

Request for Proposals (RFP)

The provision of Manufacturing *Siphonochilus aethiopicus* capsules services to CSIR

RFP No. 1048/16/11/2022

Date of Issue	02 November 2022
Closing Date	16 November 2022@ 16:30
RFP Responses and queries to be send to	tender@csir.co.za
Enquiries	E-mail: tender@csir.co.za
CSIR business hours	08h00 – 16h30
Category	Professional Services

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SECTION A – TECHNICAL INFORMATION

1 INTRODUCTION

The Council for Scientific and Industrial Research (CSIR) is one of the leading scientific research and technology development organizations in Africa. In partnership with national and international research and technology institutions, CSIR undertakes directed and multidisciplinary research and technology innovation that contributes to the improvement of the quality of life of South Africans. The CSIR's main site is in Pretoria while it is represented in other provinces of South Africa through regional offices.

2 BACKGROUND

The CSIR, through its Advanced Agriculture and Food and Next Generation Health Clusters, is implementing a project which seeks to add value to a South African indigenous plant species, *Siphonochilus aethiopicus*, also known as African ginger through manufacturing of the capsules that would be investigated for safety on humans in Phase I clinical studies. The CSIR has fully characterized the plant species in research and development, both from the biological and chemical point of views. The plant species did not demonstrate any toxicity profiles as shown by the CSIR data, both in vitro and in vivo. Furthermore, the CSIR has developed and optimized the extraction process technology during the research and development phase based on the plant species for the manufacture of safe and quality capsules, which can be implemented into the controlled manufacturing facility for manufacturing purposes. However, the CSIR does not have the manufacturing capabilities to fully implement the project to completion. We are therefore requiring your services in support of the CSIR project using your best and certified manufacturing processes and practices that are recognized by the South African Health Product Regulatory Authority (SAHPRA).

3 INVITATION FOR PROPOSAL

Proposals are hereby invited for the supply of services to manufacture about 2000 African ginger capsules and 2000 placebo capsules (capsules without African extracts) using Good Manufacturing Practices (GMP) for herbal and pharmaceutical drugs to the CSIR's. The service provider must be certified with SAHPRA to manufacture safe and quality pharmaceutical drugs and complementary medicines under GMP. A service provider with extensive experience to manufacture herbal and complementary medicines under GMP will be highly favored by the CSIR to provide the manufacturing services.

The type of services required:

- Manufacture about 2000 African ginger capsules and 2000 placebo (i.e. capsules that do not have African ginger extract) using the manufacturing protocols certified and recognized by SAHPRA to manufacture safe and quality capsules for Phase I clinical studies on 50 health human study participants to be conducted by a Clinical Research Organization. It is envisaged Phase I clinical studies will take 4 weeks to complete.
- The CSIR has developed the extraction and process technology, which has been optimized to manufacture African ginger safe and quality extracts and capsules. The service provider will be expected to implement the CSIR process technology in their manufacturing facility under relevant legal framework with the CSIR.
- Manufacturing data and report

4 PROPOSAL SPECIFICATION

- Certificate of Membership/Registration to professional body must be submitted together with the proposal.
- Bidders must submit responsive proposals in accordance with the RFP requirements and the evaluation criteria.

5 FUNCTIONAL EVALUATION CRITERIA

5.1 The evaluation of the functional / technical detail of the proposal will be based on the following criteria:

Selection criteria	Score
At least 10 years of track record, previous experience and past performance in the manufacturing herbal medicines under GMP conditions and have a license issued by SAHPRA to manufacture these types of medicines	35%
At least 10 years of experience in the manufacturing of pharmaceutical drugs and have a license issued by SAHPRA to manufacture pharmaceutical drugs	20%
Technical expertise in the manufacturing processes informed by research and development	25%
Supplier Portfolio of evidence on other similar manufacturing projects completed.	20%
Total	100%

5.2 Proposals with functionality / technical points of less than the pre-determined minimum overall percentage of 70% and less than 50% on any of the individual criteria will be eliminated from further evaluation.

