1.10: Whether the vector backbone sequence(s) present in the selected event?

YES NO

J.13.1.10.1: If No, provide confirmatory data ascertaining the absence of vector backbone sequence(s)

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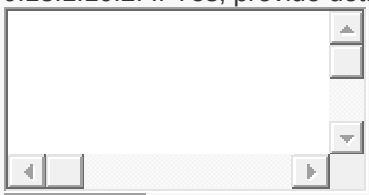
J.13.1.10.2: If Yes, provide details of the vector sequence present



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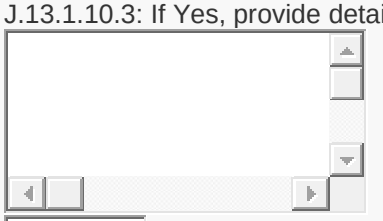
J.13.1.10.3: If Yes, provide details, if vector sequence alone is transferred elsewhere in the genome



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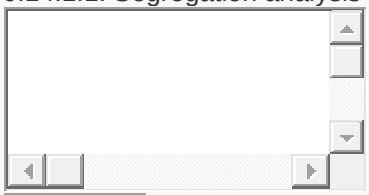
J.14: Genetic stability of the event(S) (For BRL-1 and BRL-2 trial)

J.14.1 Gene Construct

J.14.1.1: Segregation analysis of the gene construct in event(s)



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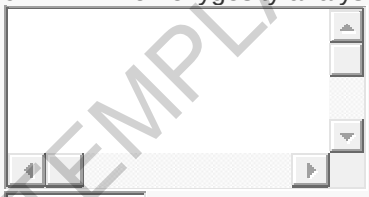
J.14.1.2: Homozygosity analysis of event(s)



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J.14.1.4: Gel images and summary table for detection of genetic fidelity of the event with non-GE parent(s)

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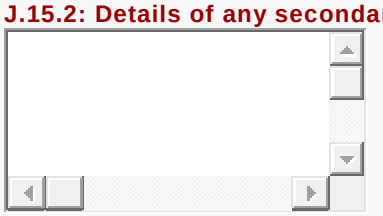
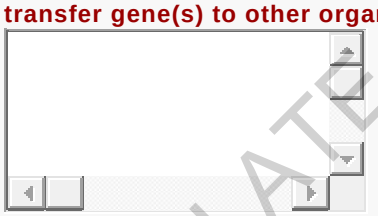
J.15: Unintended changes due to genetic modifications

J.15.1: Details of pleiotropic effects on the parent plant that may result from the expression of the transgene(s), or an insertion related mutation in the GM plant event(s), (e.g., disease susceptibility, effects on fertility, production, grain shedding) including the likelihood of any such event(s)

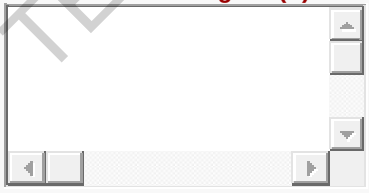
J.15.2: Details of any secondary genetic effects that is anticipated or may be anticipated



J.15.3: Details whether the genetic modification limits or eliminate any capacity to reproduce or transfer gene(s) to other organism, if any.



J.15.4: If the inserted gene construct(s)/trait(s) transferred to a related species, what advantages the recipient plant(s) are likely to have over members of the species that do not contain the transgene(s)



J.16: Identification method

J.16.1: Details of the selection markers, DNA sequences and methods that will enable the GM plant to be identified in laboratory

J.16.2: Details of the markers, sequences, and methods that will enable the GM plant to be identified in field conditions

J.16.3: Provide experimental protocol for the detection of proposed event(s) at 0.01% Limit of Detection (LOD).

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J.17: Intended on anticipated changes due to genetic modification.

J.17.1: Whether the genetic modification intended to alter plant weediness?

If YES, describe which parts/plants

Yes No

J.17.3: Whether the genetic modification intended to alter plant nutrient composition?

