Job No.: _____

STUDY REQUEST FORM

Please note: Complete one form for each Test Item / Reference Item. A separate form is required for each additional item. Please ensure all required information in Sections 1–4 is completed accurately, as it will be included in the Final Report(s).

1. DETAILS OF SPONSOR

Company Name & Address	
Sponsor's Representative Name	
Tel (Office) / Tel (Mobile)	
E-mail	

2. TEST ITEM / REFERENCE ITEM DETAILS

Please provide the information exactly as it should appear in the Final Report.

Item Type	❒ Test Item	❒ Reference Item	
Name			
Quantity Sent			
Mode of Dispatch			
Category	❒ Medical device ❒ Pharmaceutical ❒ Chemicals ❒ Feed	❒ Pesticide ❒ Herbal ❒ Cosmetic ❒ Veterinary Drug	❒ Food ingredient ❒ Biological ❒ Scheduled waste ❒ Others:
Type	❒ Final Product	❒Raw Material	❒ Others:
Intended use of Test / Reference Item			
Purpose of Testing	❒ Registration with regulatory *(please indicate regulatory authority):*		
	❒ Research & development	❒ Safety Data Sheet	❒ Others:
Appearance (solid / liquid / powder):			

Lot / Batch No. :	CAS No. (if applicable) :
Color :	pH :
Expiry Date :	Stability :
Homogeneity (if applicable) :	Concentration (if applicable) :
Purity (if applicable) :	Density (if applicable) :

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Composition *(may also be provided as an attachment)*:	
Solubility *(form a clear solution)*	❒ Water ❒ Ethanol ❒ Methanol ❒ Acetone ❒ Dimethyl Sulfoxide ❒ Cottonseed Oil ❒ Others: ..... Soluble at which concentration:
Sterility	❒ Non-sterile ❒ Sterile If sterile, method of sterilization: ❒ Ethylene Oxide ❒ Steam ❒ Radiation ❒ Others: .....
Storage Condition	❒ Ambient ❒ 18°C to 30 °C ❒ Refrigerated (2°C to 8 °C) ❒ Frozen (≤-20°C) ❒ Other requirements *(eg: light sensitive, hygroscopic, please specify)*:
Hazardous	❒ No ❒ Yes - Type of hazard *(e.g. irritant, corrosive)*: Please indicate safety and handling precautions, if any:
Supporting Documents	❒ Safety Datasheet ❒ Certificate of Analysis ❒ Others:
Other specific conditions *(e.g. extraction condition, properties)*	

2A. MEDICAL DEVICE INFORMATION *Complete only if applicable*

Part(s) to be tested	
Can the Test / Reference Item be cut?	☐ Yes ☐ No
Dimension / Size (L × W × D)	
Surface Area (if applicable)	
Body Contact of Test Item	❒ Intact Skin ❒ Intact Mucosal Membrane ❒ Breached or compromised surfaces (skin or mucosal membranes) or internal tissues other than circulating blood ❒ Circulating blood
Contact Duration	❒ Limited (≤ 24 hours) ❒ Prolonged (> 24 hours – 30 days) ❒ Long-term (> 30 days)
Other specific conditions *(e.g. extraction condition, properties)*	

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3. TEST(S) REQUESTED *Please tick the applicable test and study type.*

TEST METHOD NAME		STUDY TYPE			STUDY REFERENCE NUMBER *(to be filled by Makmal Bioserasi)*
		GLP	ISO	NA	
IN VITRO - CYTOTOXICITY STUDIES					
❒ MEM Elution Assay, ISO 10993-5					
❒ MTT Assay Annex C, ISO 10993-5	❒ n =				
❒ MTT Assay, J. Immunol. Methods (1983) with modification	❒ n =				
IN VITRO - GENOTOXICITY STUDIES					
❒ Bacterial Reverse Mutation Test, OECD 471 / ISO 10993-3	❒ 5 strains ❒ 2 strains				
❒ In Vitro Mammalian Cell Micronucleus Test, OECD 487					
❒ Alkaline Comet Assay, Environ. Mol. Mutagen. (2000)					
IN VITRO – SKIN IRRITATION STUDIES					
❒ In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method, OECD 439					
IN VIVO - DERMAL STUDIES					
❒ Animal Irritation Test (Single Exposure), ISO 10993-23	❒ direct patch				
	❒ polar extraction				
	❒ non-polar extraction				
❒ Skin Sensitization Test (Closed-Patch Test, Buehler Test), ISO 10993-10					
❒ Skin Sensitization Test (Guinea Pig Maximization Test), ISO 10993-10	❒ no extraction				
	❒ polar extraction				
	❒ non-polar extraction				
❒ Animal Irritation Test by Intracutaneous (Intradermal) Administration, ISO 10993-23	❒ polar & non-polar extraction				
	❒ no extraction				
	❒ polar extraction				
	❒ non-polar extraction				
❒ Acute Dermal Irritation/Corrosion Test, OECD TG 404					
IN VIVO - SYSTEMIC TOXICITY STUDIES					
❒ Acute Oral Toxicity Study, OECD 423 Dosage:					
❒ Acute Oral Toxicity: Up-and-Down Procedure, OECD 425					
❒ Acute Systemic Toxicity Study (Intravenous), ISO 10993-11	❒ polar extraction				
	❒ no extraction				

