INVITATION FOR BID

FOR THE PURCHASE AND SUPPLY OF COMMODITIES
"ZINC SYRUP, LO-ORS SACHET"

UNDER NUTRITION INTERNATIONAL PROJECT

INVITATION TO BIDDERS (ITB):	**BRSP/NI/2021/01**
TO PROCURE:	**ZINC, LO-ORS**
DELIVERY TERM:	**QUETTQ, PAKISTAN**
ISSUANCE DATE:	**AUGUST 14, 2021**
LAST BID RECEIPT DATE:	**September 07, 2021** **05:00 P.M. LOCAL TIME**

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Description:

Balochistan Rural Support Programme (BRSP), invites proposals from authorized manufacturer /distributors/companies having a legal presence in Pakistan for "Purchase of Commodity i.e., "Zinc & LO-ORS"

1.1 Technical Details:

The proposed procurement includes details as follows:

1. **Product Description**

Finished Product: Zinc Sulfate Syrup

1.1 The Zinc syrup should be supplied in bottle of 60 ml.

1.2 Zinc Sulfate syrup shall contain Zinc Sulfate Monohydrate and must conform to the general requirements of syrup given in British Pharmacopoeia (BP) or US Pharmacopoeia (USP) under Zinc Sulfate syrup.

1.3 The Active Pharmaceutical Ingredient (API) and excipients must also comply with the monograph and general notices (and general requirements) from one of the following pharmacopeias: British (BP), or United States (USP).

1.4 Each bottle of syrup shall contain Zinc Sulfate Monohydrate equivalent to 20 mg of Elemental Zinc.

1.5 The formulation of the syrup and the manufacturing process are designed and controlled to ensure that the metallic taste and smell of the zinc salt is adequately masked.

The concentration of saccharin should be such that its daily intake is not more than 5mg/kg of body weight and that of aspartame should be such that its daily intake is not more than 40mg/kg of body weight.

1.6 Each bottle should be stamped "Note for Sale" with BRSP and Nutrition Interantion

Finished Product: Low Osmolarity Oral Rehydration Salts (LO-ORS)

1.6 LO-ORS powder will be supplied in hermetically sealed sachets, each containing 20.5 g for dilution in 1 L of clean water.

1.7 LO-ORS Salts must conform to the requirements of British Pharmacopoeia (BP)/United States Pharmacopoeia

(USP).

1.8 LO-ORS salt should be white to creamy white, amorphous, or crystalline powder, odourless. It should contain dry homogenously mixed oral powders containing Anhydrous Dextrose, Sodium Chloride, Potassium Chloride and Sodium Citrate.

1.9 L-ORS may contain suitable pharmaceutical aids (e.g., suitable flow agent in minimal quantities to improve the flow characteristics) and/or flavoring agents.

1.10 The following table outlines the composition of the recommended L-ORS formulation with a total osmolarity of

245 mOsmol/l.

Reduced osmolarity ORS	grams/litre
Sodium chloride	2.6
Glucose, anhydrous	13.5
Potassium chloride	1.5
Trisodium citrate, dehydrate	2.9

Ingredients	Label Claim
Zinc Sulfate *Syrup* 20 mg	Zinc Sulfate Monohydrate equivalent to 20 mg elemental Zinc *Molecular formula:* *$ZnSO_4 \cdot H_2O$ Relative* *molecular mass: 179.46* *Chemical name: zinc sulfate monohydrate*
Reduced osmolarity ORS	L-Oral Rehydration Salts 20.5 g Sachet for 1/L Solution (New WHO Formula) *Sodium: 75mmol/litre* *Chloride: 65 mmol/litre* *Glucose, anhydrous; 75 mmol/litre* *Potassium; 20 mmol/litre* *Citrate; 10 mmol/litre* ***Total Osmolarity: 245 mmol/liter***

2. **Dosage:**

2.1 Zinc Oral Solutions at Concentration of 20mg/5ml are recommended as 5ml corresponds to one teaspoon, therefore infants will receive half teaspoon while older children will receive one teaspoon.

2.2 Each 20.5 g L-ORS packet is to be mixed in 1 liter of clean water. A family member should be taught to prepare and give ORS solution. The solution should be given to infants and young children using a clean spoon or cup. Children under 2 years of age should be offered a teaspoonful every 1-2 minutes; older children (and adults) may take frequent sips directly from the cup. Breastfeeding should be continued for infants and young children.