If yes, provide details thereof

Yes No

J.17.4: Whether the genetic modification intended to alter allelopathic characteristics of a plant?

If yes, provide details thereof

Yes No

J.17.5: Whether the genetic modification intended to alter seed dormancy, viability or germination rate?

If yes, provide details thereof

Yes No

J.17.6: Whether the genetic modification intended to alter pollen dispersal?

If yes, provide details thereof

Yes No

J.17.7: Whether the genetic modification intended to alter seed dispersal?

If yes, provide details thereof

Yes No

J.17.8: Whether the genetic modification intended to alter vegetative dispersal?

If yes, provide details thereof

Yes No

PART 4

K. Information on the trial site

K.1 Trial in charge

Name :

Designation :

Organization :

Address/Line-1 :

State / UT :

District :

Village / Town / City :

Pin Code :

Office Phone Number :

With STD Code

Mobile No :

Email :

K.2 Trial site

K.2.1 Applicant's site location code

K.2.2 No. of trials to be conducted at this location

K.2.3 Trial site/ plot size (ha or m^2)

Provide details of gross and net plot size

K.2.4 Provide Trial site location and GPS coordinates.

K.2.5 Details of ownership and agreement

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K.2.6 Distance to nearest cultivated crop of the same species (m)

K.2.7 Distance to nearest commercial crop of any kind (m)

K.2.8 Is the isolation distance under the control of Trial-in Charge's control?

Yes No

If No, provide details thereof

K.2.9 Whether the isolation distance is in conformity with the standards specified for certified seed production of the crop?

Yes No

If No, provide the reason thereof

K.2.10 Whether the trial site soil is suitable for cultivation of the crop proposed?

Yes No

- If yes, provide basic soil data (soil type, pH, EC, etc.)
- If No, provide reason(s) for proposing trial at this location

K.2.11 Whether the trial site falls in the location of hot spot areas of target pest/disease as per the previous information available?

Yes No

If No, provide reason(s) for proposing trial at this location

K.2.12 Whether the trial site is suitable for the crop proposed and intended trait as per the previous information available(e.g hot spot for biotic and abiotic stress traits)?.Provide details.

Yes No

If No, provide reason(s) for proposing trial at this location

K.3 Trial Layout Plan and Trial Protocol

K.3.1 Has a complete map of the trial site been enclosed?

Yes No

If No, the completed map must be provided to RCGM/ GEAC within seven (7) working days following sowing/ planting.

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K.3.2 Have you attached the experimental design of the trial?

Yes No

- If Yes, specify trial design (i.e. Split-block, strip-plot, Randomized Block, etc.)and enclose relevant experimental details
- If No, provide the reason thereof

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K.4 Habitat

K.4.1 Is the trial site part of a managed ecosystem (i.e. agricultural land)?

Yes No

If YES, how close is the nearest natural ecosystem?

K.4.2 Is there an area of special ecological interest (e.g. biodiversity park, protected area, Sanctuary) near the trial site?

Yes No

If YES, briefly describe

K.5 Indigenous Species

K.5.1 Describe any sexually compatible wild or cultivated plant species that are in the vicinity of the trial site.

K.5.2 Are there any endangered or threatened species on or near the trial site?

Yes No

If YES, list them

K.5.3 What mechanisms are in place to prevent local fauna from removing plant material from the trial site?

PART 5

L. The Trial Protocol

L.1 Important Dates

L.1.1 Anticipated planting date

L.1.2 Anticipated Flowering date

L.1.3 Anticipated harvest date

L.2 Study Description

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L.2.1 Purpose of the field trial

L.2.2 Experimental Design

Shall also include details of site characterization, soil physiochemical properties, crop management practices, imposition of treatments - care during sprays, soil applications of nutrients/ manure/ bio-inoculants, irrigation management, sampling, avoiding spray drifts, past weather data (if trial is for abiotic stresses), etc.

