



Request for Proposals

RFP No: 31-08-2026

50,000IU Vitamin A Soft Gelatin Capsules

Issued by Nutrition International

Deadline for receipt of proposals at Nutrition International:

Monday, October 5th, 2026
16:00 Eastern Standard Time

Table of Contents

1.0	REQUEST FOR PROPOSALS	3
2.0	ELIGIBILITY OF CONTRACTORS	3
3.0	GENERAL CONSIDERATIONS.....	4
4.0	SCOPE OF PROPOSAL	4
5.0	INSTRUCTIONS FOR SUBMISSION OF PROPOSALS	6
6.0	COMMERCIAL AND TECHNICAL REQUIREMENTS	7
7.0	WARRANTY AND WARRANTY PERIOD	8
8.0	SOURCE OF FUNDS	8
9.0	EVALUATION AND SELECTION PROCESS.....	8
10.0	NOTIFICATION OF AWARD.....	10
11.0	LIST OF ANNEXES	10
12.0	KEY DATES & DELIVERABLES	11

1.0 REQUEST FOR PROPOSALS

- 1.1 This Request for Proposals (“RFP”) is an invitation by Nutrition International to prospective contractors to submit proposals for 50,000IU Vitamin A Soft Gelatin Capsules that meet the specifications presented in Annex B of this RFP. While this RFP is for a small project, there may be subsequent RFPs in the future to procure larger quantities of product.
- 1.2 All enquiries pertaining to this RFP must be sent in writing by email to proposals@nutritionintl.org with the subject line including the words “**RFP No. 31-08-2026**”, **before 16:00 EST on Friday, September 25th, 2026**. Questions received thereafter will not be answered. Substantive enquiries (without attribution of the source) and responses to them shall be shared with all parties and shall form part of this RFP. Responses will be sent as soon as possible. Should questions not be answered, Contractors should submit their proposals prior to RFP closing just the same.
- 1.3 Proposals must be sent electronically (via email to proposals@nutritionintl.org) by **no later than 16:00 EST (Ottawa) on Monday, October 5th, 2026**.

2.0 ELIGIBILITY OF CONTRACTORS

- 2.1 This RFP is open only to Contractors who have received invitation from NI.
- 2.2 Contractors will be required to demonstrate to NI that they are able to meet all the requirements of this RFP; 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 evaluation.
- 2.3 Contractors must disclose in their proposal details 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 should a contract be awarded.
- 2.4 Where Contractors identify any potential conflicts, they must state how they intend to avoid any impact arising from such conflicts. NI reserves the right to reject any proposals which, in NI's opinion, give rise, or could potentially give rise to, a conflict of interest.
- 2.5 Contractors must also disclose:
- 2.6.1 If they are or have been the subject of any proceedings or other arrangements relating to bankruptcy, insolvency or the financial standing of the Contractor including, but not limited to, the appointment of any officer, such as, a receiver in relation to the Contractor's personal or business matters or an arrangement with creditors or of any other similar proceedings.
- 2.6.2 If the company or key management have been convicted of, or are the subject of any proceedings, relating to:
- I. a criminal offence or other offence, a serious offence involving the activities of a criminal organization or found by any regulator or professional body to have committed professional misconduct
 - II. corruption including the offer or receipt of any inducement of any kind in relation to obtaining any contract, with NI, or any other contracting body or authority
 - III. failure to fulfil any obligations in any jurisdiction relating to the payment of taxes

3.0 GENERAL CONSIDERATIONS

- 3.1 Contractors are responsible for all costs associated with proposal preparation and submission.
- 3.2 Proposals shall remain irrevocable in the form submitted by a Contractor for a period of 180 days after the deadline for submission of proposals.
- 3.3 If NI selects a Contractor(s) to supply vitamin A Soft Gelatin Capsules to NI, the selected Contractor(s) will be notified by NI and must enter into an agreement in the form of the contract attached as Annex E: Sample Contract to this RFP (the "Contract"). In the event of a Contract award, all the terms and conditions of this RFP and its Annexes, including the Contractor's response to the RFP, will form part of the Contract, unless otherwise negotiated.

A selected Contractor(s) who enters into a Contract with NI is referred to in this Request for Proposals as a "Contractor".

4.0 SCOPE OF PROPOSAL

- 4.1 **SUPPLY REQUIRED:** Bottled soft gelatin capsules containing Vitamin A meeting the specifications for the product, packing, bottling, labelling and all other requirements detailed in Annexes B & D as follows:

- 1.1.1 Refer to Annex B for Vitamin A Soft Gelatin Capsules Technical Product Specifications.

Refer to Annex D for the following:

- 1.1.2 Desiccant Pack Specifications.

- 1.1.3 Bottle and Bottle Label Specifications.

- 4.2 All references to Vitamin A capsules in all documents of the proposal should use NI's product item classification system below.

- 4.2.1 **Item 1:** 50,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules, **25-50** capsules per bottle, Optimal Shelf-Life: 36 months, Acceptable Shelf-Life: 24 months

- 4.2.2 **Item 2:** 50,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules, **25-50** capsules per blister pack, Optimal Shelf-Life: 36 months, Acceptable Shelf-Life: 24 months

- 4.3 **QUANTITIES REQUIRED:** Final quantities of Vitamin A Soft Gelatin Capsules will be determined based on the requirements of the project, with consideration given to the Contractor's production batch sizes and minimum order quantities (MOQ). Required quantities are to be packaged in bottles/blisters of 25 capsules or packaged in bottles/blisters of 50 capsules.

Contractors will be asked to propose prices for each product Item shown below, based on applicable MOQ and packaging configurations:

Capsule Type	Bottle count size (Number of capsules/ bottle)	MOQ (Number of packs)	MOQ (Total Number of capsules)
Item 1: 50,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules, 25-50 capsules per bottle, Optimal Shelf-Life: 36 months, Acceptable Shelf-Life: 24 months	25-50		
Item 2: 50,000 IU Vitamin A Oral Liquid Preparation (USP) as Soft Gelatin Capsules, 25-50 capsules per blister pack, Optimal Shelf-Life: 36 months, Acceptable Shelf-Life: 24 months	25-50		

4.4 COMPLIANCE WITH GOOD MANUFACTURING PRACTICE: Vitamin A Soft Gelatin Capsules at these high doses are to be considered pharmaceutical products and must be manufactured in accordance with prevailing Good Manufacturing Practices (GMP) Standards for pharmaceutical products as verified by the relevant National Drug Regulatory Authority, and by one or more internationally recognized authorities (that are members or partners of the Pharmaceutical Inspection Cooperation Scheme [PIC/S]).

4.5 It will be a condition for receiving a contract from NI that a Contractor demonstrates adherence to Good Manufacturing Practices meeting pharmaceutical Standards to NI. Selected Contractors will be asked to make available their facilities, on short notice, so that NI or their designated representatives may carry out a site inspection and quality assessment at any time prior to or while the Contract is in force.

4.6 REQUIRED DELIVERY SCHEDULE: The target arrival date for the first shipments of capsules at the DAP point is **31 March 2027**. **Contractors should propose shipments that are most efficient and cost effective for NI, however contractors should also include proposed shipments via air freight to be evaluated to ensure the most timely implementation of the project.**

4.7 DELIVERY DETAILS:

Contractors should note that:

- 4.7.1** The delivery date at the DAP point is to be understood as the date the goods arrive at DAP point (final destination). The DAP point is Karachi Port, Pakistan.
- 4.7.2** Only goods meeting the technical product specifications in Annex B: Vitamin A Soft Gelatin Capsules Technical Product Specifications are to be shipped from the Contractor.
- 4.7.3** At the time of shipment from the Contractor, 24-month shelf life products must be no more than three (3) months old from the date of manufacture and 36-month shelf life products must be no more than four (4) months old from the date of manufacture.
- 4.7.4** Any and all shipments must be made by full container loads only. Any lesser quantity, such as half container loads, is not acceptable, unless otherwise authorized by NI.
- 4.7.5** No goods in quarantine are to be shipped.
- 4.7.6** For shipments arriving via sea, NI will need to be notified on the number of free days that has been negotiated at the port with the Contractor's freight forwarder. The required number of days is not contract bound, but it would be ideal to have 7 free (work) days if possible.

4.8 FREIGHT, FREIGHT INSURANCE AND PRODUCT LIABILITY INSURANCE: The Contractor will pay freight as per the DAP terms (Incoterms 2010) as specified in 4.7. NI will reimburse the actual cost thereof in accordance with the Contract.

4.9 The Contractor will be required to arrange and pay for freight insurance at 110% of the value of the shipment. NI will reimburse the actual cost thereof in accordance with the Contract.

4.10 **PRODUCT LIABILITY INSURANCE:** The Contractor shall carry Product Liability Insurance in an amount of no less than CAD \$6,000,000 with respect to the Contract. The Contractor warrants that it will include NI as additional insured for the Contract and for its duration including the warranty period (see 7.1).

4.11 Such insurance may be renewed but cannot be changed or cancelled without the prior written approval of NI. The Contractor will be required to provide a copy of the insurance policy each year until the end of the warranty period on the expiration date of the policy.

5.0 INSTRUCTIONS FOR SUBMISSION OF PROPOSALS

5.1 Cover letter

5.1.1 Contractors **are required** to submit a cover letter expressing interest in participating in the RFP, confirming that all information submitted is true and correct, and confirming that the manufacturing facility has the capacity to produce Vitamin A in accordance with the technical requirements for the product as set out in this RFP and the delivery schedule and pricing table provided in their proposal.