3. **Shelf Life and Storage**

3.1 The finished products (both Zinc Sulfate syrup and L-ORS) must contain a shelf-life of at a minimum 24 months.

4. **Conservation and Packaging**

4.1 The products must be packed in a child proof/ tamper-evident container.

4.2 Packaging must conform to the latest edition of British (BP), United States (USP), European (Ph. EUR) or other internationally recognized Pharmacopeia Standard for Pharmaceutical packaging and should be suitable for shipment, storage and use at elevated temperatures and humidity typical of Zone IV a and/or Zone IV b country climate.

4.3 The label on the package should include the name and amount of the active ingredient, batch number, expiry date,

manufacturer’s name and address, number of units per package, and dosage form.

Annex - 1

Additional information and quality standards for suppliers (applicable to both Zinc Sulfate Syrup and L-ORS products):

- The drug shall be currently registered in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug also shall be currently registered in Pakistan and shall meet all the requirements of the licensing authority. The drug should have minimum 2 years shelf life. Products with longer shelf life may be preferred.
- The bidder shall guarantee that the both zinc sulfate syrup and Lo ORS (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the bidder (d) are free from defects in workmanship and in materials and (e) it has been manufactured as per GMP included in Schedule M of the Drug Act.
- The bidder shall provide a copy of the Certificate of Analysis for each lot intended for shipment**.** The Supplier shall provide to BRSP a copy of the approval of each source material, constituent material and component for each lot intended for shipment.
- The bidder shall provide a copy of validation records with regards to process validation demonstrating batch to batch consistency. The Supplier shall provide documentary evidence that the artificial sweetening and the flavouring agents used, are harmless and within the permitted requirements; that they do not impair therapeutic efficacy and safety of the preparation and do not interfere in the analysis by official methods.
- The bidder shall retain samples of 5 units from each lot shipped for two years beyond the printed expiration date.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to the NI's representatives when requested.

- The BRSP may conduct independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. Complete Test Protocol and samples are taken and sent to the laboratory (identified by the BRSPby the Inspecting Officer duly sealed and signed by him or his authorized representative. Protocols of tests should include the requirements given in British Pharmacopoeia for syrup and those included in USP under Zinc Sulfate syrup. It should also include protocol to tests given in British Pharmacopoeia for Oral Rehydration Salt and for Oral powders.

Packaging and Labeling Requirements

Zinc Sulphate: The Zinc syrup should be supplied in bottle of 60 ml.

Oral Rehydration Salt: The quantity of ORS in each sachet should be 20.5gms. A combination of polyethylene, aluminium and polyester has proved to be a very effective combination for packing ORS. The polyethylene on the inner side is essential for heat sealing the compound together, the aluminium in the Middle reduce the permeability to gas and steam and the Polyester on the outside protects the aluminium, and the ink on the aluminium The Quality and Composition of the thickness should be within the following limits:

		Micron	Mm	g/m2
Inside	Polyethylene	50	0.040 – 0.050	36.9 – 46.1
Middle	Aluminium	09	0.009 – 0.015	24.3 – 40.5
Outside	Polyester	12	0.012 – 0.015	12.9 – 20.9

The size of the Lo ORS sachet may be 75mm X 105mm

Printed Insert Material: Information sheets, printed in Urdu, in one colour shall be included in each box of Zinc bottle. Design, content, and the specification of the printed insert will be developed in consultation with the NI. Approximate size of the printed material will be 20 X 15 cm and shall include the following information:

- directions for use
- content of all ingredients
- adverse effects, contraindications, and
- storage conditions.

Labelling:

The label on each bottle of Zinc syrup and Lo ORS sachets shall conform to the requirements of DRAP or as per following:

- Name of the manufacturer,
- Manufacturing license number,
- Address of manufacturer
- Usage dose
- Direction for use.
- Amount of active ingredient(s) and pharmacopoeia standard
- Warnings
- Flavouring agents
- Instruction for storage
- Lot number
- Date of Manufacture (month and year)
- Expiry date (month and year)
- Permanent stamp of “NOT FOR SALE” with Logo of BRSP and Nutrition International

Annex - 2

Uniformity of content, seals integrity test and microbial count test for Zinc Sulfate Syrup

Uniformity of Content:

The test is determined by measuring the content of each of bottle of syrup. Each bottle of Zinc syrup is individually powdered and used separately to make a solution of Zinc Sulfate. The method given in USP for the assay is followed. The content of Zinc in each bottle is estimated. The amount of Zinc in each bottle should be within _+15% of the average amount of the active ingredient. However, if one bottle deviates by more than _+ 15%, but is within _+ 25% of the average amount of the active ingredient, examine a further 20 bottles drawn from the same original sample. The preparation complies only if the amount of Zinc found in no more than one out of 20 bottles deviates by more than _+ 15% of the average amount and none should deviate by more than _+ 25% of the average amount.