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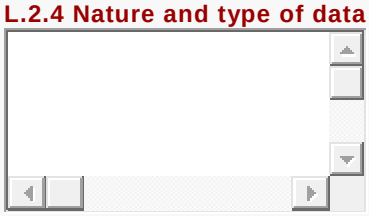
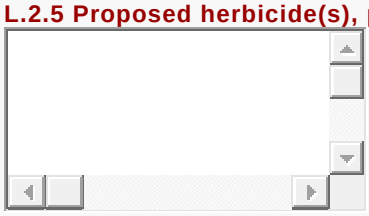
L.2.3 Number of trap rows and length

L.2.4 Nature and type of data to be collected



L.2.5 Proposed herbicide(s), pesticide(s) to be used



L.2.6 Elaborate statistics to be applied for trait efficacy and agronomic parameter.

L.2.7 Whether the training/ awareness for field/ground staff involved in conduct and handling of material of CFTs and Good Agricultural Practices is proposed

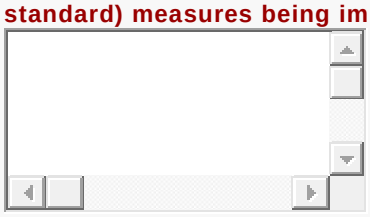
Yes No

- If Yes, provide relevant information
- If No, provide reason(s) there of

L.3 Reproductive Isolation

--Select--

L.3.1 Describe the reproductive isolation (according to the Indian minimum seed certification standard) measures being implemented for this trial and give details



L.3.2 Whether the size of trial site(s) is adequate to maintain isolation distance from experimental plot(s) according to the Indian minimum seed certification standard?

Yes No

- If Yes, provide relevant information
- If No, provide reason(s) thereof

L.4 Transportation

L.4.1 Describe how genetically engineered seed and/or plant material will be packaged for transport

L.4.2 Describe how containers and/or packaging material will be sanitized and/or disposed of after use.

L.4.3 Describe how containers or packets containing genetically engineered seed or plant material will be labelled.

L.4.4 Describe how safe custody will be ensured and the type of records that will be retained.

L.5 Planting

L.5.1 How will material be planted?

By Hand Mechanically

L.5.2 Will any unmodified plants of the same or a related species be planted at the trial site location?

Yes No

- If Yes, briefly explain why?
- Also provide complete details of nursery raising in case the final trial is conducted using transplanted seedlings.

L.5.3 If any equipment is to be used during planting, explain how it will be cleaned on the trial site.

YES

NO

L.5.4 Describe how surplus planting material will be rendered nonviable at the trial site.

L.5.5 Describe how quantities of seed planted and any excess will be recorded.

L.6 Pesticide(s)/herbicide(s) Applications

Complete this section only if an unregistered product will be used at the trial site.

L.6.1 Name of the proposed pesticide(s)/ herbicide(s)

L.6.2 Whether the application to CIB & RC has been made for registration of pesticide(s)?

Yes No

- If Yes, briefly explain the status of the application
- If No, provide reason(s) thereof

L.6.3 Active ingredient(s)

L.6.4 Number of applications per crop season

L.6.5 Anticipated stage(s) of crop at which pesticide(s)/ herbicide(s) will be used

L.6.6 Total area to be sprayed (square meters) along with details of treatment plot(s) to be sprayes

L.6.7 Steps taken to avoid spray drift to nearby plots

L.7 Harvesting

L.7.1 Will plants be allowed to set seed?

Yes No

L.7.2 How will material be harvested?

By Hand Mechanically

L.7.3 Will any harvested plant material be retained from the trial?

Yes No

If Yes, briefly explain the purpose of retaining plant material.

L.7.4 Describe the storage method and storage location of harvested materials, if applicable.

L.7.5 If any equipment is to be used during trial, explain how it will be cleaned on the trial site.

L.8 Monitoring the trial site

L.8.1 Describe the extent and frequency of trial site monitoring during the current growing season.

L.8.2 Describe what monitoring results will be recorded.