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TEST(S) REQUESTED *(please tick)*		STUDY TYPE			STUDY REFERENCE NUMBER *(to be filled by Makmal Bioserasi)*
		GLP	ISO	NA	
❒ Acute Systemic Toxicity Study (Intraperitoneal), ISO 10993-11	❒ polar extraction				
	❒ non-polar extraction				
	❒ no extraction				
❒ 28 Days Repeated Oral Toxicity Study, OECD 407					
❒ Rabbit Pyrogen Test, USP	❒ no extraction				
	❒ with extraction				
OTHER STUDIES					
❒ Antioxidant Assay	❒ FRAP assay				
	❒ DPPH Assay				
	❒ TPC Assay				
OTHER STUDIES *(please specify)*:					
1.					
2.					
3.					

4. ARCHIVE SECTION

GLP Study

1) Study-specific Quality Document

The study-specific quality document shall be archived in the Test Facility for 10 years. Upon archive retention period completion, the quality document shall be:

❒ Returned to the Sponsor ❒ Disposed by Test Facility

If Sponsor want to archive more than 10 years, additional charges will be applicable.

2) Test / Reference Item

The Test / Reference Item shall be archived in the Test Facility as long as: (whichever earlier)

i) the Test / Reference Item has not reached the expiry date
ii) the Test / Reference Item permits evaluation.
iii) the Test / Reference Item shall be archived for 10 years (as per internal procedure).

Upon the above-mentioned conditions, whichever comes earlier, the Test Item / Ref Item will be:

❒ Returned to the Sponsor ❒ Disposed by Test Facility

ISO Study / Non-Accredited Study

1) Test Item / Ref Item

Upon completion of study, the balance of Test Item shall be:

❒ Returned to the Sponsor ❒ Disposed by Test Facility

5. TERMS OF AGREEMENT

Definition

1. Sponsor - Any entity that commissions, supports and/or submits testing/study on the product stated in this Study Request form.
2. Laboratory / Test Facility – Refers to Makmal Bioserasi, Universiti Kebangsaan Malaysia which performs testing/study on products as stated in this Study Request Form.

Sponsor Responsibilities:

1. The Sponsor hereby engages and grants permission and consent to the Laboratory to conduct testing/study on the product as stated in the Study Request Form.
2. The Sponsor should understand the requirements of the ISO 17025/OECD GLP, in particular those related to the responsibilities of the Laboratory Director/Test Facility Management and the Approved Signatories/Study Director.
3. When commissioning a testing/study, the Sponsor should ensure that the Laboratory/Test Facility is able to conduct the testing/study in compliance with ISO 17025/OECD GLP and that it is aware that the study is to be performed under that quality system.
4. Where several studies are presented to a regulatory authority in a single package, the responsibility for the integrity of the assembled package of unaltered final reports lies with the Sponsor. The sponsor must ensure that adequate communication links exist between his representatives and all parties conducting a study, such as the Approved Signatories/Study Director, Quality Assurance unit and Laboratory Director/Test Facility Management.
5. The sponsor shall understand that the test report applies and refers only to the sample of the specific Test/Reference Item submitted and that the results shall not be used to indicate or imply that they are applicable to other similar articles/products. In addition, such results must not be used to indicate or imply that the Laboratory approves, recommends or endorses the manufacturer, supplier or user of such articles/products or that the Laboratory in any way guarantees the later performance of the articles/products.
6. The test report or any part thereof will not be reproduced for advertising or other purposes by any means or form without written permission from the Laboratory Director/Test Facility Management of Makmal Bioserasi.
7. All communications between the Sponsor and Laboratory/Test Facility which are required to be given under this conduct of testing/study shall be in writing and shall be sent by hand, by registered post or by official/working email to the person and address of the recipient as stated in the Study Request Form.
8. The ultimate responsibility for the scientific validity of a study lies with the Approved Signatories/Study Director, and not with the Sponsor, whose responsibility is to make the decision, based on the outcome of the studies, whether or not to submit a chemical/product for registration to a regulatory authority.