5.1.2 New Contractors are requested to complete the New Supplier References as set out in (Annex H).

5.2 Pricing table

5.2.1 The Pricing Table (Annex F) must be completed and submitted as part of the proposal.

5.2.2 Contractors must provide cost per bottle for capsules in CAD.

5.2.3 All prices provided in the Pricing Table shall be firm and fixed until completion of the award period.

5.2.4 Prices for capsules must be provided separately in the Pricing Table. All manufacturing-related expenses and charges must be included within the unit price for capsules, including but not limited to production, quality assurance, packaging (including labels), packing suitable for export and in accordance with terms and conditions as set out by this RFP, and preservation in accordance with standard commercial practices unless otherwise specified.

5.2.5 Prices for Freight must be provided separately in the Pricing Table. Shipping terms used must be in accordance with the International Chamber of Commerce Incoterms 2010. Freight prices must be quoted on the basis of:

5.2.6 Delivered at Place (DAP) Karachi Port, Pakistan

5.2.7 Prices for Insurance must be provided separately in the Pricing Table. Freight insurance must be 110% of the value of the shipment.

5.3 Discounts

5.3.1 Contractors are requested to advise as to quantity/volume discounts in the form of large quantity/volume discounts and staircase pricing (i.e. varying prices according to different quantities procured).

5.3.2 Should the Contractors determine that a number of bottles other than the ranges specified in the Pricing Table (Annex F) result in a preferable pricing scheme, Contractors are encouraged to submit a second, additional table specifying these alternative ranges.

5.4 Lead time

- 5.4.1 Contractors are required to indicate the realistic lead time for delivery of each product in the Lead Timetable (Annex F).
- 5.4.2 Delivery lead time is the period from the date of receipt of a purchase order by the Contractors to the date of delivery of the goods to the Delivered at Place (DAP) point in accordance with the applicable delivery terms and instructions specified. The lead time includes the period for manufacturing and packing the products, pre-delivery inspection (if applicable), obtaining any necessary regulatory authority approvals or licenses, shipping, and provision of all documentation required in connection with such delivery.
- 5.4.3 The DAP point is Karachi Port, Pakistan

5.5 Delivery schedule

- 5.5.1 The Delivery Schedule (Annex G) must be completed and submitted as part of the proposal.
- 5.5.2 All delivery dates shall be firm and fixed until completion of the period of award and will remain firm for any amendment of the award.
- 5.5.3 The delivery date at the Delivered at Place (DAP) is the date the goods arrive at DAP point (final destination). The DAP point is: Karachi Port, Pakistan
- 5.5.4 Only goods meeting the technical specifications set out in this RFP are to be shipped.
- 5.5.5 At the time of shipment from the Contractors, products with a shelf life of 24 months must be no more than three months from the date of manufacture and products with a shelf life of 36 months must be no more than four months from the date of manufacture. No goods in quarantine are to be shipped.

5.6 Audited financial statements

- 5.6.1 Contractors **must submit** their most recent audited financial statements in support of their proposals.

6.0 COMMERCIAL AND TECHNICAL REQUIREMENTS

I. **LETTER OF CONTRACTOR CERTIFICATION**

A signed original letter as per **Annex A** is required.

II. **PRICING TABLE**

The Pricing Table in **Annex F** must be completed and submitted as part of the proposal. All prices shall be firm and fixed until completion of contract and will remain firm for any amendment of contract.

Contractors must quote unit prices for pre-qualified product(s), where applicable using bottles or blisters of 25 and 50 capsules as the units of measure, net of freight and insurance costs. Product prices must cover all expenses and charges of whatever nature including but not limited to production, quality assurance, packaging (including labels), packing suitable for export and in accordance with terms and conditions as set out in this RFP, and preservation in accordance with standard commercial practices, unless otherwise specified.

Contractors must quote freight and insurance separately in the Pricing Table in **Annex F**. Contractors must quote freight prices on the basis of DAP Karachi Port, Pakistan. The shipping terms used must be in accordance with the International Chamber of Commerce Incoterms 2010.

Contractors must quote all prices in Canadian Dollars (CAD), exclusive of Goods and Services Tax (GST), Harmonized Sales Tax (HST), Value Added Tax or refundable Excise Taxes or customs duties paid on imported materials, parts and components incorporated or to be incorporated in the supplies.

III. DELIVERY SCHEDULE

Contractors must provide their best delivery schedule and indicate the validity period of the proposed delivery schedule based on the DAP point using the delivery schedule format in **Annex I**. Delivery schedules will be evaluated against the delivery date at the DAP point. The target arrival date for the first shipments of capsules at the DAP point is **31 March 2027**.

Where possible, Contractors should limit each shipment to five containers per shipment.

Should a lesser quantity of product be awarded in the Contract, the Contractor will adhere to the delivery schedule submitted in its proposal **until the total quantity of product ordered has been shipped**. Failure to respect the delivery schedule could result in cancellation of the Contract at no cost to NI.

IV. AUDITED FINANCIAL STATEMENTS

Contractors must submit their most recent audited financial statements in support of their proposals.

V. TECHNICAL REQUIREMENTS

Contractors must submit a completed, signed copy of the following documents, along with any and all listed supporting documents within:

- a. Manufacturer Technical Questionnaire (Annex I)
- b. Product Technical Questionnaire (Annex J)

All certification documents provided must be the most recently available documents and must not be expired. If the certification is currently up for renewal and being processed by authorities, please note in the submission.

7.0 WARRANTY AND WARRANTY PERIOD

7.1 Contractors are made aware that a successful Contractor will be required to warrant the quality of the Goods and their expiry date (at minimum 24 months from the date of original manufacture) and that the Goods will be free from defects in material workmanship. The product shall conform to the specifications provided in Annex B;

7.2 The Goods shall be fit for the purposes for which such goods are ordinarily used or purposes expressly made known to the Contractor by NI. All defective Goods identified before the expiry date that can be attributed to the original manufacturing process as a result of a joint investigation will be replaced by the Contractor at no cost to NI, or an amount equivalent to re-procurement costs will be paid by the Contractor, whichever is most advantageous to NI.

8.0 SOURCE OF FUNDS

8.1 Procurement of the Vitamin A Soft Gelatin Capsules is subject to the availability of funds from NI's third party donor.

9.0 EVALUATION AND SELECTION PROCESS

9.1 The objective of the Evaluation Process is to identify the Proposal that effectively meets the requirements of this RFP and provides the best value. All determinations are made at the sole discretion of NI.

9.2 Review of Mandatory Requirements - Each proposal first will be evaluated for completeness of the submission. Failure to comply with any of the terms and conditions contained in the RFP including, but not limited to, failure to provide all the required information or documentation, may result in disqualification.

- 9.3 Commercial Offers will be evaluated based on their compliance with the requirements as set out in Section 5 of this RFP. Evaluation considerations include but are not limited to:
- competitiveness of pricing.
 - compatibility of delivery schedule with needs.
 - prior performance (for previously contracted Contractors):
 - risk assessment and identification; and
 - managerial and financial ability to complete the tasks set out in the RFP.
- 9.4 Contractors may be requested to correct errors or inconsistencies identified by NI during the proposal evaluation process. Contractors that do not comply with such requests within the timeframe communicated will be disqualified.
- 9.5 As needed, each Contractor will permit NI, either themselves or through a designated representative entity, to have access to the facilities where the products are manufactured, at all reasonable times to inspect the manufacturing site and processes for the production, quality control, quality assurance, and packing of the products. The Contractor will provide reasonable assistance to the representatives for such appraisal, including copies of any documentation (including, but not limited to, test results or quality control reports) as may be necessary, at its own cost. The inspection may be carried out in conjunction with the appropriate national authority. Failure to do so may result in the rejection of the proposal.
- 9.6 All the terms and conditions of this RFP and its Annexes, including the Contractor's response to this RFP will form a part of the award unless otherwise negotiated. The Contractor understands that if it proposes an amendment or additional terms to the award, these must be clearly detailed in the proposal and may affect the evaluation of the proposal.
- 9.7 NI reserves the right to:
- a. At any time prior to submission deadline, and for any reason, amend the RFP document. All Contractors that have confirmed their intent to submit will receive notification of the amendment, and it will be posted on the NI website.
 - b. Disqualify any or all Contractor(s) without incurring any liability to the affected Contractor(s).
 - c. Negotiate with one or more technically compliant suppliers and seek a best and final offer (BAFO) on any part of the technical or price/cost proposals submitted, as part of this RFP process.
 - d. Accept other than the lowest price proposal.
 - e. Reject any proposals which, in their opinion, give rise, or could potentially give rise to, a conflict of interest.
 - f. Accept any proposal, in whole or in part; to reject any or all proposals; or to cancel this solicitation process in its entirety.
 - g. Verify any information contained in the Contractor's response. The Contractor will provide reasonable cooperation with such verification.
 - h. Invalidate any proposal received from a Contractor that, in the sole opinion of NI, has previously failed to perform satisfactorily or complete contracts or purchase orders on time, or that NI believes is not able to meet the requirements of the RFP.
 - i. Invalidate any proposal that, in the sole opinion of NI fails to meet the requirements and instructions stated in this RFP.
 - j. Suspend negotiations or withdraw an award to a Contractor at any time. NI is not required to provide any justification but will give notice prior to any such suspension of negotiations or withdrawal of award.

10.0 NOTIFICATION OF AWARD

10.1 In the event of a delay in the Contract award, and prior to the expiration of the 180-day period referred to in Section 3.2, NI will notify the successful Contractor(s) in writing, and a Contract will be issued shortly thereafter subject to the considerations listed in 9.7.

