



#### **REQUEST FOR PROPOSAL**

Date: 07 November 2024

Reference: RFP CO-24-041SVP

1. The Philippine Institute of Traditional and Alternative Health Care (PITAHC), through its Bids and Awards Committee (BAC), invites interested bidders to submit a proposal for the procurement of the item stated below with the total Approved Budget for the Contract (ABC) amounting to Seven Hundred Thousand Pesos (PhP700,000.00) inclusive of all costs, applicable taxes, and service charges:

2.

PITAHC	PR	
2024 APP Ref	Number	Item Description
5020702002	24-08-0178	LABORATORY SERVICES FOR STABILITY STUDY OF ULASIMANG BATO 500 MG TABLET OF THE PITAHC TACLOBAN HERBAL PROCESSING PLANT (2 <sup>ND</sup> REPOSTING) (See Terms and Conditions for detailed requirements)

- 3. Procurement shall be conducted through Small Value Procurement under Section 53.9 Negotiated Procurement as prescribed under Rule XVI- Alternative Methods of Procurement of the 2016 Revised Implementing Rules and Regulations (IRR) of Republic Act (R.A.) No. 9184, otherwise known as the "Government Procurement Reform Act".
- 4. The proposal must be duly signed by the bidder or bidder's authorized representative and must be submitted to the BAC Secretariat, PITAHC Building, Matapang St., East Avenue Medical Center Compound, Barangay Central, Quezon City or sent thru fax at (02) 8376-3067 or email at bac@pitahc.gov.ph. The proposal shall be received until **14 November 2024, 11:59PM**.
- 5. The bidder must **submit a copy** of the following documents, **together with the proposal forms**, to ensure that the said bidder is technically, legally and financially capable to undertake the proposed project:
  - a. Valid and current Mayor's/Business Permit
  - b. Notarized Omnibus Sworn Statement by the prospective bidder in the new prescribed form as per GPPB Resolution No. 16-2020
  - c. Latest Income/Business Tax Returns CY 2023
  - d. PHILGEPS Registration Number (to be indicated in the Price Proposal Form)
- 6. PITAHC reserves the right to waive any formality in the responses to the eligibility requirements and to this invitation. PITAHC further reserves the right to reject all proposals, or declare a failure of small value procurement, or not award the contract, and makes no assurance that the contract shall be entered into as a result of this invitation without thereby incurring any liability to the affected bidder or bidders in accordance with R.A. No. 9184 and its Implementing Rules and Regulations.
- 7. For any clarification, you may contact Mr. **Louie C. Sibug** at telephone no. (02) 8282-8194 loc 542.

(SGD.) ATTY. KEENTH N. ALMEÑE Chairperson, PITAHC BAC



#### **OTHER TERMS AND CONDITIONS**

- 1. Bidders shall provide the **correct and accurate information** required in this form.
- 2. Delivery Schedule: **See Item VII of the Terms and Conditions (DURATION OF ENGAGEMENT AND IMPLEMENTING ARRANGEMENT)** "The engagement shall be completed within nine (9) months from the receipt of the Notice to Proceed (NTP)"
- 3. Delivery Site: PITAHC
- 4. Payment Term: See Item VI of the Terms and Conditions (PAYMENT SCHEDULE)
- 5. Price proposal must be valid for a period of **thirty (30) calendar days** from the date of submission.
- 6. Price proposal to be denominated in **Philippine Peso (PhP)**, include all taxes and duties and/or levies payable.
- 7. Proposals exceeding the ABC shall be automatically rejected.
- 8. As part of the submission aside from Item No. 5 of the RFP and the Price Proposal Form, bidder shall submit a Certificate of Satisfactory Completion/Performance for those who have previous contracts with PITAHC, if applicable.
- 9. The **contract shall be awarded** to the single or lowest calculated and responsive proposal, which complied with the minimum technical specifications and other terms and conditions stated herein.
- 10. Any interlineations, erasures, or overwriting shall be valid only if they are signed or initialed by the bidder or any of his/her duly authorized representative/s.
- 11. Liquidated damages equivalent to one tenth of one percent of the value of the goods not delivered within the prescribed delivery period shall be imposed per day of delay. PITAHC shall rescind the contract once the cumulative amount of liquidated damages reaches ten percent (10%) of the amount of the contract, without prejudice to other courses of action and remedies open.