Microbial Count:

When the test is conducted as per British Pharmacopoeia

Total viable aerobic count- Not more than 103 bacteria and not more than 102 fungi per gram

- Absence of Escherichia coli
- Salmonella species
- Staphylococcus aureus
- Pseudomonas aeruginosa

L-ORS Seals Integrity Test:

Check 10 sachets. Bundle up the packets and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa (15 cm of mercury or -0.8 bar) and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Re-establish normal pressure and open sachets to examine for water penetration

Moisture Content:

Limits: maximum 2%

Check two sachets by drying the contents to constant mass at 500C. The drying should be continued until the results of two consecutive weighing's do not differ more than 0.5mg, the second weighing being made after additional hour of drying under the prescribed conditions.

They should not lose more than 20mg/g. If the limit is exceeded in one packet, check another

18 sachets

If two or more sachets are found to exceed the limit, reject the batch.

Appearance of Solution:

Dissolve the entire contents of one sachet of ORS in 500/1000 ml of water and the solution should be clear on reconstitution.

pH of Solution:

Check the pH of the solution reconstituted as directed on the label. It should be within the range of 7.0 – 8.8.

Microbial Count:

When the test is conducted as per British Pharmacopoeia

-Total viable aerobic count- Not more than 103 bacteria and not more than 102 fungi per gram

-Absence of Escherichia coli

To qualify for the tender, firms must address the entire scope outlined above and detailed in other annexures/appendix of this document as well as any further communication issued in association with this ITB.

5. ACCEPTANCE:

The acceptance criterion for successful bids is defined in the following sections with details being provided for the bidding procedure to be followed for this tender by the BRSP.

5.1 Instructions for Bidders

5.1.1 Only those bidders are eligible to apply who have registration of Zinc Sulphate Syrup and/or LO- ORS.

5.1.2 The manufacture should be GMP certified.

5.1.3 Bidding is open to all Bidders that meet the given minimum qualification criteria relating to previous experience, delivery capability, firms standing, etc., as stated in the ITB.

5.1.4 Any inquiry concerning this ITB and any return bid(s) must be submitted in writing, to be received sufficiently in advance of the Last Bid Receipt Date to permit a thorough and accurate response by BRSP. Such inquiries shall be sent to e-mail procurement@brsp.org.pk. B R S P is under no obligation to consider or respond to questions that are not received in a timely manner.

5.1.5 A bidder can submit only one bid as multiple bids and offers shall not be considered.

5.1.6 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Purchaser will in no case be responsible or liable for those costs.

5.1.7 Bidders are expected to examine all instructions, forms, terms, specifications, and other information in the ITB.

Failure to furnish all information required by the ITB or to submit a bid not substantially responsive in every respect will be at the Bidder's risk and may result in the rejection of its bid.

5.1.8 The bidder should quote a composite price inclusive of all taxes & duties for all required items etc.

5.1.9 The bidder should mention clear timelines as to when the all the required commodities would be delivered.

5.1.10 Top three successful bidders may ask to provide samples for the approval from the concerned.

5.2 Procedure for Submission of Bid

- For this tender 'Single stage- one envelope procedure' open competitive bidding shall be adopted
- Bidder may submit Technical brochure of the offered Product (if any).
- Company profile with Income Statement or Annual report showing financial status, cliental list of the company.

6. GENERAL TERMS & CONDITIONS:

6.1 Registration

6.1.1 Zinc & LO-ORS should be individually registered with DRAP.

6.2 Third Party Sampling & Acceptance of Consignment

6.2.1 After manufacturing, the products will be tested by the manufacturer through GOP run Drug Testing Labs (DTLs) for Quality Assurance and will share reports with BRSP.