Test Item / Reference Item

1. All the information provided in Sections 1, 2, and 3 is correct and relates to the sample of the Test/Reference Item to be submitted for testing/study.
2. The Test/Reference Item is transported and submitted to the Laboratory in conditions that ensure that its integrity remains intact.
3. The Sponsor should inform the Laboratory/Test Facility of any known potential risks of the test item to human health or the environment as well as any protective measures which should be taken by the Laboratory/Test Facility personnel.

Only Applicable to GLP Study:

1. There are requirements call for the careful identification of the test item and description of its characteristics. This characterization is carried out either by the contracted test facility or by the Sponsor. If the characterization is indeed conducted by the Sponsor, this fact should be explicitly mentioned in the final report. Sponsors should be aware that failure to conduct characterization in accordance with GLP could lead to the rejection of a study by a regulatory authority in some Member countries.
2. If characterization data are not disclosed by the Sponsor to the Test Facility, this fact should also be explicitly mentioned in the final report.
3. Sponsor should ensure that materials and records in support of regulatory studies are retained and maintained under conditions that ensure their integrity and continued access.
4. If records and materials are transferred into Sponsor's possession, storage should be in archives that meet the requirement of the Principles of GLP.
5. The Sponsor should ensure that such material and records are retained for as long as required by relevant/regulatory authorities.
6. The archive and retained materials and records should be available for inspection during normal office hours.
7. If electronic records are kept, it should be possible to make them available in human-readable form.

Confidentiality

1. The Laboratory/Test Facility acknowledges that the Sponsor may disclose its Confidential Information for purposes of testing and the information shall be used only for the testing and preparation of report.
2. The Laboratory/Test Facility will not, without the prior written approval of the Sponsor, disclose the Confidential Information to any person.
3. The Laboratory/Test Facility shall not be in breach of this clause in circumstances where:
   (a) it is legally compelled to disclose the Confidential Information as required by law or by any government or judicial authority; or
   (b) it disclose the Confidential Information to its parent company, subsidiaries, associated companies, solicitors, auditors, insurers and accountants on a need-to-know basis.

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6. TEST ITEM / REFERENCE ITEM SUBMISSION GUIDELINE

Test Item / Reference Item / Sample

1. Free from any foreign materials.
2. Undamaged, intact.
3. Conforms to information provided in the Study Request Form.

Container/packaging

1. Please label each unit of the test item with the test item name, batch number, and storage condition.
2. Please ensure the test item name and quantity stated in the Study Request Form is the same as that written on the label of the test item.
3. Ensure it will not affect the test item's integrity.
4. If the test item is light/heat/moisture sensitive, kindly ensure the container and transportation is appropriate.
5. Kindly ensure the temperature of the test item during transportation follows the storage condition.
6. The usage of the data loggers may be required proportionate to risk during transportation.
7. If liquids or powder, prefer glass bottles/containers with screws on the lid or any other material which does not react to the test item. Seal for extra precaution to avoid leaks.
8. DO NOT use plastic bags.
9. If the test item is sterile, packaging must be sterile packaging AND packed individually according to the item and test.
10. Undamaged, intact.

7. SPONSOR ACKNOWLEDGEMENT

I hereby declare that I have read and agree to all the Terms of Agreement.	
Signature / Company Stamp : ……	
Name:	Date:

8. REVIEW OF REQUEST *(To be completed by Makmal Bioserasi)*

Laboratory Director / Test Facility Management *(sign)* Date:	Job Number:
Remarks:	

Note: NP = Not provided by Sponsor | NA = Not applicable