#### **TERMS AND CONDITIONS**

### LABORATORY SERVICES FOR STABILITY STUDY OF ULASIMANG BATO 500 MG TABLET OF THE PITAHC TACLOBAN HERBAL PROCESSING PLANT

#### I. BACKGROUND AND RATIONALE

The Philippine Institute of Traditional and Alternative Health Care (PITAHC) is the lead agency in the research and development, promotion and advocacy, and development of standards on traditional and complementary medicine (T&CM); and the Institute ensures its accessibility, availability, sustainability and integration into the national health care. system.

The Institute has three (3) existing Herbal Processing Plants located in Cagayan Valley, Tacloban and Davao. In the past, these HPPs produced Lagundi and Sambong tablets and supplied the Department of Health (D0 OH) offices, hospitals, and other local government agencies.

Currently, PITAHC has a licensing agreement with the University of the Philippines (UP) Manila for five (5) herbal medicines, under which PITAHC has secured a non-exclusive license for the commercial development, production, manufacture, use, and sale of the licensed goods. One of the licensed products is the Ulasimang Bato 500 mg Tablet.

Shelf-life testing, also known as stability testing, is an assessment of a product's functioning, acceptability, safety, effectiveness, and stability over time in order to determine or verify its expiration date.

The Philippine Institute of Traditional and Alternative Health Care (PITAHC - Tacloban) is responsible for ensuring the safety, efficacy, and quality of herbal medicine being produced. As part of this mission, PITAHC Tacloban requests laboratory assistance to undertake a Stability Study on Ulasimang bato. These services are vital for determining the product's stability and quality throughout time. The service will include a variety of testing to guarantee product quality and safety. The results of these laboratory services for the Ulasimang bato 500 mg tablet developed by PITAHC-THPP will be critical for its FDA registration.

#### II. OBJECTIVES

The General Objective of this project is to render service of a third-party provider for laboratory services for PITAHC THPP's Ulasimang bato 500 mg tablet for FDA registration.

The specific objectives of this project are as follows:

- **a.** To conduct the stability study on three samples of lot or batch of Ulasimang bato over 0, 3, 6, 12, 18, and 24 months
- **b.** To evaluate the physical and chemical properties of the samples at different time intervals, including weight variation, moisture content, tablet hardness, friability, disintegration, TLC profiling, and organoleptic properties.
- **c.** To assess the microbial load of the samples, including testing for Total Aerobic Count (TAC), Total Yeast and Mold (TYM), Escherichia coli (*E. coli*), Pseudomonas aeruginosa, Enterobacteria, Staphylococcus aureus, and Salmonella spp.
- **d.** To determine the levels of heavy metals, including lead, cadmium, arsenic, and mercury in the samples.

#### III. METHODOLOGY

The main purpose of this\_project is to conduct the analytical tests necessary to assess the quality of *Ulasimang bato* tablets upon manufacturing and over defined time periods as defined in the regulatory requirements in FDA A.O. 172 s. 2004 ("Guidelines on the Registration of Herbal Medicine").





#### 1. Physicochemical and Microbiological Analysis of the Raw Material

The quality of the raw material (*Peperomiae Pellucidae Herba Pulveratum*) shall be assessed against the set of physicochemical and microbiological technical specifications defined in the Philippine Pharmacopoeia, as seen in **Table 1** below.