11.0 LIST OF ANNEXES

Reference Documents:

Annex A: Letter of Manufacturer Certification

Annex B: Product Technical Specifications

Annex C: Minimum Information Requirements for Stability Testing Protocols and Report

Annex D: Technical Specifications for Packaging

Annex E: NI Sample Contract for Commodities

Required for Completion by all Contractors:

Annex F: Pricing Table

Annex G: Delivery Schedule

Annex H: New Manufacturers Reference Format

Annex I: Manufacturer Technical Questionnaire

Annex J: Product Technical Questionnaire

Annex K : Risk Assessment Register

12.0 KEY DATES & DELIVERABLES

Activity	Dates
RFP Issued	September 18 th , 2026
Confirmation by Contractors on Intent to Bid (via email) proposals@nutritionintl.org	September 25 th , 2026
Inquiries & Questions from Contractors (via email) proposals@nutritionintl.org	September 25 th , 2026
Deadline for Receipt of complete RFP submissions (technical and commercial offers)	October 5 th , 2026
Notification by NI on outcome of the evaluation process (via email) proposals@nutritionintl.org	November 2 nd , 2026

Annex A: Letter of Manufacturer Certification

Re: RFP No.XX-XX-XXXX

DD/MM/YYYY

[Company Name] has examined your Request for Proposals (RFP) and offer to undertake the work described in accordance with requirements as set out within.

This proposal, submitted in response to your RFP, is irrevocable for a period of 180 days after the deadline for submission of proposals. 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 RFP. 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 RFP 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.

We accept that any contract that may result will comprise the contract documents issued with the RFP and be based upon the documents submitted as part of our proposal.

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

Company Name

Name and Title

Signature of Proponent's Representative

Date

I have authority to bind the Proposer

ANNEX B - 50,000IU VITAMIN A SOFT GELATIN CAPSULE TECHNICAL SPECIFICATIONS

Specification reference: 50,000 IU VITAMIN A Oral Liquid Preparation (USP) or VITAMIN A Oral Solution (Ph. Int.) as SOFT GELATIN CAPSULES

Version: 1.0

Date of issue: 1 September 2022

Compiled by: Laura Nurse

Reviewed by:

Approved by:

A. PRODUCT DESCRIPTION: 50,000IU VITAMIN "A" SOFT GELATIN CAPSULE

Finished Product

- 1.1. Vitamin A soft gelatin capsules must be manufactured to comply with the United States Pharmacopeia (USP¹) Vitamin A Oral Liquid Preparation monograph (USP 37-NF32 or latest edition)² or the International Pharmacopoeia (Ph. Int.³) Retinol Oral Solution monograph (Ph. Int. Fourth Edition, 3rd Supplement, 2013).
- 1.2. Halal certification for the Finished Product is required for each batch.
- 1.3. A vanilla flavouring agent must be added to mask any unpleasant smell or taste.
- 1.4. Vitamin A soft gelatin capsules must be free of preservatives such as parabens.
- 1.5. Vitamin A soft gelatin capsules must be suitable for shipment, storage and use world-wide. In particular, the vitamin formulation and packaging must be suitable for delivery and use in countries having adverse climatic and storage conditions (e.g. high temperature and humidity, etc. herein considered as Climatic Zones IVa and/or IVb).
- 1.6. The product shelf life stability must be demonstrated with results of stability studies conducted under long-term testing conditions for climatic Zone IVa and/or Zone IVb countries

DESCRIPTION

- 1.7. Yellow, opaque, soft gel elongated tube shaped capsules with nipple to allow for cutting and administration drop by drop with ease such that the entire vitamin A liquid contents of the capsule can be squeezed gently into the child's mouth.

CAPSULE

Gelatin:

- 1.8. Gelatin must be without BSE infectivity: Reference is made to the Resolution AP/CSP(99)4, AP/CSP(99)T, to EMEA/410/01 – rev. 1.

¹ USP Vitamin A Oral Liquid Preparation Monograph compliant product.

² The Dietary Supplements Dosage Forms Subcommittee members have agreed to support the request to reduce the lower limit of vitamin A from NLT 95.0% to NLT 90.0% of labeled claim. This change was reflected in the April, 2013 publication of the USP Revision Bulletin.

³ Ph. Int. Retinol Oral Solution Monograph compliant product.

- 1.9. All Gelatin used for the vitamin soft gelatin capsules must be manufactured to meet the criteria described in the latest edition of the International (Ph. Int), United States (USP) or European (Ph.Eur) Pharmacopoeia.

Hardness:

- 1.10. The vitamin A soft gelatin capsules procured by NI are used in public health programs worldwide. Unlike other preparations, the soft gelatin capsule is used in this case as a dropper to deliver its liquid contents directly into the recipient's mouth. The capsule is not swallowed. To allow for optimal use of vitamin A soft gelatin capsules in the field, the capsule shell must be hard enough to withstand hot and humid conditions (i.e. not leaking or clumping with other capsules) but soft enough to be used as a dropper such that the entire liquid contents of the capsule can be squeezed gently into the child's mouth with ease by health workers even while dosing numerous children in sequence during campaigns. In addition capsules must not be brittle (i.e. breaking or cracking at the seal when squeezed). In light of these considerations, manufacturers must set their own hardness limits (i.e. minimum and maximum) for (i) stability trials and (ii) point of release as measured by a Bareiss Hardness Tester, or equivalent.

CAPSULE CONTENTS

- 1.11. The Active Pharmaceutical Ingredient (API) and excipients must comply with the monograph and general notices (and general requirements) from one of the following pharmacopeias: British (BP), European (Ph. Eur.), International (Ph. Int.) or United States (USP).

- 1.12.

Item No.	Proposed Product	Description
1	50,000 IU VITAMIN A Oral Liquid Preparation (USP) or VITAMIN A Oral Solution (Ph. Int.) as SOFT GELATIN CAPSULES 25 capsules per bottle, or 50 capsules per bottle Desired Shelf-life: at minimum 24 months	Yellow, Opaque, Soft gelatin capsules with nipple. Each soft gelatin capsule must deliver : Vitamin A (Retinol palmitate) 50,000 IU as the API DL-alpha-tocopherol or tocopheryl acetate- 10 IU in oily solution as the antioxidant
2	50,000 IU VITAMIN A Oral Liquid Preparation (USP) or VITAMIN A Oral Solution (Ph. Int.) as SOFT GELATIN CAPSULES 25 capsules per bottle, or 50 capsules per bottle Desired Shelf-life: at minimum 24 months	Yellow, Opaque, Soft gelatin capsules with nipple. Each soft gelatin capsule must deliver : Vitamin A (Retinol palmitate) 50,000 IU as the API DL-alpha-tocopherol or tocopheryl acetate- 10 IU in oily solution as the antioxidant

PACKAGING

- 1.13. Vitamin A soft gelatin capsules are bottled as 25 or 50 capsules per bottle with a bottle size proportional to its contents. All vitamin A soft gelatin capsules must be kept in tight, light- and tamper-resistant containers. Bottles must conform to the latest edition of British (BP), United States (USP), European (Ph. EUR) or other internationally recognized Pharmacopoeia Standard for Pharmaceutical containers and should be suitable for shipment, storage and use worldwide at elevated temperatures and humidity typical of Zone IVa and/or Zone IVb country climate. The bottles must be: tamper-evident opaque plastic securitainer bottles with screw-cap, each containing 25 or 50 capsules and sufficient desiccant material to minimize humidity.
- 1.14. Vitamin A soft gelatin capsules are packaged in appropriately labeled bottles, including directions for use and delivery of each dosage unit of vitamin A soft gelatin capsules. Statements and Labelling must comply with the relevant pharmacopoeia standard: United States Pharmacopoeia (USP) Vitamin A Oral Liquid Preparation monograph (USP 37-NF32 or latest edition) or International Pharmacopoeia (Ph. Int) Retinol Oral Solution monograph (Ph. Int. Fourth Edition, 3rd Supplement, 2013).

STABILITY

- 1.15. Vitamin A soft gelatin capsules **should** demonstrate at least 24 months of shelf life under conditions of high temperature and humidity of Zone IVa and/or IVb. Preference will be given to products that demonstrate a longer shelf life. Submission of the following will be required:
- Stability data from at least three primary batches^{4,5}, and
 - A written commitment (signed and dated) to continue long-term testing over the shelf-life period
- 1.16. Shelf-life compliance must be demonstrated using a High-performance liquid chromatography (HPLC) assay method to measure vitamin A.

CERTIFICATION

- 1.17. The Active Pharmaceutical Ingredients (API) used in the vitamin A soft gelatin capsules must be manufactured and handled according to GMP Standards for Pharmaceutical Products, as certified by an internationally recognized authority that is a member of or partner to the Pharmaceutical Inspection Cooperation Scheme (PIC/S)⁶.
- 1.18. The vitamin A soft gelatin capsules at this dose of 50,000 IU is to be considered as a pharmaceutical product and must be manufactured in accordance with prevailing Good Manufacturing Practices (GMP) Standards for pharmaceutical products by the National Drug Regulatory Authorities and by an internationally recognized authority that is a member or a partner of the Pharmaceutical Inspection Scheme (PIC/S).
- 1.19. A certificate of suitability is required to demonstrate that vitamin A, vitamin E and all gelatin used for the vitamin A soft gelatin capsules has been manufactured to meet Pharmacopoeial standards.

⁴ Primary batches should be of the same formulation and packaged in the same container closure system as proposed for marketing. The manufacturing process used for primary batches should simulate that to be applied to production batches and should provide product of the same quality and meeting the same specification as that intended for marketing.