6.2.2 The Goods (Zinc and LO-ORS) shall comply with the specifications in SoW, Annexure 1 & 2. Strict compliance with these quality standards is mandatory and deviations or alternatives to the stated requirements shall not be permitted under any circumstances. Any deviation from specifications shall lead to an automatic rejection of the Goods and entitle NI to immediately terminate the Contract.

6.2.3 Third Party lab testing for each manufactured batch number, along with the testing method used to identify results on the Certificate of Analysis, will be sent for testing to a third party certified laboratory in Pakistan.

6.3 Validity of the Proposal

6.3.1 All proposal and price shall remain valid for a period of 60 days from the last date of bid submission. However, validity could be extended with mutual consent of the parties.

6.4 Clarification and Amendment to ITB (Pre-bid Meeting)

6.4.1 To clarify issues and answer queries on any matter that may be raised at this stage, a pre-bid conference if required will be held in the office of BRSP

6.4.2. In order to give prospective Bidders reasonable time in which to take the amendment into account in preparing their bids, the BRSP may, at its discretion, extend the deadline for the submission of bids.

6.5 Delivery Timelines:

6.5.1 Selected vendor should complete the required quantities within the period of One (01) month.

6.6 Insurance:

6.6.1 The manufacturer will get the products insured until they reach the BRSP Warehouse.

6.7 Penalty Clause:

6.7.1 The contract to be executed between BRSP and the successful vendor will contain penalty clauses for delay in the delivery of the required items.

6.8 Currency:

6.8.1 All currency in the ITB shall be quoted in Pakistan Rupees (PKR).

6.9 Withholding Tax, Sales Tax and other Taxes:

6.9.1 The interested firms are hereby informed that the BRSP shall deduct applicable tax(es) at the rate prescribed under the tax laws of land, from all payments. The firm will be responsible for all taxes levied by government from time to time.

6.10 Submission Date & Address:

6.10.1 Last date for submission of bids is **September 07, 2021 (05:00 P.M.)** at the BRSP's address as follows:

BRSP Procurement Unit;
5A, Gulshan E Janan Street,
Sariab Road, Quetta- Pakistan.

6.11 Sealed Envelope:

6.11.1 On the top of the sealed envelope should be clearly mark **"Bids for Commodities".**

6.12 Disqualification:

6.12.1 The firm(s) who had defaulted in their P.O's/contracts to perform a contract awarded by BRSP is not eligible to participate in the tender.

6.12.2 The firms who have not fulfilled their contractual obligation with BRSP shall also not be eligible to participate in the Bid(s), unless they clear their dues along with penalties or fulfill their contractual obligations with BRSP.

6.13 Earnest Money:

6.13.1 Earnest money @ 2% (refundable) of the total amount should be submitted with the ITB in shape of "Pay Order/Demand Draft" in the name of "Balochistan Rural Support Programme" BRSP

6.14 Rights:

6.14.1 BRSP reserve the right to accept or reject any or all tender(s) without assigning any reason thereof.

6.15 ELIGIBILITY OF BIDDERS

6.15.1 Bids are invited directly from pharmaceutical manufacturers herein referred to as Bidders. Companies which have been **Blacklisted/de-registered or process of such or any other penal action have been initiated against them by the Government of Pakistan are barred from submitting a quotation.**

6.15.2 Bidders shall submit an affidavit sworn stating that "the company has not been blacklisted/de-registered/barred by Government of Pakistan'

6.15.3 Bidders will be required to demonstrate to the BRSP that they are able to meet all the requirements of this ITB; are technically, managerially and financially able to perform and complete any resulting Contract; and will be production-ready at the time of expected award of Contract. These factors will be considered in the bid evaluation.

6.15.4 Bidders must disclose in their bid details of any circumstances, including personal, financial and business activities that will, or might, give rise to a conflict of interest. This disclosure must extend to all personnel proposed to undertake the work.

6.15.5 Bidders must have a minimum three-year-old Manufacturing License for zinc sulphate syrup and/or ORS with the latest license renewal certificate and product list. The Manufacturing Licence must be valid on the last date of submitting the quotation. The Licence should be issued by the competent Drug Licensing Authority (Pakistan).