**Table 1.** Technical specifications for *Peperomiae Pellucidae Herba Pulveratum* 

Parameter	Specification	<b>Test Method</b>
Macroscopic Description	Conforms to morphological	Taxonomic Description
	description of <i>Peperomia pellucida</i>	
	in Philippine Pharmacopoeia	
Botanical Identity	Certification Available from	Taxonomic Description
	Registered Herbarium	
Organoleptic Description	Greenish-brown to brown fine	Sensory Evaluation
	powder with characteristic odor	
Ash Content		
Total Ash	NMT 27%	Gravimetry
Acid-insoluble Ash	NMT 8%	Gravimetry
Water-soluble Ash	NMT 16%	Gravimetry
Extractives Content		
Ethanol-soluble	NLT 5%	Gravimetry
Extractives	NLT 25%	Gravimetry
Water-soluble Extractives		
Moisture Content	NMT 10%	Gravimetry
Heavy Metals Content		
Lead	NMT 10 ppm	AAS / ICP-MS
Cadmium	NMT 0.3 ppm	AAS / ICP-MS
Mercury	NMT 0.5 ppm	AAS / ICP-MS
Arsenic	NMT 0.3 ppm	AAS / ICP-MS
Pesticide Residue		
Organochlorine	Absent	HPLC
Organophosphate	Absent	HPLC
Carbamate	Absent	HPLC
Foreign Matter	NMT 2%	
Microbial Limits		
Aerobic Plate Count	NMT 1 x 10 <sup>5</sup>	Microbial Enumeration
Yeast and Mold Count	NMT 1 x 10 <sup>3</sup>	Microbial Enumeration
Escherichia coli	Absent	Microbial Enumeration
Salmonella spp.	Absent	Microbial Enumeration
Staphylococcus aureus	Absent	Microbial Enumeration
Other Enterobacteriaceae	NMT 1 x 10 <sup>3</sup>	Microbial Enumeration
Aflatoxin Content		
Total Aflatoxin	NMT 20 ppb	ELISA
Aflatoxin B1	NMT 10 ppb	ELISA
Identification Test	Conforms to Phytochemical	
	Profile for <i>Peperomia pellucida</i>	TLC

#### 2. Physicochemical and Microbiological Analysis of Finished Product

The quality of the finished product (*Peperomiae pellucidae* Tablet) shall be assessed against the set of physicochemical and microbiological technical specifications defined in the Philippine Pharmacopoeia, as seen in **Table 2** below.





**Table 2.** Technical specifications for *Peperomiae pellucidae Tablet* 

Parameter	Specification	Test Method
Organoleptic Description	Plain, uncoated, brown tablets	Sensory Evaluation
	with characteristic pungent	
	odor	
Moisture Content	NMT 10%	Gravimetry
Ph	Informative	Conductivity
Microbial Limits		
Aerobic	NMT 1 x 10 <sup>5</sup>	Microbial Enumeration
	NMT 1 x 10 <sup>3</sup>	Microbial Enumeration
Plate Count	Absent	Microbial Enumeration
Yeast and Mold Count	Absent	Microbial Enumeration
Escherichia coli	Absent	Microbial Enumeration
Salmonella spp.	Absent	Microbial Enumeration
Staphylococcus aureus	NMT 1 x 10 <sup>3</sup>	Microbial Enumeration
Pseudomonas aeruginosa		
Other Enterobacteriaceae		
Identification Test	Conforms to Phytochemical	TLC
	Profile for <i>Peperomia</i>	
	pellucida	
Weight Variation	675 mg ± 5% RSD	Gravimetry
Disintegration Time	NMT 30 mins	Disintegration Test
Hardness	<98 N	Hardness Test
Friability	<1.0%	Friability Test

#### 3. Nutritional Analysis of Finished Product

In addition to the physicochemical and microbiological parameters of the finished product, nutritional analysis will be conducted to assess the nutritional value of the drug product and to provide additional data in the preparation of the Certificate of Analysis of the finished product. **Table 3** below shall define the parameters to be assessed. Nutritional analysis shall be conducted on the finished product and shall not constitute a parameter for stability study.

**Table 3.** Technical specifications for nutritional analysis.

Parameter	Specification	Test Method
Calories		
Total Calories	Informative	Calculation
Calories from Fat	Informative	Calculation
Fat Content		
Total Fat	Informative	FAO Food 14/7-1986
Saturated Fat	Informative	FAO Food 14/7-1986
Trans Fat	Informative	FAO Food 14/7-1986
Cholesterol	Informative	FAO Food 14/7-1986
Sodium	Informative	AAS / ICP-MS
Potassium	Informative	AAS / ICP-MS
Carbohydrate Content		
Total Carbohydrates	Informative	AOAC 986.25
Dietary Fiber	Informative	AOAC 986.25
Sugar	Informative	AOAC 986.25
Protein Content	Informative	FAO Food 14/7-1986

