

Form C5a: SUBMISSION OF REPORT OF PRECLINICAL OR OTHER SAFETY STUDIES OF SIMILAR BIOLOGIC DEVELOPED USING GENETICALLY MODIFIED ORGANISMS (GMOs)/ LIVING MODIFIED ORGANISMS (LMOs) FOR HEALTHCARE USE

1. Applicant Details :

Instructions to follow

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 :

2. Application for :

3. 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.

--Select--

4. Objective(s) of the proposal :

Furnish details of key objectives and scientific background of the projects as bullet points.

5. Status of the Project :



Revised Submission



New Submission

6. Approval(s) granted by IAEC for the study procedures and usage of animals :

- Mention the date(s) of IAEC meeting wherein the said proposal was deliberated and approved.
- Enclose colored photocopy(ies) of the minutes of the relevant IAEC meeting

Upload

please upload upto 1 MB only .pdf,.doc,.png,.gif and .docx file.

7. Chronology of approval(s) accorded so far by the IBSC for the Similar Biologic under investigation:

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

Upload

please upload upto 2 MB only .pdf,.doc,.png,.gif and .docx file.

8. Chronology of approval(s) accorded so far by the RCGM for the Similar Biologic under investigation:

- Mention the date of permission(s) issued previously by the RCGM for the product under investigation.
- Enclose colored photocopy(ies) of permit(s) issued earlier

Upload

please upload upto 4 MB .pdf,.doc,.png,.gif and .docx file.

9. Background about the Reference Biologic(s):

9.1 Product scientific name/INN:

9.2 Trade name and its proprietary:

9.3 Type :

9.4 Source:

9.5 Therapeutic indication(s):

To be submitted as bullet points

9.6 Active Ingredient(s):

9.7 Target molecule(s):

9.8 Mode of Action:

9.9 Strength(s):

9.10 Storage condition(s) and stability :

9.11 Dosages :

9.12 Number & route(s) of administrations per day/ per week/ per month:

9.13 Known side effects, if any :

9.14 Known toxicity both in animals and humans, if any :

9.15 Country of Origin :

9.16 Status of approval & marketing history in India, country of origin and worldwide :

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please upload upto .5MB .pdf, .doc, .png, .gif and .docx file.

9.17 Existing treatments for the proposed indications :

10. Details of Similar Biologic :

Have you used/ planning to use more than one 'Reference Biologic' while assessing the similarity of proposed 'Similar Biologic'? If so, Please click on Add button.

10.1: Trade name and its proprietary:

10.2: Strength(s) :

10.3: Product Formulation :

	S.No.	Active Ingredient(s) and Excipient(s)	Final Concentration		
			Reference Biologic 1	Reference Biologic 2 as applicable	Similar Biologic
<input type="checkbox"/>	01				

10.4: Indication(s) for which applied for :

To be submitted as bullet points

11. Product Development & Characterization :

11.1: Flow chart depicting fermentation/ production & purification process highlighting key features:

Please enclose the relevant information as annexure

Upload

please upload upto 5 MB .pdf,.doc,.png,.gif and .docx file.

11.2: Summary of product characterization :

Explain in brief about physico-chemical & efficacy assessments performed, and conclusion drawn to ascertain similarity of the product under investigation with the Reference Biologic

12. Stability studies of Drug Substance (DS) and Drug Product (DP) generated from PCT Batch:

If the provided space is insufficient to furnish complete details, please enclose the relevant information as annexure

Only in case, where PCT batch is similar in 'size, process & characterization' but was not analysed as one of the consistency batch

12.1: Consolidated batch information :

S.N o.	Batch No	Batch Size	Details of Upstream Process		Details of Downstream Process		Details of Formulation		Details of Drug Substance Stability Studies			Details of Drug Product Stability Studies		
			Date of initiation	Date of Completion	Date of initiation	Date of Completion	Date of initiation	Date of Completion	Date of initiation of Real Time- Real Storage Condition studies	Date of initiation of Stress Studies (5°C ±3°C)	Date of initiation of Stress Studies (25°C ±2°C, 60% ±5% R.H.)	Date of initiation of Real Time- Real Storage Condition studies	Date of initiation of Stress Studies (5°C ±3°C)	Date of initiation of Stress Studies (25°C ±2°C, 60% ±5% R.H.)
01														