⁵ Each primary batch should be at minimum pilot scale (one-tenth that of a full production scale batch) and ideally manufactured using different batches of the API

⁶ <http://www.picscheme.org/members.php>

- 1.20. Vitamin A soft gelatin capsules must be certified Halal by an internationally recognized certifying body such as the Islamic Food and Nutrition Council of America (IFANCA) to meet Islamic Halal requirements. This requirement applies to the finished pharmaceutical product and excipient manufacturers involved in the manufacturing process. In the event of prequalification and invitation to submit a proposal, proof of valid certification will be required.

PRODUCT REGISTRATION

- 1.21. Although not required at this time, Vitamin A soft gelatin capsule mentioned above, may be required to have evidence of registration/marketing authorisation in the country of manufacture/origin. A marketing authorisation from a stringent regulatory authority is desired. Proof of valid registration/market authorization will be required and where this cannot be provided immediately, as an interim measure, manufacturers will be required to submit a Letter of Commitment to obtaining domestic registration status as well as making available any documentation requested by the country of import needed for in-country product registration required to receive the goods.
- 1.22. Vitamin A soft gelatin capsule mentioned above, should have a Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme, or an equivalent, issued by the National Regulatory Authorities and specified in the WHO Technical Report Series 863.

Annex C: Minimum Information Requirements for Stability Testing Protocols and Reports

Table 1. Stability study testing parameters and frequency for vitamin A soft gelatin capsules:
The below table indicates minimum requirements

Storage		Testing parameters						
		General appearance		Assay of capsule contents/fill			Functionality	Level of microbial contamination ¹
Testing interval	Condition	Vit. A oil ² or ³	Soft gel caps ⁴	Vit.A ⁵ or ⁶	Vit. E	Uniformity of dosage units	Hardness	
Specifications		Pass/ fail	Pass/ fail	90.0-120.0% of labeled amount of Vit. A	Limits (min. and max. as % LC) of Vit. E	Meets USP <905> requirement or Meets Ph. Int. Uniformity of deliverable dose (single-dose container) requirement	Limits (min. and max. in Newtons) to be provided by mfrs	Total viable count (NMT10 ⁴ /g) Yeast- mold (NMT 10 ² /g) Enterobac. (NMT 10 ² /g) Absence of E.Coli, Staph.aureus, Salmonella
				Report in IU and %				
Initial*		X	X	X	X	X	X	X
Accelerated								
1 Month	40°C ± 2°C/75% RH ± 5% RH	X	X	X	X	X	X	X
2 Months		X	X	X	X	X	X	X
3 Months		X	X	X	X	X	X	X
6 Months		X	X	X	X	X	X	X
Long-term								
3 Months	30°C ± 2°C/65% or 75% RH ± 5% RH	Δ	Δ	Δ	Δ	Δ	Δ	
6 Months		Δ	Δ	Δ	Δ	Δ	Δ	
9 Months		Δ	Δ	Δ	Δ	Δ	Δ	
12 Months		Δ	Δ	Δ	Δ	Δ	Δ	
18 Months		Δ	Δ	Δ	Δ	Δ	Δ	Δ
24 Months		Δ	Δ	Δ	Δ	Δ	Δ	
36 Months		Δ	Δ	Δ	Δ	Δ	Δ	Δ

*Time point "0" (TP0), the initial time point, should correspond to the study start date, i.e. the day the product is placed in the appropriate stability chamber. Subsequent time points indicate the time at which the samples are removed from the stability chamber in reference to TP0 as described above.

¹ Ph. Eur 6th Total viable count 2.6.12/2.6.13 Tests for specified microorganisms (Pharmaceuticals products which contain excipients/APIs of animal origin).

² Current official version of USP – VA OLP monograph (Identification)

³ Current official version of Int. Ph. – Retinol Oral Solution monograph (Identity test)

⁴ To be defined by mfrs to meet NI technical specification – Look for organoleptic properties such as leaking, clumping, melting, etc.

⁵ USP – VA OLP monograph (Assay Vit A). As per official correspondence with the USP, the Dietary Supplements Dosage Forms Subcommittee members have agreed to support the request to reduce the lower limit of vitamin A from NLT 95.0% to NLT 90.0% of labeled claim. This change was reflected in the April, 2013 publication of the USP Revision Bulletin.

⁶ Current official version of Int. Ph. – Retinol Oral Solution monograph (Assay).

Evaluation of data required

A systematic approach should be adopted for the presentation and evaluation of the stability information, which should include, as appropriate, results from the physical, chemical, biological and microbiological tests, including particular attributes of the dosage form (*for example, hardness for softgel capsules where an oral solution is the dosage form*). Stability studies should be presented in an appropriate format (e.g. tabular, graphical and narrative).

In addition to *Table 1*, above, the stability study reports need also to include:

- FPP: Ingredients & formulation, dosage strength, batch number, size and mfg date;
- API: Ingredients & formulation, manufacturer and batch number;
- Packaging: Description, materials used, and no. of units per container;
- Study start date, individual time points and total duration of the study;
- Specification reference / Acceptability limits for each parameter tested;
- For quantitative tests, actual numerical results should be provided (avoid using terms like “within limits” or “conforms”);
- Information on analytical procedures used to generate the data and validation of these procedures (if applicable);
- Information on characterization of impurities;
- Study conclusions.

Any variation introduced to the FPP such as changes in the formulation, manufacturing process, container closure system, properties of the packaging materials etc. that could adversely affect the stability of the product and/or where the existing data no longer supports the quality, safety or efficacy of the varied product throughout its shelf life must be reported to NI for assessment.

Annex D: Technical Specifications for Packaging

I. BOTTLE SPECIFICATIONS FOR NI

1.0 BOTTLES

- 1.1 Vitamin A Soft Gelatin Capsules are to be packed as 25 or 50 capsules per bottle/blister
- 1.2 All Vitamin A Soft Gelatin Capsules must be kept in tight, light- and tamper-resistant containers.
- 1.3 Bottles must conform to the latest edition of British (BP), United States (USP), European (Ph. EUR) or other internationally recognized Pharmacopoeia Standard for Pharmaceutical containers and should be suitable for shipment, storage and use worldwide at elevated temperatures and humidity typical of Zone IVb country climate.
- 1.4 The preferred bottles are: tamper-evident opaque plastic securitainer bottles with screw-cap, each containing 25 or 50 capsules. Desiccant Packs are to be included in each 25 or 50 -capsules container manufactured for NI. **See detailed specifications for desiccants.**
- 1.5 The size of the bottle should be proportional to its contents with the addition of appropriate padding and dessicant pack(s) to prevent damage to the product during shipment.

II. BOTTLE LABEL SPECIFICATIONS FOR NI

- 2.0 Vitamin A Soft Gelatin Capsules are packaged in appropriately labeled bottles, including directions for use and delivery of each dosage unit of Vitamin A Soft Gelatin Capsules. Statements and Labelling must comply with the United States Pharmacopeia (USP) Vitamin A Oral Liquid Preparation monograph (USP 35-NF30 or latest edition) or International Pharmacopoeia (Ph. Int) Retinol Oral Solution monograph (Ph. Int. Fourth Edition, 3rd Supplement, 2013) or latest edition.
- 2.1 Bilingual labels in English and French will be required.
- 2.2 The colours of lettering for amount of active ingredient must be:

Yellow: Vitamin A (Retinol palmitate) 50,000 IU (15 mg)
stabilized with 10 IU Vitamin E

All other lettering on the bottle labels must be black.
- 2.3 The writing on the labels must be in indelible ink, and varnish free.
- 2.4 Self-adhesive, white, pharmaceutical defiberized paper (80 g/m2)
- 2.5 Film or UV coated for protection against humidity.
- 2.6 Labels must be firmly affixed to be tamper proof and to prevent detachment in tropical climates.
- 2.7 The label shall contain the following information:
 - a. Contents per bottle: 25 or 50 capsules
 - b. The name of the product and the pharmacopoeial standard of the FPP:
"VITAMIN A Oral Liquid Preparation (USP)" in a bold, clearly visible font size.

- c. The ester form in which the vitamin A is present
- d. Stabilized with Vitamin E and the proportions added.
- e. The amount of Vitamin A delivered in each capsule both in International Units/capsule and in terms of the equivalent amount of retinol in mg/capsule, on the basis that 1 USP vitamin A unit equals the biological activity of 0.3 µg of all-trans-retinol: "Each/Chaque capsule Delivers/Fournie:"
- f. Usage: "Cut off small end of capsule, gently squeeze contents into child's mouth. The capsule must not go in child's mouth or be swallowed"
- g. Utilisation: "Couper l'embout de la capsule, puis presser avec douceur pour que son contenu s'écoule dans la bouche de l'enfant. La capsule ne doit ni entrer dans la bouche de l'enfant, ni être avalée."
- h. Warning: "Not to be administered to pregnant women"
- i. Précaution: "Ne pas administrer aux femmes enceintes"
- j. Storage: "Do not store above 30° C. Keep container tightly closed, protected from moisture and light. Keep out of the reach and sight of children."
- k. Entreposage : "A conserver à une température ne dépassant pas 30°C. Conserver le conditionnement primaire soigneusement fermé, à l'abri de l'humidité et de la lumière. Tenir hors de la vue et de la portée des enfants."
- l. Batch identification
- m. Manufacturing date: **Date format: numerical format MM/YYYY**
- n. Expiry date: **Date format: numerical format MM/YYYY**
- o. Manufactured in (Country Name) by (manufacturer's Name) /Fabriqué au (Country Name) par (manufacturer's Name)
- p. NI logo (in black) in middle left:
- q. Government of Canada wordmark/logo (in black), bottom left with text as follows:
"Funded by / Financé par: "
- r. For all products, the word "Halal" must not appear on any of the labels

2.8 A mock-up of the label must be pre-approved by NI (to the attention of **Molly Venables**, mvenables@nutritionintl.org and **Alison Greig**, agreig@nutritionintl.org prior to use.