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#### 4. Accelerated Stability Study

A six-month stability study under accelerated IVB climatic zone conditions (40°C ± 2°C / 35% RH ± 5% RH) shall be conducted on two (2) distinct production or commercial scale batches of *Ulasimang bato* tablets following the ASEAN Guideline on Stability of Drug Product (R1) using the minimum recommended testing frequency of **0**<sup>th</sup>, **3**<sup>rd</sup>, **and 6**<sup>th</sup> month testing. The parameters defined in Section III-2 ("Physicochemical and Microbiological Analysis of Finished Product") shall constitute the specification of the product to be assessed throughout the course of the stability study. The contract service provider shall define the minimum number of samples (including contingency samples) to be provided by DOH-PITAHC necessary to conduct the stability study. For each batch tested, the contract service provider must provide and issue a **Stability Study Protocol**. The project manager from DOH-PITAHC shall be notified within 7-14 working days from the release of the result regarding any deviations or out-of-specification (OOS) results from the protocol.

#### 5. Long Term Stability Study

A twelve-month stability study under standard IVB climatic zone conditions (30°C ± 2°C / 35% RH ± 5% RH) shall be conducted on two (2) distinct production or commercial scale batches of *Ulasimang bato* tablets following the ASEAN Guideline on Stability of Drug Product (R1) using the minimum recommended testing frequency of **0**<sup>th</sup>, **3**<sup>rd</sup>, **6**<sup>th</sup>, **9**<sup>th</sup>, **and 12**<sup>th</sup> month testing. The parameters defined in Section III-2 ("Physicochemical and Microbiological Analysis of Finished Product") shall constitute the specification of the product to be assessed throughout the course of the stability study. The contract service provider shall define the minimum number of samples (including contingency samples) to be provided by DOH-PITAHC necessary to conduct the stability study. For each batch tested, the contract service provider must provide and issue a **Stability Study Protocol**. The project manager from DOH-PITAHC shall be notified within 7-14 working days from the release of the result regarding any deviations or out-of-specification (OOS) results from the protocol.

#### 6. Data Presentation

Data for all physicochemical, microbiological, and nutritional analyses shall be summarized into a **Report of Analysis (RoA)** and an electronic copy of a corresponding **Certificate of Analysis (CoA)** shall be issued to the Project Manager from DOH-PITAHC within 7-14 working days upon complete availability of results for all test parameters listed in the CoA.

For stability study results, a CoA shall be issued for each stability testing time point in the study period, an electronic copy of which shall be sent to the Project Manager from DOH-PITAHC within 7-14 working days upon complete availability of results for all test parameters listed in the CoA. An accompanying **Technical Summary Report** shall also be included with an interpretation of the data observed as of the period of testing.

Upon completion of the stability study, a **Stability Study Summary Sheet** briefly detailing the main results of the study shall be provided to the Project Manager from DOH-PITAHC within 7-14 working days upon complete availability of results. An accompanying **Technical Summary Report** shall also be included with a final interpretation of the data observed as of the end of the study.

#### 7. Sample and Data Retention

A minimum retention sample size of 10.0 g shall be retained and stored at  $-40^{\circ}$ C for each sampling interval throughout the duration of the stability study to serve as a reference for use in identification tests. A minimum retention sample size equivalent to three (3)

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additional testing points for accelerated, and eight (8) additional testing points for long term, shall be included in the stability study.

Data generated from the study shall be retained and made accessible to DOH-PITAHC for a period of four (4) years following the end of the contract of service, after which all data shall be destroyed in a manner deemed appropriate by the contract service provider.

All unrefrigerated unused stability study samples shall be destroyed within two (2) years from the end of the contract of service, in a manner deemed appropriate by the contract service provider.

All refrigerated samples shall be destroyed within one (1) year from the end of the contract of service, in a manner deemed appropriate by the contract service provider.