5.3 Refer to **Annexure A** for the scoring sheet that will be used to evaluate functionality.

6 ELIMINATION CRITERIA

Proposals will be eliminated under the following conditions:

- Submission after the deadline;
- Supplier is not certified with and recognized by SAHPRA to manufacture safe and quality herbal medicines under GMP conditions.
- Supplier is not a South African company registered with the relevant laws of South Africa governing the operations of private sector companies and does not have physical manufacturing to operate in South Africa
- Supplier that is going to outsource the manufacturing services to the third party
- Bidders that submit to the incorrect location or email address will be eliminated.
- Bidders that are listed on the NT database of restricted suppliers will not be considered.
- Bidders that are registered on the NT Register of Tender Defaulters will not be considered.
- Bidders that do not submit a fully completed and signed SBD 1 and SBD 4 Form will not be considered

7 NATIONAL TREASURY CENTRAL SUPPLIER DATABASE (CSD) REGISTRATION

Before any negotiations will start with the winning bidder it will be required from the winning bidder to:

- be registered on National Treasury's Central Supplier Database (CSD). Registrations can be completed online at: www.csd.gov.za;
- provide the CSIR of their CSD registration number; and
- provide the CSIR with a valid copy of their B-BBEE certificate. If no certificate can be provided, no points will be scored during the evaluation process. (RSA suppliers only)

SECTION B – TERMS AND CONDITIONS

8 PROPOSAL SUBMISSION

All proposals must be submitted at tender@csir.co.za

9 TENDER PROGRAMME

The tender program, as currently envisaged, incorporates the following key dates:

- Issue of tender documents: 02 November 2022
- Last date for submission of queries: 10 November 2022
- Closing / submission Date: 16 November 2022
- Estimated contract duration (in months/years) 3 months

10 SUBMISSION OF PROPOSALS

10.1 All proposals should be labelled and emailed. No late submission will be accepted.

10.2 All proposals are to be clearly marked with the RFP number and the name of the tenderer on the subject line of the email. Price proposals should be labeled and emailed separately from technical proposals both clearly marked:

PART 1: Technical Proposal: RFP No 1048/16/11/2022

PART 2: Pricing Proposal, B-BBEE and other Mandatory Documentation:
RFP No 1048/16/11/2022

10.3 Proposals submitted by companies must be signed by a person or persons duly authorized.

10.4 The CSIR will award the contract to qualified tenderer(s)' whose proposal is determined to be the most advantageous to the CSIR, taking into consideration the technical (functional) solution, price and B-BBEE.

11 DEADLINE FOR SUBMISSION

Proposals shall be submitted to the email address mentioned above no later than the closing date of **16 November 2022**, during CSIR's business hours. The CSIR business hours are between 08h00 and 16h30.

Where a proposal is not received by the CSIR by the due date and stipulated place, it will be regarded as a late tender. Late tenders will not be considered.

12 AWARDING OF TENDERS

12.1 Awarding of tenders will be published on the CSIR's tender website. No regret letters will be sent out.

13 EVALUATION PROCESS

13.1 Evaluation of proposals

All proposals will be evaluated by an evaluation team for functionality, price and B-BBEE. Based on the results of the evaluation process and upon successful negotiations, the CSIR will approve the awarding of the contract to successful tenderers.

A two-phase evaluation process will be followed.

- The first phase includes evaluation of **elimination** and **functionality criteria**.
- The second phase includes the evaluation of **price** and **B-BBEE** status.

Pricing Proposals will only be considered after functionality phase has been adjudicated and accepted. Only proposals that achieved the specified minimum qualification scores for functionality will be evaluated further using the preference points system.

13.2 Preference points system

The 80/20 preference point system will be used where 80 points will be dedicated to price and 20 points to B-BBEE status. If all tenders received are more than R50m, the proposal will be cancelled and re-issued.

Provide a valid copy of a B-BBEE Certificate or valid sworn affidavit. No B-BBEE status will equal to zero points. B-BBEE certificate must be issued by SANAS accredited agency or a valid sworn affidavit in line with DTI regulations. (RSA suppliers only).

B-BBEE Verification Agency issued B-BBEE Certificates can be verified on SANAS website on Verification Agency (B-BBEE) under Accredited Facilities (Quick Access Links): <https://www.sanas.co.za/Pages/index.aspx> to check validity of the B-BBEE Certificate.

14 PRICING PROPOSAL

14.1 Pricing proposal must be cross-referenced to the sections in the Technical Proposal. Any options offered must be clearly labelled. Separate pricing must be provided for each option offered to ensure that pricing comparisons are clear and unambiguous.

- 14.2 Price needs to be provided in South African Rand (excl. VAT), with details on price elements that are subject to escalation and exchange rate fluctuations clearly indicated.
- 14.3 Price should include additional cost elements such as freight, insurance until acceptance, duty where applicable.
- 14.4 Only firm prices* will be accepted during the tender validity period. Non-firm prices** (including prices subject to rates of exchange variations) will not be considered.