2.9 The label sample shown in Figure 1 below is for information on label structure.

Batch No: Mfg. date: Exp. date:	50 capsules VITAMIN A Oral Liquid Preparation (USP) EACH/CHAQUE capsule DELIVERS/FOURNIE: Vitamin A (retinol palmitate)..50000 IU (15 mg) stabilized with 10 IU Vitamin E
 Funded by / Financé par: 	USAGE: Cut off small end of capsule, gently squeeze contents into child's mouth. The capsule must not go in child's mouth or be swallowed WARNING: Not to be administered to pregnant women STORAGE: Do not store above 30°C. Keep container tightly closed, protected from moisture and light. Keep out of the reach and sight of children UTILISATION: Couper l'embout de la capsule, puis presser avec douceur pour que son contenu s'écoule dans la bouche de l'enfant. La capsule ne doit ni entrer dans la bouche de l'enfant, ni être avalée. PRECAUTION: Ne pas administrer aux femmes enceintes. ENTREPOSAGE: A conserver à une température ne dépassant pas 30°C. Conserver le conditionnement primaire soigneusement fermé, à l'abri de l'humidité et de la lumière. Tenir hors de la vue et de la portée des enfants

 Manufactured in (Country name) by/ Fabriqué au (Country Name)
 par Manufacturer's name:

III. Desiccant Pack Specifications

3.0 GENERAL:

3.1 Desiccant Packs are to be included in each 25 or 50 capsule container of Vitamin A Soft Gelatin Capsules manufactured for Nutrition International.

3.2 PURPOSE OF THE DESICCANT PACKS:

3.3 Softening and clumping of soft gelatin capsules has been reported from tropical countries during vitamin A capsule distribution. The purpose of including a desiccant in the 100 or 500 capsule containers is to minimize the occurrence of capsule clumping due to moisture-induced softening and degradation.

3.4 PERFORMANCE:

3.5 The desiccant should protect the soft gelatin capsules from moisture and avoid softening and clumping while the capsules remain enclosed in a sealed high density polyethylene opaque container and up to 6 weeks after the container's protective seal has been broken for use in conditions of RH 60%-100% and temperatures of 25-45° C.

3.6 PRODUCT SPECIFICATION:

3.7 Sufficient B-type or wide pore spherical synthetic amorphous silica (silicon dioxide, SiO₂) in accordance with US Military Specifications for desiccant materials, which details requirements for bagged, chemically inert and dehydrating agents (Desiccant Materials-MIL-D-3464). Each 100 or 500-capsule container may include 1-3 desiccant packs of desiccant to achieve best humidity absorption results.

3.8 PACKAGING OF THE PRODUCT:

3.9 Individual bags of high-density polyethylene spun into continuous fibres (Tyvek®) to prevent the silica from dusting.

OR

3.10 Package in accordance with US military specification MIL-P-116, Method II, modified to eliminate the evacuation process and desiccant. Barrier Bags will meet or exceed the requirements of Type III, Class E. Humidity indicators are not required. This specification requires that the desiccant material be sealed in a water vapour-proof, grease-proof heat-sealable Barrier Bag of size sufficient to enclose the desiccant package necessary to dehydrate the chosen container size. Note that silica gel conforming to MIL-D-3464 will be included in packages of products expected to be subjected to prolonged storage in tropical geographical regions.

ANNEX E – SAMPLE SUPPLIER CONTRACT

Supplier	Buyer
\$formula(UPPER(\$company_name)) \$formula(\$location_id.address_1_and_2_in_block_format) \$formula(\$location_id.city), \$formula(\$location_id.state_province) \$formula(\$location_id.zip_or_postal_code) \$formula(\$location_id.country0) (herein called the “Supplier”)	NUTRITION INTERNATIONAL 180 Elgin Street. Suite 1000 Ottawa, Ontario, K2P 2K3 Canada (herein called “NI”)

Contract Start Date:

Upon signature of both Parties

Contract End Date:

\$formula(dateformat(“MMMMMM dd, yyyy”, \$contract_end_date))

Contract Price:

\$formula(\$contract_currency_short_)

\$formula(\$contract_amount_contract_currency)

We, the above named Supplier, agree to sell to Nutrition International (NI) in accordance with the terms and conditions set out herein, and on the attached Schedules, the Goods listed in Section 1 at the price(s) set out therein.

Authorized by:	Accepted by:
Signature	Signature
 Sig_es_:signer1:signature }} \$formula(\$internal_signer_full_name) \$formula(\$internal_signer_title) Nutrition International	 Sig_es_:signer2:signature }} Name {{N_es_:signer2:fullname }} Title {{Ttl_es_:signer2:title }} \$formula(\$company_name)
Date Signed {{Dte_es_:signer1:date}}	Date Signed {{Dte_es_:signer2:date}}

Delivery of this contract by facsimile or electronic transmission constitutes valid and effective delivery. This contract and all attached Schedules forms the entire Contract between the Parties, and no variation thereof, irrespective of wording or terms of acceptance by the Supplier, will be effective unless specially agreed to in writing by Nutrition International.

1. DESCRIPTION AND PRICE OF GOODS

1.1. The goods ("Goods") to be supplied under this Contract are the following:

ITEM No	ITEM DESCRIPTION	QUANTITY	PACKING (WEIGHT) & CONTAINER TYPE	UNIT PRICE	EXTENDED (TOTAL) PRICE
1.					
2.					
Total					

1.2. The Goods shall comply with the specifications in Schedule 1. 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.

1.2.1 Quantity from each manufactured batch number, along with the testing method used to identify results on the CofA, will be sent for testing to a third party laboratory, specified in section 3.1. A Copy of the CofA for each manufactured batch will be sent to NI. NI will pay the third party laboratory directly for this testing.

The shipment of goods to the consignee, will only take place once NI has reviewed the test results from the third party laboratory and provided written approval to the Supplier, that:

- a) the results meet the specifications in Schedule I; and
- b) the shipment of goods to the consignee has been approved

NI will not be responsible for any costs associated with this agreement if the test results do not meet all of the specifications in Schedule I, or the shipment is sent to the consignee before written approval from NI is provided to the Supplier.

1.3. All prices are [SHIPPING TERMS i.e. CIF/FOB, etc] to the destination specified in the delivery schedule, IN section 3, and inclusive of packing and repacking, freight and freight insurance costs, and all applicable taxes. Prices will remain firm until the completion of delivery and no escalation shall be admissible on any account, whatsoever.

1.4. NI will be responsible for clearing all shipments through customs in \$formula(\$travel_destination_country) and paying all related charges.

1.5. NI's liability to the Supplier in relation to this Contract shall not at any time exceed the Contract Price, unless otherwise agreed upon in writing by NI. For the purpose of this Contract, NI's Canadian dollar liability shall be limited to CAD \$formula(\$canadian_dollar_liability_value).

2. CONSIGNEE AND NOTIFY PARTY

Consignee	The Notify Party for this order is as follows:
[CONSIGNEE NAME] [CONSIGNEE ADDRESS]	1. [CONSIGNEE CONTACT NAME] [CONSIGNEE CONTACT DETAILS] 2. [NI REPRESENTATIVE] Contact details

3. DELIVERY SCHEDULE

The Goods will be shipped according to the following schedule:

Shipment No.	Destination	ETA Destination	Goods	Quantity shipped
1	Third Party Lab Name	No later than Date	Samples for third party testing (provide the number of samples required per batch)	Total number of samples
2		Within 60 days of NI Approval of the samples from each batch as specified in section 1.2.1		

4. PACKING, SHIPPING, AND LABELLING INSTRUCTIONS

The Goods will be packed, shipped, and labelled in accordance with the instructions in Schedule 2.

5. PERFORMANCE GUARANTEE

Within 30 days of the Supplier's receipt of notification of Award of Contract, the Supplier shall furnish a performance guarantee/security equivalent to 10 percent of the Contract Price in a format and from a bank acceptable to NI. The Performance Guarantee will be returned to the Supplier upon satisfactory completion of supply.

5.1. The proceeds of the Performance Guarantee shall be payable to NI as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

6. ADVANCE PAYMENT AND BANK GUARANTEE

An advance payment of _____(xxx) percent of the Contract Price will be released upon contract signature and submission of a Bank Guarantee equal to the amount of advance payment in a format and from a bank acceptable to NI. The Bank Guarantee will be valid until satisfactory completion of supply is confirmed by NI.

7. TERMS OF PAYMENT

7.1. Payment will be made according to the following schedule:

Installment	Deliverable	Date/Month	Amount in (\$formula(\$contract_currency_short_))
Advance			
Second Installment			
Final Installment			

The Supplier, having previously provided banking information to NI, shall review the details in Attachment D. Only upon confirming the accuracy of the banking information will the Supplier proceed to sign this Agreement. By signing this agreement, the Supplier certifies that the banking information therein is accurate.

This will facilitate electronic payment to the Supplier's account. NI is not responsible for any loss incurred by the Supplier due to exchange rate fluctuations or bank charges.