#### IV. SCOPE OF WORK

#### A. Responsibilities of the Service Provider:

To meet the above-mentioned objectives, the Service Provider should be able to:

- 1. Implement the project on the design/development the institutional contracting mechanism;
- 2. Providing an accelerated storage chamber capable of simulating conditions for 18-24 months of storage.
- 3. Conducting weight variation tests to assess the uniformity of weight among tablets.
- 4. Performing moisture content analysis to determine the moisture content of the samples.
- 5. Testing tablet hardness and friability to evaluate the mechanical strength of the tablets.
- 6. Conducting disintegration tests to assess the time taken for tablets to disintegrate.
- 7. Performing TLC profiling to identify and quantify the active constituents of Ulasimang bato.
- 8. Assessing microbial load through testing for TAC, TYM, E. coli, P. aeruginosa, Enterobacteria, S. aureus, and Salmonella spp.
- 9. Testing for heavy metals, including lead, cadmium, arsenic, and mercury, to ensure compliance with safety standards.
- 10. Conducting organoleptic tests to evaluate the sensory properties of the samples. and help clients answer specialized business questions with its market research.

#### B. Responsibilities of the PITAHC

- 1. Allocate the amount of Php700,000.00 inclusive of applicable taxes, chargeable against the funds of PITAHC- THPP and Research and Development Division, the disbursement of which shall follow the schedule of payment;
- 2. PITAHC through the PITAHC-THPP and R&DD shall oversee the overall conduct of this project;
- 3. Responsible for the timely provision of access, information, decision-making which are necessary for the achievement of the project
- 4. Make prompt review of the work produced and presented by the Service Provider in the different phases of the project;
- 5. Review and evaluate all the technical progress reports and final report submitted by Service Provider;
- 6. Process payment on schedules as stated in the section VI of this term;
- 7. Issue certification of final acceptance and recommendation for payment.

#### V. QUALIFICATIONS FOR SERVICE PROVIDER

- 1. The Service Provider must possess the following qualifications:
  - a. Service Provider must have a valid FDA License to Operate (LTO) and certified with Current Good Manufacturing Practices (cGMP) or proof of application for renewal;





- b. Product development team lead must be a graduate of BS Pharmacy, Chemistry, Biotechnology or equivalent;
- c. Certification that bidder has at least 10-year experience in providing verifiable data, analysis in the pharmaceutical sector, locally and globally;
- d. Service Provider must have an experience dealing with Government Owned and Controlled Corporations (GOCCs) State Universities, and/or national government agencies in the provision of market share data/information and analysis;
- e. Service Provider must have an experience with working with pharmaceutical companies in product development and contract manufacturing

#### VI. APPROVED BUDGET FOR THE CONTRACT (ABC) AND PAYMENT SCHEDULE

- 1. The approved budget for the contract is Seven Hundred Thousand Pesos (Php 700,000.00).
- 2. For and in consideration of the services of the Service Provider, PITAHC shall make the following payment tranches:

PAYMENT TRANCHE	ACCOMPLISHMENT	PERCENT	AMOUNT
1 <sup>st</sup> (within fourteen (14) calendar days from the submission of inception report)	<ol> <li>Acceptance of Notice to Proceed</li> <li>Signed contract of service</li> <li>Submission of Inception Report (Stability Study Protocol)</li> </ol>	15%	105,000.00
2 <sup>nd</sup> (Delivery of the first progress report within ninety (90) calendar days from the submission of the inception report)	Submission of Progress Report/s  (4 hard copies with electronic copy)  Report on the initial phase of stability study, on 0 & 3 month condition (long term and accelerated)  a. Detailed analyses of physical and chemical properties, including weight variation, moisture content, tablet hardness, friability, disintegration, TLC profiling, and organoleptic properties.  b. Microbial load analysis reports, including results for TAC, TYM, E. coli, P. aeruginosa, Enterobacteria, S. aureus, and Salmonella spp.  c. Heavy metal testing reports, providing levels of lead, cadmium, arsenic, and mercury in the samples.	45%	315,000.00
3rd  (Delivery of progress reports within ninety (90) calendar days from the submission of the first progress report)	Report on the initial phase of stability study, on 6 month condition (long term and accelerated)  a. Detailed analyses of physical and chemical properties, including weight variation, moisture content, tablet hardness, friability, disintegration, TLC profiling, and organoleptic properties.  b. Microbial load analysis reports, including results for TAC, TYM, E. coli, P. aeruginosa, Enterobacteria, S. aureus, and Salmonella spp.	30%	210,000.00