L.8.3 If any controlled monitoring protocols are proposed (e.g., planting of unmodified plants of a related species to determine the possibility and frequency of gene flow), describe these.

L.9 Emergency plans for accidental release

L.9.1 Describe your contingency plans in the event of an accidental release of seed or plant material or a breach of reproductive isolation.

L.9.2 Describe your contingency plan in the event of an unexpected spread of genetically engineered plant material after an accidental release.

PART 6

M. Environmental safety studies

M.1 Weediness and aggressiveness potential

M.1.1 Whether the proposed study is to be conducted? If "NO", provide reason(s)

- 1. On opting "Yes" for whether weediness and aggressive potential studies to be conducted, fill details in this section. In case of "No",the applicant is required to provide a reason for thereof and the section (M1.2-1.4) automatically gets disabled and the applicant can move on to next section(M2).
- 2. Protocol to include parameters % seed germination , speed of germination, seed dormancy, seedling & vegetative vigour index to be tested for laboratory studies and field based studies.
- 3. Mentioned " Not applicable" wherever required.

YES

NO

M.1.2 Objective(s)

M.1.3 Protocol for weediness and aggressiveness potential.

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (Upload NMT 5 MB).

M.1.4 Whether any additional information is to be submitted.

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 5 MB).

M.2 CROSSABILITY AND POLLEN FLOW

- 1. On opting "Yes" for whether crossability and pollen flow studies conducted, fill details in this section. In case of "No",the applicant is required to provide a reason for thereof and the section (M2.2-2.4) automatically gets disabled and the applicant can move on to next section (M3).
- 2. Name of the trail in charges and address of the field where the proposed studies are to be conducted.
- 3. Pollen parameters protocol to include sampling details, microscopic analysis proposed, pollen viability, pollen longevity and physical parameter of pollen to be tested.
- 4. Intraspecies crossability study protocol to include detailed concentric plot design, name of Non-GE crop grown around GE crop and name of species planted in border rows, method proposed for testing presence of transgene in next generation.

- 5. Interspecies crossability study protocol to include detailed plot design, snowing details, number of interspecies to be studied and name of species planted in border rows if any, method proposed for testing presence of gene in next generation.
- 6. Mentioned "Not applicable" wherever required.

YES

NO

M.2.2 Objective(s)

Use bullets for different objectives

M.2.3 Provide details of person responsible for the disposition and/or storage of harvested material

Name :

Designation :

Organization :

Address/Line-1 :

State / UT :

District :

Village / Town / City :

Pin Code :

Office Phone Number :

With STD Code

Mobile No :

Email :

M.2.4 Crossability study

M.2.4.1 Protocol for study of pollen parameters.

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 5 MB).

M.2.4.2 Protocol for Intraspecific crossability.

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 5 MB).

M.2.4.3 Protocol for Interspecific crossability.

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 5 MB).

M.2.4.4 In case of any additional information is to be submitted please provide details otherwise mention mention NA.

Upload

M.3 Assessment of effects of GE plants on soil microorganisms

M.3.1 Whether the proposed study is to be conducted? if "NO" provide reason(s).

- 1. On opting "Yes" for whether assessment of effects of GEplants on soil microorganisms studies to be conducted, fill details in this section. In case of "No",the applicant is required to provide a reason for thereof and the section (M.3.2-2.7) automatically gets disabled and the applicant can move on to next section (M4).
- 2. Appropriate statistical methods to be followed for all the data collection.

YES

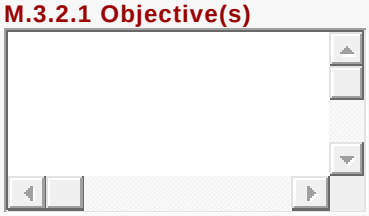
NO

M.3.2 Protocol for soil microbial study

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 5 MB).

M.3.2.1 Objective(s)



Use bullets for different objectives

M.3.2.2 Indicate soil sampling procedure(s)

Upload

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M.3.2.3 Indicate methodologies for microbiological analysis.