8. DOCUMENTATION AND INVOICING INSTRUCTIONS

8.1. Notification prior to shipment (fax or email) must be sent to the Notify Parties (Article 2) and include the following information:

- a) Bill of Lading number
- b) Container number
- c) Packing list, including weights and volumes, description, quantity per batch, expiry date and expected date of arrival

8.2. One full set of originals of the following documentation must be sent by courier to the Consignee prior to arrival of each shipment:

- a) Bill of Lading
- b) Packing list, including weights and volumes, description, quantity per batch, expiry date
- c) Certificate of Origin
- d) Signed commercial invoice

8.3. For each payment, the Supplier shall send the one copy of all the documentation listed above to NI, Attention: _____. Payment due date of each signed invoice will be calculated at 30 (thirty days) from the date of receipt at NI of all the required documentation subject to receipt of a satisfactory delivery report from _____.

9. WARRANTY, INDEMNITY AND LIABILITY

9.1. The Supplier warrants the quality of the Goods and their expiry date/warranty period (at least _____ months from the date of delivery). All defective Goods will be replaced by the Supplier at no cost to NI, or an amount equivalent to re-procurement costs will be paid by the Supplier, whichever is most advantageous to NI.

9.2. The Supplier shall indemnify and save harmless NI (and the Governments which receive the Goods), from and against all claims, damages, losses, costs and expenses arising out of any injury to, sickness of, or death to persons or any loss of or damage to property caused by the fault or negligence of the Supplier.

9.3. The Supplier warrants that the use or supply to NI of the Goods offered under the Contract does not infringe on any patent, trade-name, or trade-mark. In addition, the Supplier shall, pursuant to this warranty, indemnify, defend and hold harmless the Purchaser from any action or claims brought against the Purchaser pertaining to the alleged infringement of a patent, design, trade-name or trade-mark arising from the Contract.

9.4. The Supplier shall indemnify, defend and hold harmless NI from any action or claims brought against NI pertaining to the alleged infringement of a patent, design, trade-name or trade-mark arising from the Contract.

10. TITLE AND RISK

The supply and consequent transfer of ownership of the Goods supplied under this Contract, will be completed only upon the acceptance of the Goods by NI after verification of the contents, and documents accompanying each shipment comprised in the supply. All risks, liabilities and obligations in the Goods as related to production and shipment to prescribed final destinations prior to the acceptance of the Goods by NI shall be borne by the Supplier. The Supplier shall

always ensure that the Goods supplied by it under this order shall be free of any liens, charges or other claims.

11. FORCE MAJEURE

11.1. Delays in or failure of performance by a Party under this PO shall not constitute default hereunder or give rise to any claim for damages if and to the extent caused by occurrences beyond the control of the Party affected, including, but not limited to, decrees of Government, acts of God, strikes or other concerted acts of workers, inability to procure materials or labour, fires, floods, explosions, riots, war, rebellion, sabotage and atomic or nuclear incidents, but lack of finances shall in no event be deemed to be a cause beyond a Party's control.

11.2. In the event that performance of this Contract in the reasonable opinion of either Party is made impossible by force majeure, then either Party shall so notify the other in writing and NI shall either (a) terminate the Contract, or (b) authorize the Supplier to complete performance of the Contract with such adjustments as are required by the existence of the force majeure and are agreed upon by the Parties.

12. CONTRACT CHANGES

12.1. NI may at any time, by written order given to the Supplier make changes within the general scope of the Contract in any one or more of the following aspects:

- a) specifications, where Goods to be furnished under the Contract are to be specifically manufactured for NI;
- b) method of shipment or packing;
- c) services to be provided by the Supplier; or
- d) timing of supply.

12.2. If any such change causes an increase or decrease in the cost of or the time required for the Supplier's performance of any part of the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended.

13. PENALTIES/LIQUIDATED DAMAGES

In case of late delivery of Goods beyond the periods specified in the Delivery Schedule, liquidated damages @ _____% per day up to maximum 30 days of the cost of late delivered supply shall be imposed upon the Supplier.

14. TERMINATION

14.1. Termination for Default. In case the Supplier fails to fulfil any term of this Contract, NI may, after giving the Supplier 5 (five) days written notice, and without prejudice to any other rights and remedies, exercise one or more of the following rights:

- a) procure all or part of the undelivered Goods from other sources;
- b) refuse to accept delivery of all or part of the Goods;
- c) terminate this Contract; and/or
- d) claim damages resulting from the default, including any consequential damages, such as excess re-procurement costs, etc.

14.2. The Supplier shall have five (5) days to respond from the date of the notice, to explain how the default will be remedied. If no response is received by NI within such five-day period, or if the response is not acceptable to NI, NI may, by further written notice, exercise the rights involved in 14.1 as of the date of such further notice.

14.3. If the Contract is terminated for default, NI shall process payments due to the Supplier up to the date of termination less all eligible deductions as applicable. If the total amount due to NI exceeds any payment due to the Supplier, the difference shall be a debt payable by the Supplier to NI.

14.4. Termination without Cause. Notwithstanding anything contained in this Contract, NI may, at any time prior to the delivery of the Goods, by giving the Supplier 5 (five) days written notice, terminate this Contract as regards all or any part of the Goods not completed. Upon a termination notice being given, the Supplier shall cease work (including the manufacture and procuring of materials for the fulfilment of the Contract) in accordance with and to the extent specified in the termination notice, but shall proceed to complete such part or parts of the Goods as are not affected by the termination notice.

14.5. In the event of a termination notice being given pursuant to 15.4, the Supplier shall be entitled to be paid, to the extent that costs have been reasonably and properly incurred for purposes of performing this Contract, on the basis of the Contract price, for all completed work that is inspected and accepted in accordance with this Contract, whether completed before, or after and in compliance with the instructions contained in, the termination notice.

14.6. In the procuring of materials and supplies required for the performance of this Contract and in the subcontracting of any of the Goods, the Supplier shall, unless otherwise authorized by NI, place purchase orders and subcontracts on terms that will enable the Supplier to terminate the same upon terms and conditions similar in effect to those provided in this Section.

15. CONFIDENTIALITY AND INTELLECTUAL PROPERTY

15.1. Confidential Information

The Supplier will keep confidential any and all information, trade secrets, data or material belonging to NI and which the Supplier acquires from NI as a result of this Contract and will not disclose the same to others without the prior written approval of NI. The Supplier will not use any information or data acquired from NI as a result of this Contract for any other purpose than to carry out the Contract.

15.2. Maintenance of Confidential Information

The Supplier's employees, permitted sub-contractors, successors and assignees will not, without authority, use or disclose, or assist the use or disclosure of any such confidential information belonging to NI. The Supplier will at all times use all reasonable precautions (and in any event, efforts that are no less than those used to protect its own confidential to protect confidential information from disclosure, unauthorized use, dissemination or publication. The Supplier shall, on request, promptly return to NI any information or material provided by NI and in the Supplier's possession.

15.3. Limitation

The obligations of confidentiality assumed by the Supplier here do not apply to any information: (i) that was known by the Supplier before disclosure to the Supplier by NI as evidenced by prior written records; (ii) which becomes part of the public domain through no fault of the Supplier; (iii) which was obtained by the Supplier from a third party under no obligation to NI not to disclose the information, (iv) which is developed by the Supplier independently of disclosures made hereunder as shown by written documentation, or (v) which is required to be disclosed by law or by audit standards. This confidentiality provisions in this article shall survive the termination of this Contract.

15.4. Intellectual Property

Design documents, specifications, reports and all relevant data such as maps, diagrams, plans, statistics and supporting records and materials compiled or prepared in the course of carrying out the work under this Contract shall remain the property of NI. The Supplier may retain a copy

thereof, provided that such copy shall not be used for purposes unrelated to the Contract without the approval of NI.

The disclosure of Confidential Information in 16.1 shall in no way be considered as a license or conveyance of any intellectual property rights. The Confidential Information, including any documents, drawings, sketches, designs, materials or samples provided by NI, shall remain the property of NI and no rights are granted to the Supplier except the right to use the Confidential Information as set forth above.

16. SAFEGUARDING, SOCIAL RESPONSIBILITY AND HUMAN RIGHTS

16.1 Responsibilities of the Supplier and the Suppliers' Downstream Partners

Safeguarding, social responsibility and respect for human rights are central to NI's expectations of the Supplier and the Suppliers' downstream partners supporting this agreement. It is the responsibility of the Supplier to ensure that its downstream partners comply with Section 16 in its entirety. The Supplier must ensure that robust procedures are adopted and maintained to eliminate the risk of poor human rights practices within their delivery chain environments. These practices include: sexual exploitation, abuse and harassment; all forms of child abuse; inequality or discrimination on the basis of race, gender, age, religion, sexuality, culture or disability.

The Supplier and their downstream partners supporting any NI activities must place an emphasis on the control of these and further unethical and illegal employment practices, such as modern-day slavery, forced and child labour and other forms of exploitative and unethical treatment of workers and aid Suppliers.

The Supplier declares and guarantees that neither the Supplier, nor its employees involved in the Agreement:

- (a) have been convicted during a period of three (3) years prior to and since the submission of the proposal, by a court of law in Canada or in any other jurisdiction for an offence involving fraud, bribery, corruption, sexual misconduct, harassment, assault, or any related offense; or
- (b) are under sanction, for an offence involving fraud, bribery, corruption, sexual misconduct, harassment, assault, or any related offense, imposed by a government, an international governmental organization, or an organization providing development assistance.