PAYMENT TRANCHE	ACCOMPLISHMENT	PERCENT	AMOUNT
	c. Heavy metal testing reports, providing levels of lead, cadmium, arsenic, and mercury in the samples.		
Final	Submission of Final Report	10%	70,000.00
(Delivery of final reports within seventy-six (76) calendar days from the submission of the second progress report)	<ul> <li>a. Detailed analyses of physical and chemical properties, including weight variation, moisture content, tablet hardness, friability, disintegration, TLC profiling, and organoleptic properties.</li> <li>b. Microbial load analysis reports, including results for TAC, TYM, E. coli, P. aeruginosa, Enterobacteria, S. aureus, and Salmonella spp.</li> </ul>		
	c. Heavy metal testing reports, providing levels of lead, cadmium, arsenic, and mercury in the samples.		
	d. Recommendations based on the findings, including any necessary actions to maintain or improve product quality		
	TC	TAL ABC	700,000.00

3. Payments shall be based on the completion of the above-mentioned activities and submission of required deliverables/reports subject to acceptance of the authorized representative of the Head of the Procuring Entity.

#### VII. DURATION OF ENGAGEMENT AND IMPLEMENTING ARRANGEMENT

The engagement shall be completed within nine (9) months from the receipt of the Notice to Proceed (NTP).

The PITAHC Research and Development Division and Tacloban HPP shall be the focal office in this engagement and the highest oversight authority.

#### MARIA TERESA CO IÑIGO, MD, FPCAM, CESE

**Director General** 

#### MARIA VENUS K. APOLONIO, RPh

Plant Manager Tacloban Herbal Processing Plant

#### MICHAEL D. JUNSAY, RPh, CPS, MBAH

OIC, Research and Development

Failure to fulfill the obligations stipulated within the nine (9) months, or within the approved extension thereof, shall render the party liable for damages due to delay. The party shall be obligated to pay PITAHC liquidated damages amounting to one-tenth (1/10) of one percent (1%) of the total project cost for each day of delay. Such liquidated damages shall be payable upon the completion of the project. In the event that the cumulative liquidated damages reach ten percent (10%) of the total contract amount, PITAHC reserves the right to rescind or terminate the contract, without prejudice to pursuing any other remedies or courses of action available under the law.





#### VIII. CONFIDENTIALITY

The Service Provider shall not use (except for PITAHC's benefit) or divulge to anyone-either during the term of this Agreement or thereafter - any of the PITAHC's trade secrets, the proprietary information, or other proprietary data, personal information covered by the Data Privacy Act, or information of any kind whatsoever acquired by the Service Provider in carrying out the terms of this agreement. In this regard, the Service Provider shall:

- 1. Warrant, represent and undertake reliability of the service required;
- 2. Agree to hold the proprietary information in strict confidence;
- 3. Agree not to reproduce, transcribe or disclose the proprietary information to third parties without prior written approval from the CLIENT; and
- 4. Uphold strict confidentiality of all information that will come to Service Provider knowledge.

#### IX. TERMINATION

The PITAHC may, in case of material default on the part of the Service Provider, terminate the contract, through written notice to the Service Provider at least thirty (30) days prior to the termination, and that the Service Provider failed to resolve the fault within the conditions and period specified in the Notice. The CLIENT shall only be liable to pay the Service Provider on the accomplishments delivered prior to the termination of the contract, and shall not in any way, prevent or prejudice any other claims which the parties may have against each other.

#### X. OTHER DOCUMENTARY REQUIREMENTS

- 1. List of Proposed completed and ongoing projects; and
- 2. List of technical personnel with their Curriculum Vitae indicating the relevant training and certification, and Professional Licenses, if applicable.