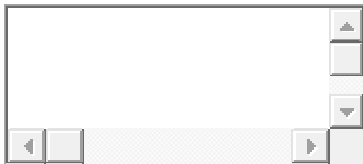
12.2: Physical Appearance, pH, Active Ingredient Concentration, etc :

Samples representing various stability time-points for a particular batch must be analyzed and represented

12.3: SDS-PAGE analysis :

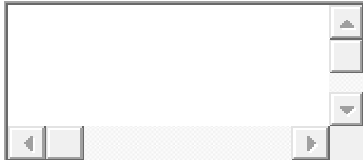
- Samples with uniform quantity (µg/well) representing various stability time-points for a particular batch must be resolved and analyzed simultaneously on a same gel under reduced and non-reduced conditions
- Preferably silver stained

12.4: Size Exclusion Chromatography analysis :



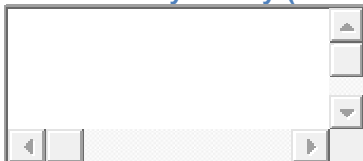
Samples representing various stability time-points for a particular batch must be analyzed and represented as an overlay chromatogram

12.5: Reverse Phase/ Ion Exchange chromatograms, as applicable:



Samples with uniform concentration representing various stability time-points for a particular batch must be analyzed and represented as an overlay chromatogram

12.6: Activity Assay (bioassay) :



Samples representing various stability time-points for a particular batch must be represented and analyzed as an overlay graphical representation

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13. Acceptability criteria/ Certificate of Analysis (as specified in pharmacopeia or equivalent regulation) :

Please enclose the relevant information as annexure

Upload

please upload upto .5 MB .pdf,.doc,.png,.gif and .docx file.

14. Approved pre-clinical/ other safety studies :

Provide list of approved safety studies as bullet points

Upload

please upload upto .5 MB .pdf,.doc,.png,.gif and .docx file.

15. Name, address, accreditation status and details of contact person(s), where these studies were conducted

16. Pre-clinical safety studies & immunogenicity study reports :

16.1: List of studies completed and deviation(s) with appropriate justification, if any from the approved protocols :

To be submitted as bullet points

16.2: Summary of study design approved earlier :

- Provide details of dose(s) tested, dose calculation (w.r.t. human equivalent dose) & basis of dose calculation, dose preparation; vehicle; route(s), mode(s) & number of administration(s) per day/ per week/ per month
- Provide details of test samples (along with batch & lot number, and date of manufacturing); initiation and completion of study; test species, test group and number of animals per test group utilized in each study; and monitoring scheduled followed

16.3: Summary data along with statistical analysis for each group in each study :

- Data must have details of grouped mean analysis of the treated animals along with comparative graphical representation of various patho-physiological profiling with error bar of either SD or range
- Any abnormal or statistically significant results should be made BOLD and highlighted (and a reason given thereof)
- All values should have correct units

16.4: Tabulated individual animal data over time indicating mean test results substantiated with line/ bar charts :

- Any abnormal or statistically significant results should be made BOLD and highlighted (and a reason given thereof)
- All values should have correct units

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please upload upto 20 MB .pdf,.doc,.png,.gif and .docx file.

17. Conclusions :

18. Compliance measures and study management :

18.1: Measures for containment & ethical compliance observed during the study :

18.2: Decontamination and disposal mechanisms followed :

18.3: Contingency plan and risk management measures observed in case of an unintentional release of the HMOs, GMOs/LMOs and product(s) thereof :

19. Appropriate references and any other relevant information :

If the provided space is insufficient to furnish complete details, please enclose the relevant information as annexure

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please upload upto 25 MB .pdf,.doc,.png,.gif and .docx file.

20. Confidential information?

☐ Yes ☒ No

21. Whether the HMOs, GMOs/LMOs 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)
<input type="checkbox"/>	<input type="text" value="01"/>	<input type="text"/>

22. 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 Government 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 am aware that making false or misleading statements may attract penalty under the Environment (Protection) Act, 1986.

Name :

Designation :

Signature with stamp & Date:

- To be signed in original by hand. (Electronic/ scanned signatures not acceptable)

23. 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 also undertake that provisions of the Biological Diversity Act, 2002 are complied with.
- 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).

Name :

Designation :

Chairman

Signature with stamp & Date:

- To be signed in original by hand. (Electronic/ scanned signatures not acceptable)