16.2 Child Safeguarding

The Supplier fully acknowledges the duty of care to protect and promote the welfare of children and young people. The Supplier will be committed to ensuring child safeguarding practice reflects statutory, legal, legislative responsibilities, as well as current guidance and advice, and complies with NI's child safeguarding policy. Should the Supplier not have a child safeguarding policy, then [NI's Global Child Safeguarding Policy](#) shall be the guiding document, taking into consideration best practices and any specific local requirements. The Supplier will promptly notify NI of any changes to any specific statutory, legal, legislative child safeguarding responsibilities or organizational child safeguarding policy changes.

16.3 Anti-Terrorism

- a) The Supplier hereby certifies that consistent with Local and International, including Canadian and United Nations Security Council resolutions, both NI and the Supplier are fully committed to the international fight against terrorism and that the Supplier does not advocate, support, assist or engage in, and has not advocated, supported, assisted or engaged in, any terrorist activity.
- b) The Supplier will seek to ensure that none of the funds or assets provided under this Agreement are made available or used to provide support to individuals, groups or entities

associated with terrorism including those named on the following lists as updated from time to time.

Government of Canada – Office of the Superintendent of Financial Institutions:
<http://www.osfi-bsif.gc.ca/Eng/fi-if/amlc-clrpc/atf-fat/Pages/default.aspx>

Government of Canada – Public Safety Canada:
<https://www.publicsafety.gc.ca/cnt/ntnl-scrf/cntr-trrrsm/lstd-ntts/crrnt-lstd-ntts-en.aspx>

United Nations: <https://www.un.org/sc/suborg/en/sanctions/un-sc-consolidated-list>

- c) The Supplier shall immediately notify NI in writing if it becomes aware of any breach of Clause 16.3, or has reason to believe that it has or any of the Suppliers Personnel, servants, agents or sub-contractors, or any person acting on their behalf have:
 - (i) been subject to an investigation or prosecution which relates to an alleged infringement of Clauses 16.3;
 - ii) been listed by any government department or agency as being debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for participation in programs or contracts.
- d) In the event of material breach of this clause, NI will reserve the right to terminate this Agreement in accordance with Clause 14 - Termination, suspend funding to Supplier or sanction the Supplier and any of its related or affiliate parties from any future NI funding or take any other corrective action as necessary, including reimbursement of funds utilized in contravention of this section of the Agreement.
- e) The Supplier shall include a corresponding provision related to Anti-Terrorism in any sub-contract or sub-agreement that the Supplier enters into for the purposes of this Agreement.

16.4 Anti-Fraud and Corruption

- a) Nutrition International has zero tolerance for fraud and corruption and expects the Supplier to share NI's values of integrity and transparency as a trusted partner. The Supplier therefore commits to preventing and detecting corruption and bribery in accordance with Nutrition International's Anti-Fraud and Corruption Policy.
- b) The Supplier, through its employees, agents, representatives or subcontractors, will not make or cause to be made, or receive or seek to receive, any offer, gift or payment, consideration or benefit of any kind, which would or could be construed as an illegal or corrupt practice, either directly or indirectly to any party, as an inducement or reward in relation to the execution of this agreement or any arrangement or provision of funds in relation to its operations.

Information with respect to any actual or suspicious corrupt or fraudulent practice in relation to this Agreement can be forwarded to confidential@nutritionintl.org

- c) In the event of actual or suspected fraud and corruption, the Supplier will notify NI within five (5) business days of such occurrence and any remedial actions or steps taken.
- d) The Supplier will fully co-operate with any investigation into events covered under this section, whether led by NI or their authorized agents.

- e) The Supplier will use its best endeavors to ensure that any employee, agent, representative or other entity it is responsible for will comply with this section.
- f) Any actual or proven amounts of fraud and corruption will be considered an ineligible expenditure under this Agreement. The Supplier is required to reimburse NI any amount misappropriated through Fraudulent and Corrupt Activities.
- g) In the event of an actual or suspected fraudulent or corrupt practices, NI will reserve the right to terminate this Agreement in accordance with Clause 14 - Termination, suspend funding to the Supplier or sanction the Supplier and any of its related or affiliate parties from any future NI funding or take any other corrective action as necessary.
- h) The Supplier shall include a corresponding provision related to Anti-Fraud and Corruption in any sub-contract or sub-agreement that the Supplier enters into for the purposes of this Agreement.

16.5 International Sanctions

The Supplier declares and guarantees that any fees paid for the services provided under this Contract will not knowingly be used, either directly or indirectly, to do business with countries or persons subject to sanctions imposed by Canada or the United Nations under the Special Economic Measures Act, S.C. 1985, c.17, the United Nations Act, S.C. 1985, c. U-2, the Export and Import Permits Act, S.C. 1985, c. E-19, and all other international conventions related to sanctions to which Canada has adhered. A general list of, and information about, sanctions in effect can be accessed via the link below:

[Click here to access a list of current sanctions](#)

16.6 Gender Equality

The Supplier acknowledges that it has a Gender Equality Policy which aims to promote gender equality in all its operations to prevent gender discrimination. Should the Supplier not have a Gender Equality Policy, then [NI's Gender Equality Policy](#) shall be the guiding document. The Supplier will promptly notify NI of any changes to any specific statutory, legal, legislative responsibilities in relation to gender equality or organizational Gender Equality Policy changes.

16.7 Whistleblower Protection

The Supplier will ensure that it has a Whistleblower Protection Policy in place that supports its employees, whereby acting in good faith and on the basis of reasonable belief, if employees become aware of actual, suspected or intended misconduct, unlawful activity, suspicious financial management, or other accountability concerns, are given the opportunity to report such misconduct or incidents without reprisal to their senior management. Should the Supplier not have a Whistleblower Protection Policy, then [NI's Whistleblower Protection Policy](#) shall be the guiding document.

16.8 Sexual Harassment

The Supplier acknowledges that it has a Sexual Harassment Policy which provides and maintains a work environment in which all employees are free from sexual harassment. Furthermore, the Supplier is committed to creating a healthy and safe work environment that enables its employees to work free from unwelcome, offensive and discriminatory behaviour. Sexual harassment at the workplace is a form of discrimination. Protection against sexual harassment and right to work with dignity are universally recognized human rights by international conventions and instruments. The Supplier will ensure that its rules and procedures for the prevention, prohibition and punishment of sexual harassment of individuals at the workplace are strictly enforced. Should the Supplier not have a Sexual Harassment Policy, then [NI's Sexual Harassment Policy](#) shall be the guiding document.

16.9 Sexual Exploitation

The Supplier acknowledges that it has a Sexual Exploitation Policy, and any such policy will ensure that any person working for, or representing, the Supplier must respect the rights and dignity of the individuals and communities in which the Supplier serves. In upholding these rights, the Supplier will promote an environment free of sexual exploitation and sexual abuse. Sexual exploitation includes, but is not limited to:

- a) Any act or type of harassment that could cause physical, sexual or psychological harm or suffering to individuals, especially women and children.
- b) Any act or behaviour that exploits the vulnerability of beneficiaries or that allows them to be put in compromising situations.
- c) Engaging in sexual activity with persons under the age of 18.
- d) Engaging in sexual exploitation or abuse of beneficiaries under any circumstances.
- e) Any act or behaviour that seeks sexual acts or favours in exchange for access to participate in – or to receive benefit from – any Nutrition International program or activity.

The Supplier will use its best endeavors to ensure that any employee, agent, representative or other entity it is responsible for will comply with this paragraph. The Supplier will promptly notify NI of any suspected or detected exploitation or abuse and the actions taken by the Supplier in response. Should the Supplier not have a Sexual Exploitation Policy, then [NI's Sexual Exploitation Policy](#) shall be the guiding document.

17. **SUPPLIER REPRESENTATION**

The Supplier represents and warrants that it has the personnel, experience, qualifications, facilities and all other skills and resources to perform its obligations under this Contract.

18. **STATUTORY COMPLIANCE, PERMITS AND LICENSES**

The Supplier is responsible for all statutory and regulatory compliance and for obtaining any permits, licenses or other documents required by any Government authorities in connection with the production and shipment of the Goods.

19. **APPLICABLE LAWS**

This Contract shall be governed by, and interpreted and enforced in accordance with the laws in force in the province of Ontario, Canada.

20. **TRANSMISSION BY FACSIMILE OR OTHER ELECTRONIC MEANS**

Delivery of this agreement by facsimile or electronic transmission constitutes valid and effective delivery.

21. **DISPUTES UNDER THIS CONTRACT**

If there is a dispute between NI and the Supplier regarding any matter, prior to the initiation of any formal proceedings, the Parties shall first attempt to resolve any dispute or controversy informally. If the dispute cannot be resolved informally, the matter shall be referred for arbitration by a single

arbitrator in Ontario pursuant to the International Commercial Arbitration Act (Ontario) whose decision shall be final.

22. USE OF NUTRITION INTERNATIONAL'S LOGO

Where the Supplier wishes to affix NI's (or NI Donor's) corporate identity (logo) on publications, banners, or any other form of material or products, the Supplier should contact an NI representative to obtain: a) approval for each use of the logo and, b) an authorized version of these logos.

23. ENTIRE CONTRACT

This Contract constitutes the entire Contract between the Supplier and NI pertaining to the subject matter of this Contract and supersedes all previous negotiations and documents pertaining thereto. \$startif(\$donor_grant_flow_down_clause != "")

24. DONOR SPECIFIC CLAUSES

\$donor_grant_flow_down_clause_text \$endif

SCHEDULE 1
SPECIFICATIONS

SCHEDULE 2
PACKING, SHIPPING, AND LABELLING INSTRUCTIONS

SCHEDULE 3

BANK INFORMATION FORM

Complete banking information must be provided here for every new agreement to enable NI to make any payments.