#### PRICE PROPOSAL FORM

Date:						
<b>The Bids and Awa</b> PITAHC Building, N Barangay Central C	Natapang Street, East Avenue Medical	Center Compound,				
Sir/Madam:						
After having carefuthe item as follows	ully read and accepted the Terms and ( ::	Conditions, I/we submit o	our proposal for			
	Item Description	Total Price (Exclusive of all costs, applicable taxes, and service charges)	Total Price (Inclusive of all costs, applicable taxes, and service charges)			
ULASIMANG BAT	LABORATORY SERVICES FOR STABILITY STUDY OF ULASIMANG BATO 500 MG TABLET OF THE PITAHC TACLOBAN HERBAL PROCESSING PLANT					
(2 <sup>ND</sup> REPOSTING)						
Amount in W	ords:					
·	price is inclusive of <b>all costs</b> and appl	icable taxes.				
Very truly yours,						
	Signature :					
Printed Name	:					
Date	:					
Company Name	:					
Contact Number	:					
PHILGEPS Registra	tion Number:					





#### **TERMS AND CONDITIONS COMPLIANCE**

	Compliance to Terms and Conditions / Technical Specifications / Terms of Reference (Check the corresponding box)		
Terms and Conditions / Technical Specifications / Terms of Reference			
	Compliant	Non-Compliant	Remarks: (Counter Specs Offer)
LABORATORY SERVICES FOR STABILITY STUDY OF ULASIMANG BATO 500 MG TABLET OF THE PITAHC TACLOBAN HERBAL PROCESSING PLANT			
OBJECTIVES: As per Item II of the Terms and Conditions	Yes ( )	No ( )	
The General Objective of this project is to render service of a third-party provider for laboratory services for PITAHC THPP's Ulasimang bato 500 mg tablet for FDA registration.			
The specific objectives of this project are as follows:			
a. To conduct the stability study on three samples of lot or batch of Ulasimang bato over 0, 3, 6, 12, 18, and 24 months			
<ul> <li>b. To evaluate the physical and chemical properties of the samples at different time intervals, including weight variation, moisture content, tablet hardness, friability, disintegration, TLC profiling, and organoleptic properties.</li> </ul>			
c. To assess the microbial load of the samples, including testing for Total Aerobic Count (TAC), Total Yeast and Mold (TYM), Escherichia coli (E. coli), Pseudomonas aeruginosa, Enterobacteria, Staphylococcus aureus, and Salmonella spp.			
<ul> <li>d. To determine the levels of heavy metals, including lead, cadmium, arsenic, and mercury in the samples.</li> </ul>			
METHODOLOGY: As per Item III of the Terms and Conditions	Yes ( )	No ( )	
Physicochemical and Microbiological     Analysis of the Raw Material	Yes ( )	No ( )	
2. Physicochemical and Microbiological Analysis of Finished Product	Yes ( )	No ( )	
3. Nutritional Analysis of Finished Product	Yes ( )	No ( )	
4. Accelerated Stability Study	Yes ( )	No ( )	
5. Long Term Stability Study	Yes ( )	No ( )	
6. Data Presentation	Yes ( )	No ( )	





7. Sample and Data Retention	Yes ( )	No ( )	
RESPONSIBILITIES of the Service Provider: As per Item IV.A of the Terms and Conditions	Yes ( )	No ( )	
To meet the above-mentioned objectives, the Service Provider should be able to:			
<ol> <li>Implement the project on the design/development the institutional contracting mechanism;</li> <li>Providing an accelerated storage chamber capable of simulating conditions for 18-24 months of storage.</li> <li>Conducting weight variation tests to assess the uniformity of weight among tablets.</li> <li>Performing moisture content analysis to determine the moisture content of the samples.</li> <li>Testing tablet hardness and friability to evaluate the mechanical strength of the tablets.</li> <li>Conducting disintegration tests to assess the time taken for tablets to disintegrate.</li> <li>Performing TLC profiling to identify and quantify the active constituents of Ulasimang bato.</li> <li>Assessing microbial load through testing for TAC, TYM, E. coli, P. aeruginosa, Enterobacteria, S. aureus, and Salmonella spp.</li> <li>Testing for heavy metals, including lead, cadmium, arsenic, and mercury, to ensure compliance with safety standards.</li> <li>Conducting organoleptic tests to evaluate the sensory properties of the samples. and help clients answer specialized business</li> </ol>			
questions with its market research.  QUALIFICATIONS for Service Provider: As	Yes ( )	No ( )	
per Item V of the Terms and Conditions  1. The Service Provider must possess the following qualifications:  a. Service Provider must have a valid FDA License to Operate (LTO) and certified with Current Good Manufacturing Practices (cGMP) or			
proof of application for renewal; b. Product development team lead must be a graduate of BS Pharmacy, Chemistry, Biotechnology or equivalent; c. Certification that bidder has at least 10- year experience in providing verifiable data, analysis in the pharmaceutical sector, locally and globally; d. Service Provider must have an experience dealing with Government Owned and Controlled Corporations (GOCCs) State			
Universities, and/or national government agencies in the provision of market share data/information and analysis; e. Service Provider must have an experience with working with pharmaceutical companies in product development and contract manufacturing			
PAYMENT SCHEDULE: As per Item VI of the Terms and Conditions (refer to tranches and required accomplishments.	Yes ( )	No ( )	