6.15.6 Annual turnover of the **company or companies (for Joint bidders) should be a minimum of Rs.2 crore** in each of the last three consecutive Financial Years 2017-2018, 2018-19, 2019-20. The last three financial years of an Audited Annual Report showing details of their annual turnover should be submitted. An **Auditor / C.A. Certificate of turnover will not be accepted**.

6.15.7 The income tax return report for assessment years 2017-2018, 2018-19, 2019-20 should be submitted.

6.15.8 Bidders should submit their NTN & Sales Tax Registration Certificate copies.

6.15.9 Bidders should submit their Certificate of large scale manufacturing /production capacity of drugs/pharmaceuticals issued by concerned Licencing Authority from the Drugs Regulatory Authority.

6.15.10 The successful bidder will be asked to submit the license for manufacturing of Zinc Sulphate & Lo ORS from the appropriate national authority prior to award of the contract.

A. Appendix: Format for Financial Proposal:

S.#.	Product Name	Quantity	Pack Size	MRP (Rs.)	Cost Price to BRSP (Rs.)	Amount (Rs.)
1	Zinc Syrups	76,000	60 ml			
2	LO-ORS Sachet	76,000	Sachet (Pack of 30's)			

Company Name:_____

Contact Person: _____

Contact Number:_____

Designation: _____

Date: _____

Authorized Signature: _____

Company Seal_____

2. LETTER OF BIDDER CERTIFICATION

Re: ITB No.XXXX dd/mm/yr

Dear

We have examined the information provided in your ITB Document and offer to undertake the work described in accordance with requirements as set out in the ITB. This proposal is irrevocable for a period of 60 days after the deadline for submission of proposals and we confirm that this proposal will remain binding upon us and may be accepted by you at any time before its expiry date.

We acknowledge, that we are not involved in any collusion or arrangement with any other Respondent in connection with this ITB. We have no knowledge of and have made no comparison of the information in our Proposal with the information contained in any other Proposal. All statements and responses to this ITB are true and accurate.

We confirm that to the best of our knowledge at the time of this submission all suppliers named in the proposal will be available to undertake the supply. We agree to bear all costs incurred by us in connection with the preparation and submission of this proposal and to bear any further pre-contract costs.

I confirm that I have the authority of **[Company Name]** to submit this proposal and to clarify any details on its behalf.

SIGNED

_____
Company Name

_____
Print Name and Title

_____
Signature of Proposer

_____
Date

I have authority to bind the Proposer

3. TABLE OF INGREDIENTS, MATERIALS AND SUPPLIERS

Bidders must list all excipients in descending order (by weight) and the intended sources of supply.

Material(s) to be supplied:	**Material Supplier:** **Name and address of plant from which materials will be supplied**
1a) Ingredients including flavoring agents: Zinc Sulphate syrup	
1b) Ingredients including flavoring agents: LOORS	
2) Primary Packaging (sachets, Syrup)	

Attachment F: Bidder Client References

Reference no. 1

Name of Client: _____

Contact person: _____

Contact information: _____

Email: _____

Telephone: _____

Product supplied: _____

No. of years in business with client: _____

Start/End date of contract: _____

Contract Value: _____

Reference no. 2

Name of Client: _____

Contact person: _____

Contact information: _____

Email: _____

Telephone: _____

Product supplied: _____

No. of years in business with client: _____

Start/End date of contract: _____

Contract Value: _____

Reference no. 3

Name of Client: _____

Contact person: _____

Contact information: _____

Email: _____

Telephone: _____

Product supplied: _____

No. of years in business with client: _____

Start/End date of contract: _____

Contract Value: _____

Checklist for Completeness of Bids

S.#.	Document Type	Submitted		Comments
		Yes	No	
1	Earnest Money 2% of the total bid value			
2	Letter of Bidder Certification			
3	Company Profile			
4	Income Statement or Annual Report (2018-2019, 2019-2020, 2020 – 2021)			
5	Clientle List			
6	Affidavit (non blacklisting/de-registered/barred by Government of Pakistan)			
7	Manufacturing License			
8	Income Tax Return (2018-2019, 2019-2020, 2020 – 2021)			
9	NTN & Sales Tax Registration Certificate (Copy)			
10	Certificate of Large Scale Manufacturing / Production			
11	Table of Ingredients, Materials and Suppliers			
12	Bidder Client References			
13	Appendix: Format for Financial Proposal			
14	Delivery Timeliness			
15	Validity of Proposal (60 days)			

Company Seal_____