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 5 MB).

M.3.2.4 Indicate methodologies for baseline assessment.

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 5 MB).

M.3.2.5 Provide details of the laboratory where microbiological analysis would be performed.

Name of the laboratory :

Address :

Existing accreditation(s) in support of the activity :

Name of laboratory in charge :

Address and contact :

M.3.2.6 Information on packaging, transport and storage of soil sample before analysis,if required

M.3.2.7 Whether any additional information is to be submitted.

Upload

M.4 STUDY ON PESTS/DISEASES AND BENEFICIAL ORGANISMs

- 1. Trait efficacy should be tested at hotspots preferably. Infestation (artificial/natural) should be above ETL.
- 2. Standard protocol to be adopted.
- 3. Appropriate statistical methods to be followed for all the data collection.
- 4. On opting "YES" for section M.4.b fill details in this section. In case of "No", the section (M.4.B) automatically gets disabled and the applicant can move on to next section (N).
- 5. Mentioned "Not applicable " wherever required.

M.4.A Study for Non target organisms

M.4.A.1 Objective(s)

Use bullets for different objectives

M.4.A.2.1 Provide names of all the non-target organisms likely to be found on transgenic plants i.e. major and minor pest, predators, pollinators, soil dwelling insects, nematodes. Also list the diseases of the crop/plant under study.

M.4.A.2.2 Provide detailed protocol and parameter to be studied at different time periods on different plant parts for assessment of all the non-target organisms including predators and pollinators at all the trial locations with supporting reference/guidelines/published papers.

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 5 MB).

M.4.A.2.3 Provide pest/disease resistant status of the parents/variety/hybrid used, if available e.g., AICRP reference or any other similar references.

M.4.A.2.4 Provide spray details (of insecticide/fungicide/herbicide) on GE and Non-GE.

M.4.B Is Trait related to plant protection

- ( ) YES
- (•) NO

If yes, then additionally furnish the following.

M.4.B.1 Study for Target organisms.

M.4.B.2 Objective(s)

Use bullets for different objectives.

M.4.B.3 Category in plant protection

	Infestation Data			
	Name of the Target pests/disease agents/nematodes	Name of the tissues of the plants infested by each pest	Visible symptoms produced by the target pests/diseases/nematodes	Vector/Carrier of the disease(s)
--Select--				

M.4.B.4 Provide in brief the mode of action of the introduced gene in relation to plant protection.

M.4.B.5 Provide detailed protocol to be followed for bioefficacy studies for all the trial locations.

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M.4.B.6 if any study on synergism or additive effect of the proteins expressed on target pests will be conducted? If yes provide details.

M.4.B.7 Provide protocol for baseline susceptibility studies for all the target pests including the disposal of experimental material(s).

Population should be preferably selected from hotspots for the study.

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 5 MB).

M.4.B.8 Provide spray details (insecticide/fungicide/herbicide) on transgenics and non transgenics at different crop stages (preferably in tabular form).

M.4.B.9 Is there any report of resistance development by the target pests to the expresses proteins anywhere in India and in world ? If yes give details and supporting references.

M.4.B.10 List of other studies to be conducted with detailed protocol and justification.

Upload

PART 7

N. Food and feed safety studies

N.1 Compositional analysis

N.1.1 Whether the proposed study is to be conducted? If "NO", provide reason(s)

- 1. On opting "Yes" for whether compositional analysis conducted, fill details in this section. In case of "No",the section (N1.2-1.7) automatically gets disabled and the applicant can move on to next section(N2).
- 2. Duration between sample collection and analysis should not exceed 1 year.
- 3. Ensure that all the samples per trial site are not less than triplicates.
- 4. Mention "Not applicable" wherever required.

YES

NO

N1.2 Objective(s) for the proposed studies.

Use bullets for different objectives.

N.1.3 Address and accreditation status of the facility where studies are proposed to be conducted

N.1.4 Different edible plant part or product derived from it (e.g., oil) to be used for analysis.