Payments shall be based on the completion of the activities and submission of required deliverables/reports subject to acceptance of the authorized representative of the Head of the Procuring Entity.)			
DURATION OF ENGAGEMENT AND IMPLEMENTING ARRANGEMENT: As per Item VII of the Terms and Conditions	Yes ( )	No ( )	
The engagement shall be completed within nine (9) months from the receipt of the Notice to Proceed (NTP).			
The PITAHC Research and Development Division and Tacloban HPP shall be the focal office in this engagement and the highest oversight authority.			
Failure to fulfill the obligations stipulated within the nine (9) months, or within the approved extension thereof, shall render the party liable for damages due to delay. The party shall be obligated to pay PITAHC liquidated damages amounting to one-tenth (1/10) of one percent (1%) of the total project cost for each day of			
delay. Such liquidated damages shall be payable upon the completion of the project. In the event that the cumulative liquidated damages reach ten percent (10%) of the total contract amount, PITAHC reserves the right to rescind or terminate the contract, without prejudice to pursuing any other remedies or courses of action available under the law.			
CONFIDENTIALITY: As per Item VIII of the Terms and Conditions	Yes ( )	No ( )	
The Service Provider shall not use (except for PITAHC's benefit) or divulge to anyone-either during the term of this Agreement or thereafter - any of the PITAHC's trade secrets, the proprietary information, or other proprietary data, personal information covered by the Data Privacy Act, or information of any kind whatsoever acquired by the Service Provider in carrying out the terms of this agreement. In this regard, the Service Provider shall:			
1. Warrant, represent and undertake reliability of the service required; 2. Agree to hold the proprietary information in strict confidence; 3. Agree not to reproduce, transcribe or disclose the proprietary information to third parties without prior written approval from the CLIENT; and 4. Uphold strict confidentiality of all information that will come to Service Provider knowledge.			
TERMINATION: As per Item IX of the Terms and Conditions	Yes ( )	No ( )	
The PITAHC may, in case of material default on the part of the Service Provider, terminate the contract, through written			





(30) the faul spe only the terr any clai	ice to the Service Provider at least thirty days prior to the termination, and that Service Provider failed to resolve the t within the conditions and period cified in the Notice. The CLIENT shall y be liable to pay the Service Provider on accomplishments delivered prior to the mination of the contract, and shall not in way, prevent or prejudice any other ms which the parties may have against hother.			
As Cor	HER DOCUMENTARY REQUIREMENTS:  per Item X of the Terms and additions	Yes ( )	No ( )	
•	List of Proposed completed and ongoing projects; and List of technical personnel with their Curriculum Vitae indicating the relevant training and certification, and Professional Licenses, if applicable.			
• Del	ivery Site: <b>PITAHC</b>	Yes ( )	No ( )	
No. For <b>Sat</b> <b>for</b>	part of the submission aside from Item 5 of the RFP and the Price Proposal m, bidder shall submit a Certificate of isfactory Completion/Performance those who have previous contracts h PITAHC, if applicable.	Yes ( )	No ( )	N/A ( )
Сог	nforme:			
	me of the Authorized Representative	N	ame of Company	 Date