*Firm price is the price that is only subject to adjustments in accordance with the actual increase or decrease resulting from the change, imposition, or abolition of customs or excise duty and any other duty, levy, or tax which, in terms of a law or regulation is binding on the contractor and demonstrably has an influence on the price of any supplies, or the rendering costs of any service, for the execution of the contract;

**Non-firm price is all prices other than "firm" prices.

- 14.5 Payment will be according to the CSIR Payment Terms and Conditions.

15 VALIDITY PERIOD OF PROPOSAL

Each **proposal** shall be valid for a minimum period of three (3) months calculated from the closing date.

16 APPOINTMENT OF SERVICE PROVIDER

- 16.1 The contract will be awarded to the tenderer who scores the highest total number of points during the evaluation process, except where the law permits otherwise.
- 16.2 Appointment as a successful service provider shall be subject to the parties agreeing to mutually acceptable contractual terms and conditions. In the event of the parties failing to reach such agreement CSIR reserves the right to appoint an alternative supplier.
- 16.3 Awarding of contracts will be announced on the National Treasury website and no regret letters will be sent to unsuccessful bidders.

17 ENQUIRIES AND CONTACT WITH THE CSIR

Any enquiry regarding this RFP shall be submitted in writing to CSIR at tender@csir.co.za with “RFP No 1048/16/11/2022” as the subject.

Any other contact with CSIR personnel involved in this tender is not permitted during the RFP process other than as required through existing service arrangements or as requested by the CSIR as part of the RFP process.

18 MEDIUM OF COMMUNICATION

All documentation submitted in response to this RFP must be in English.

19 COST OF PROPOSAL

Tenderers are expected to fully acquaint themselves with the conditions, requirements and specifications of this RFP before submitting proposals. Each tenderer assumes all risks for resource commitment and expenses, direct or indirect, of proposal preparation and participation throughout the RFP process. The CSIR is not responsible directly or indirectly for any costs incurred by tenderers.

20 CORRECTNESS OF RESPONSES

20.1 The tenderer must confirm satisfaction regarding the correctness and validity of their proposal and that all prices and rates quoted cover all the work/items specified in the RFP. The prices and rates quoted must cover all obligations under any resulting contract.

20.2 The tenderer accepts that any mistakes regarding prices and calculations will be at their own risk.

21 VERIFICATION OF DOCUMENTS

21.1 Tenderers should check the numbers of the pages to satisfy themselves that none are missing or duplicated. No liability will be accepted by the CSIR in regard to anything arising from the fact that pages are missing or duplicated.

21.2 Pricing schedule and B-BBEE credentials should be submitted with the proposal, but as a separate document and no such information should be available in the technical proposal.

22 SUB-CONTRACTING

22.1 A tenderer will not be awarded points for B-BBEE status level if it is indicated in the tender documents that such a tenderer intends sub-contracting more than **25%** of the value of the contract to any other enterprise that does not qualify for at least the points that such a tenderer qualifies for, unless the intended sub-contractor is an exempted micro enterprise that has the capability and ability to execute the sub-contract.

22.2 A tenderer awarded a contract may not sub-contract more than **25%** of the value of the contract to any other enterprise that does not have an equal or higher B-BBEE status level than the person concerned, unless the contract is sub-contracted to an exempted micro enterprise that has the capability and ability to execute the sub-contract.

23 ENGAGEMENT OF CONSULTANTS

The consultants will only be remunerated at the rates:

24.1 Determined in the "Guideline for fees", issued by the South African Institute of Chartered Accountants (SAICA); or

24.2 Set out in the "Guide on Hourly Fee Rates for Consultants", by the Department of Public Service and Administration (DPSA); or

24.3 Prescribed by the body - regulating the profession of the consultant.

24 TRAVEL EXPENSES

25.1 All travel expenses for the CSIR's account, be it directly via the CSIR's travel agent or indirectly via re-imburements, must be in line with the CSIR's travel policy. The following will apply:

25.1.1 Only economy class tickets will be used.

25.1.2 A maximum of R1400 per night for accommodation, dinner, breakfast and parking will be allowed.

25.1.3 No car rentals of more than a Group B will be accommodated.

25 ADDITIONAL TERMS AND CONDITIONS

- 26.1 A tenderer shall not assume that information and/or documents supplied to CSIR, at any time prior to this request, are still available to CSIR, and shall consequently not make any reference to such information document in its response to this request.
- 26.2 Copies of any affiliations, memberships and/or accreditations that support your submission must be included in the tender.
- 26.3 In case of proposal from a joint venture, the following must be submitted together with the proposal:
- Joint venture Agreement including split of work signed by both parties;
 - The original or certified copy of the B-BBEE certificate of the joint venture;
 - The Tax Clearance Certificate of each joint venture member;
 - Proof of ownership/shareholder certificates/copies; and
 - Company registration certificates.
- 26.4 An omission to disclose material information, a factual inaccuracy, and/or a misrepresentation of fact may result in the disqualification of a tender, or cancellation of any subsequent contract.
- 26.5 Failure to comply with any of the terms and conditions as set out in this document will invalidate the Proposal.

26 CSIR RESERVES THE RIGHT TO

- 27.1 Extend the closing date;
- 27.2 Verify any information contained in a proposal;
- 27.3 Request documentary proof regarding any tendering issue;
- 27.4 Give preference to locally manufactured goods;
- 27.5 Appoint one or more service providers, separately or jointly (whether or not they submitted a joint proposal);
- 27.6 Award this RFP as a whole or in part;
- 27.7 Cancel or withdraw this RFP as a whole or in part.

27 DISCLAIMER

This RFP is a request for proposals only and not an offer document. Answers to this RFP must not be construed as acceptance of an offer or imply the existence of a contract between the parties. By submission of its proposal, tenderers shall be deemed to have satisfied themselves with and to have accepted all Terms & Conditions of this RFP. The CSIR makes no representation, warranty, assurance, guarantee or endorsements to tenderer concerning the RFP, whether with regard to its accuracy, completeness or otherwise and the CSIR shall have no liability towards the tenderer or any other party in connection therewith.

DECLARATION BY TENDERER

Only tenderers who completed the declaration below will be considered for evaluation.

RFP No:

I hereby undertake to render services described in the attached tendering documents to CSIR in accordance with the requirements and task directives / proposal specifications stipulated in RFP No..... at the price/s quoted. My offer/s remains binding upon me and open for acceptance by the CSIR during the validity period indicated and calculated from the closing date of the proposal.

I confirm that I am satisfied with regards to the correctness and validity of my proposal; that the price(s) and rate(s) quoted cover all the services specified in the proposal documents; that the price(s) and rate(s) cover all my obligations and I accept that any mistakes regarding price(s) and rate(s) and calculations will be at my own risk.

I accept full responsibility for the proper execution and fulfilment of all obligations and conditions devolving on me under this proposal as the principal liable for the due fulfilment of this proposal.

I declare that I have no participation in any collusive practices with any tenderer or any other person regarding this or any other proposal.

I accept that the CSIR may take appropriate actions, deemed necessary, should there be a conflict of interest or if this declaration proves to be false.

I confirm that I am duly authorized to sign this proposal.

NAME (PRINT)
CAPACITY
SIGNATURE
NAME OF FIRM
DATE

WITNESSES	
1
2
DATE:	

28 ANNEXURE A

EVALUATION CRITERIA/SCORING SHEET

NO	CRITERIA	SCORING	WEI GHT
1.	At least 10 years of track record, previous experience and past performance in the manufacturing herbal medicines under GMP conditions and have a license issued by SAHPRA to manufacture these types of medicines.	10 = 10 years and more. 7 = more than 8 and up to 9 years 5 = more than 5 and up to 7 years 1 = 0 and up to 4 years	35%
2.	At least 10 years of experience in the manufacturing of pharmaceutical drugs and have a license issued by SAHPRA to manufacture pharmaceutical drugs	10 = 10 years and more. 7 = more than 8 and up to 9 years 5 = more than 5 and up to 7 years 1 = 0 and up to 4 years	20%
3.	Technical expertise in the manufacturing processes informed by research and development.	10 = Demonstrated excellent expertise informed by R&D 7 = Demonstrated good expertise informed by R&D 5 = Demonstrated average expertise informed by R&D 1 = Demonstrated poor expertise informed by R&D	25%
4.	Supplier Portfolio of evidence on other similar manufacturing projects completed.	10 = 4 or More Completed Similar Projects. 7 = 3 Completed Similar Projects. 5 = 2 Completed Similar Projects. 1 = 1 Completed Similar Project.	20%
	Total		100%
	Minimum Threshold		70%