N.1.5 List of GE hybrid/s, comparators, non-transgenic commerical varieties to be employed for analysis.

N.1.6 List of Key components to be analysed. Mention guideline(s)/full references to be followed.

Upload

N.1.7 Study Protocol.

[Including sampling condition with schedule and location; preparation of the test material for raw agricultural commodity(ies) or for any other product derived from it; Storage condition to be followed for different plant parts collected i.e. ambient/frozen/oven dried and frozen; analytical method to be followed. if the analytical methods for each key component are as per any guideline(s) mention it,if not,provide details with reference.]

Upload

N.1.8 Whether any additional information is to be submitted.

Upload

N.2 Toxicology studies

N.2.1 Whether the proposed study is to be conducted? If "NO", provide reason(s)

- 1. On opting "Yes" for whether toxicology studies to be conducted, fill details in this section. In case of "No",the section (N2.2-N.2.8) automatically gets disabled and the applicant can move on to next section(N3).
- 2.For animal studies,prior permission from Institutional Animal Ethics Committee (IAEC) has to be obtained .

- 3. In case, applicant wants exemption from any study,proper justification is to be provided.
- 4. Mention "Not applicable" wherever required.

YES

NO

N.2.2 Address and accreditation status of the facility where studies are proposed to be conducted

N.2.3 If permission from Institutional Animal Ethics Committee (IAEC) has been obtained to conduct proposed studies,upload the minutes of the meeting where approval was accorded ? If "NO" provide justification.?

YES

NO

Upload

N.2.4 List of studies to be conducted justifying the reason for conduct of proposed studies (Acute Oral Safety Study, Repeated dose 28 days oral toxicity study, 90-day whole food feeding study,Livestock feeding study etc.)

N.2.5 Selection of animal test system and reason for its selection

N.2.6 Rationale for dose selection

N.2.7 Study Protocols

To include protocol for functional equivalence of transgenic protein(s) expresses in E. coli

Upload

N.2.7.1 Whether any guidelines would be followed for aforementioned toxicology studies?

- YES
- NO

N.2.8 Whether report of the study is generated?

If yes, provide details report

- Yes
- No

N.3 ALLERGENICITY STUDIES

N.3.1 Whether the proposed study is to be conducted? If "NO", provide reason(s)

- 1. On opting "Yes" for whether allergenicity studies to be conducted, fill details in this section. In case of "No",the section (N3.2-N.3.6) automatically gets disabled and the applicant can move on to next section(N4).
- 2. In case, the source of the gene is commonly allergenic/when the bioinformatics search identifies a significant match to a know allergen/comparison of endogenous allergens has to be conducted,section N.3.4 need to be filled.
- 3. Mention "Not applicable" wherever required.

- YES
- NO

N.3.2 Provide result of bioinformatics analysis.

Upload

N.3.3 Heat stability of the transgenic proteins

Upload

N.3.4 Demonstrate the susceptibility of each newly expressed protein to pepsin digetion

Upload

N.3.5 Additional tests, if any (Specific Serum Screening and/or Basophil activating capacity/in vivo reactivity/comparison indogenous allergen

Upload

N.3.6 Whether any additional information is to be submitted ?

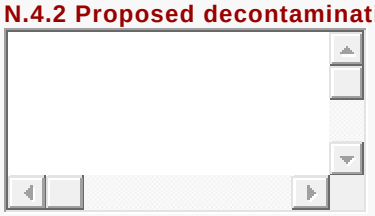
If yes, provide details report

Yes No

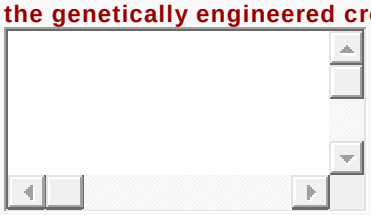
N.4 Safety compliance during environment safety and food & feed safety studies at the proposed site(s) of studies.

N.4.1 Safety norms & containment measures to be observed during studies:

N.4.2 Proposed decontamination & disposal mechanisms:



N.4.3 Contingency plan and risk management measures in case of an unintentional release of the genetically engineered crops/ plants and product(s) thereof:



N.4.4 Whether any additional information is to be submitted ?

If yes, provide details report

( ) Yes (•) No

PART 8

O. Provide appropriate references or any other relevant information from published scientific literature. :

Upload

O.1 Trait based efficacy

O.1.1 Data on Efficacy of the trait generated in during field trial?

If yes, provide details report

Yes No

O.1.2 Objective and Protocol proposed to be conducted

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 1 MB).

O.1.3 Data proposed to be generated

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 1 MB).

O.1.4 Whether data on efficacy of the trait generated in laboratory/contained conditions?

If yes, provide details report

Yes No

Upload

please upload only .pdf,.doc,.png,.gif and .docx file (NMT 1 MB).

O.2 Morphological and Phenotypic characters to be studied.

O.2.1 Reproductive and Survival Biology (crop growth, plant height, dry matter yield) in comparison with non-GE comparators

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O.2.2 Yield performance of GE in comparison with non-GE comparators & checks

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please upload only .pdf,.doc,.png,.gif and .docx file (NMT 1 MB).

O.2.3 Whether any earlier generated reports to be furnished.?

If yes, provide details report

Yes No

P. Confidential Information :

Yes No

Q. Whether the genetically engineered crops/ plants and product(s) thereof under consideration, have been deliberated earlier by the RCGM? If so, provide relevant 'Unique Application Code (UAC)' assigned for each of those deliberations

	S.No.	Unique Application Code (UAC)
☐	01	

R. Declaration by the applicant:

- I declare that I am familiar with, and agree to comply with all the provisions mentioned in the regulations and Guidelines on Biosafety of recombinant DNA Research and Biocontainment,2017 and Guidelines & Handbook for Institutional Biosafety Committee(IBSC),2011 and other applicable Guidelines, as modified time to time by the Goverment of India.
- I would ensure that all investigators/ researchers and staff working in the area of HMOs, recombinant DNA, GMOs/LMOs and product(s) thereof understand and follow the aforesaid biosafety guidelines.
- I assure that adequate training would be conducted to create awareness about compliance requirements while working with biorisk inherent microorganisms and/ or recombinant organisms.
- The HMOs, GMOs/LMOs and product (s) thereof (transferred material), if any, will be utilized for RCGM approved purpose(s) only.
- I also assure that deviations to the above provisions, if any; arising out of the experiments would be brought to the notice of the Chairman-IBSC and the Member Secretary-RCGM immediately.
- I also undertake that provisions of the Biological Diversity Act,2002 are complied with.
- I am aware that making false or misleading statements may attract penalty under the Environment (Protection) Act, 1986.

Name :

Designation : **Signature with stamp & Date:**

S. Certified & forwarded by the chairman of the IBSC :

Submission of Minutes of the IBSC meeting is obligatory. Kindly note that minutes older than two years are void. Please refer FAQs for submission of minutes of the IBSC meeting

- I certify that the information contained in this form has been checked by the Institutional Biosafety Committee (IBSC) and found to be complete.

- I further certify that investigator(s), researcher(s) and staff intended to work with HMOs, recombinant DNA, GMOs/LMOs and product (s) thereof have adequate training and experience for the proposed dealings.
- I undertake that liability of IP issues, if any, on the product under investigation, such as infringement of intellectual property shall be borne by the organization.
- The proposal set out above has been considered and approved by the IBSC in its meeting held on [ ] as the agenda item no. [ ] and is forwarded to RCGM for further necessary action (Copy of the duly signed minutes of relevant meeting is enclosed).

[ ]

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Please upload only .pdf,.doc,.png,.jpg and .docx file.

Name :

Designation : Chairman **Signature with stamp & Date:**