RECIPIENT DETAILS

Name:	{{*nameForBk_es_:signer2:string}}	}}
	Beneficiary or company name as held by your bank	
Explanation:	{{*explanation_es_:signer2:string}}	}}
	Explanation if Name is different than the name on the contract	
Address (no P.O. box)	{{*addrForBk_es_:signer2:string}}	}}
	Street name and number, house number, etc.	City
	{{*provAndCoForBk_es_:signer2:string}}	}}
	Province (if applicable), Country	Postal Code
Contact Information:	{{*phone_es_:signer2:string}}	}}
	Phone number (incl. country and area code)	Email address
	{{*companyContact_es_:signer2:string}}	}}
	Company contact person	
Tax Information:	{{*beneficiaryTaxId_es_:signer2:string}}	}}
	Beneficiary Tax ID (where applicable):	

BANK DETAILS

Bank Name:	{{*bkName_es_:signer2:string}}	}}
	Full bank name	
Branch	{{*branch_es_:signer2:string}}	}}
	Branch where beneficiary account is held	
Branch Address (no P.O. box)	{{*branchAddress_es_:signer2:string}}	}}
	Complete branch address (please include street name & number, city, postal code)	
Account Number:	{{*accountNum_es_:signer2:string}}	}}
Currency of Account:	{{*accountCurrency_es_:signer2:string}}	}}
SWIFT Code:	{{*swiftCode_es_:signer2:string}}	}}
Other Bank Codes:	{{*otherBankCodes_es_:signer2:string}}	}}
	(IFSC, IBAN, ABA, NTN Number, Transit, etc., that are applicable to your country's requirements)	

INTERMEDIARY BANK

IMPORTANT: Intermediary information is required only when the account currency is foreign to the receiving bank's local currency. (Ex.: To wire a payment to a US \$\$ bank account held within a Brazilian Bank, a US Intermediary Bank is needed)

Bank Name:	{{*intBkName_es_:signer2:string}}	}}
Bank Address:	{{*intBkAdd_es_:signer2:string}}	}}
SWIFT Code	{{*intBkSwiftCode_es_:signer2:string}}	}}
Account Number:	{{*intBkAccountNum_es_:signer2:string}}	}}
	(If applicable)	

I hereby certify that the information provided on this attachment is correct and complete. I am an authorized officer for the purpose of completing this form. I authorize NI to deposit, by electronic funds transfer, to the bank account designated above for any payments.

Signature	{{Sig_es_:signer2:signature }}	Title	{{Ttl_es_:signer2:title }}
Name	{{N_es_:signer2:fullname }}	Date	{{Dte_es_:signer2:date}}
Phone Number	{{phone_es_:signer2:required }}		

Annex F - Pricing Table + Lead Time

Instructions:

- 1.Manufacturers must provide cost per bottle for capsules in CAD.
2. Should proponents determine that a number of bottles other than the ranges specified below in the "Annual Quantity (Bottles)" would result in a preferable pricing scheme, in addition to this table, proponents are welcome to submit a second table specifying these alternative ranges.
3. Please also indicate the minimum order quantity.

Minimum order Quantity:

PRICING TABLE					
Product	Quantity per pack (Capsules)	Applicable MOQ/Batch size [Contractor to specify]	DAP Lead Time (Weeks)	Unit Price per Bottle/Blister	Insurance Price per Bottle/Blister
				CAD	CAD
Bottles					
50,000 IU Vitamin A OLP (USP) as Soft Gelatin	25				
50,000 IU Vitamin A OLP (USP) as Soft Gelatin	50				
Blister Packs					
50,000 IU Vitamin A OLP (USP) as Soft Gelatin	25				
50,000 IU Vitamin A OLP (USP) as Soft Gelatin	50				

Annex G: Delivery Schedule

Manufacturers must provide their best delivery schedule in the format below for the products listed. Where possible, manufacturers should limit 5 containers per shipment.

Note:
The target arrival date for the first shipment of capsules at the DAP point is **no later than 31 March 2027**. In the table below, please indicate the date that the supplies are intended to arrive at DAP (not the date they will ship from the manufacturing site).

Please take this into consideration when completing the table.

The minimum expected delivery volumes for this period will be determined based on the requirements of the project, with consideration given to the Contractor's production batch sizes and minimum order quantities.

				July-Sept	Oct-Dec	Jan-Mar	Apr-June
				Q3	Q4	Q1	Q2
		Proposed Delivery Schedule					
Year	Quantity to be shipped (# of bottles)						
	50,000IU	Shipment #	Container #				
EXAMPLE	1,000	1	1		05-Dec-22		
2023		1					
		2					
		3					
		4					
		5					
		6					
		7					
		8					

Annex H: New Manufacturers Reference Format

Instructions: All new proponents not previously contracted by NI must submit references from at least 3 clients within the last 2 years and with a minimum supply value of CAD \$100,000 for each reference. Such references do not have to be directly related to vitamin A commodities.

Reference 1			
Client Name			
Client Address			
Client Focal Person			
Focal Person Email			
Focal Person Telephone			
Product supplied			
# of Years in Business with Client			
Contract Start Date (DD/MM/YYYY)		Contract End Date (DD/MM/YYYY)	
Contract Value		Currency	

Reference 2			
Client Name			
Client Address			
Client Focal Person			
Focal Person Email			
Focal Person Telephone			
Product supplied			
# of Years in Business with Client			
Contract Start Date (DD/MM/YYYY)		Contract End Date (DD/MM/YYYY)	
Contract Value		Currency	

Reference 3			
Client Name			
Client Address			
Client Focal Person			
Focal Person Email			
Focal Person Telephone			
Product supplied			
# of Years in Business with Client			
Contract Start Date (DD/MM/YYYY)		Contract End Date (DD/MM/YYYY)	
Contract Value		Currency	

NI TECHNICAL QUESTIONNAIRE FOR PHARMACEUTICAL MANUFACTURERS

Note to applicant: This questionnaire must be completed for each manufacturing site involved in the supply of the products to NI. Please also note that answers are not limited to the space provided in the questionnaire. If necessary, attach answers in a separate document.

1. GENERAL INFORMATION

- Name, address, telephone, email, fax, website of the company:

2. AFFILIATES

- If the company is owned by another company, or belongs to a group of companies, please indicate your position within the structure:

3. REGULATORY ISSUES

3.1. Good manufacturing practice

- Indicate the GMP standards (WHO, PIC-S/EU, FDA or other) with which the company complies:

3.2. Manufacturing licence for medicinal products

- Please list the pharmaceutical dosage forms you are licensed to manufacture by the National Drug Regulatory Authority and attach a copy of the Manufacturing licence(s) or GMP certificate (it must indicate dosage forms manufactured):

Click or tap here to enter text.

3.3. Inspection

- Date of last inspection by the National Drug Regulatory Authority (NRA): Click or tap here to enter text.

Please attach a copy of the last inspection report by the National Drug Regulatory Authority if it can be made available for review by NI on a confidential basis.

- Names of all other Regulatory Authorities and International Organizations who have inspected the company. Please also state the outcome of the inspection. This list should include both positive and negative inspection outcomes and dates of the inspection.

Please attach a copy of the last inspection report from other Regulatory Authorities or International Organization if it can be made available for review by NI on a confidential basis.
Comments (if any):

4. MANUFACTURING

4.1. Manufacturing site

- Please state all addresses at which manufacturing of pharmaceutical products takes place, and indicate which year the factory was built (complete one questionnaire for each site):

4.2. Personnel

- Please indicate the name and the education of the following key staff:
 - Managing director: Click or tap here to enter text.
 - Production Manager: Click or tap here to enter text.
 - Quality Assurance Manager: Click or tap here to enter text.
 - Number of personnel in total: Click or tap here to enter text.
 - Number of personnel in production: Click or tap here to enter text.
 - Number of personnel in quality control: Click or tap here to enter text.

4.3. Ventilation system

- Please indicate whether the manufacturing areas are equipped with controlled ventilation systems:

☐ Yes ☐ No

4.4. Quality Control

- Chemical laboratory ☐ in-house ☐ contracted out
- Biological laboratory ☐ in-house ☐ contracted out
- Microbiological laboratory ☐ in-house ☐ contracted out

4.5. Contract manufacture

- Please indicate if you undertake contract manufacture for other companies:

☐ Yes ☐ No

- Do you subcontract to other companies?

☐ Yes ☐ No

If yes, please list products and/or services and be reminded this questionnaire must be completed for each manufacturing site involved in supply of products to NI.

4.6. Sterile products:

Do you manufacture sterile products?

☐ Yes ☐ No

Which Method of sterilisation is used: [Click or tap here to enter text.](#)

Is aseptic manufacturing processes simulated with media fills twice a year for product time and size? ☐ Yes ☐ No

4.7. Beta-lactames

Do you manufacture penicillins or other beta-lactam products?

☐ Yes ☐ No

If yes, does this production take place in separate buildings?

☐ Yes ☐ No

4.8. Recalls

▪ Do you have a recall procedure? ☐ Yes ☐ No

▪ Please indicate significant product complaints and any recalls the last three years:

[Click or tap here to enter text.](#)

4.9. Production capacity

Product	No of units per year	Last years' production - units
Tablets		
Capsules		
Ampoules		
Vials, liquids		
Vials, dry powder		
Vials, lyophilized		
Ointments		
Liquids		
Powder for oral suspensions		
Suppositories		
Penicillin, tablets/capsules		
Penicillin, powder for oral suspension		
Penicillin, powder for injection		
Other, specify		
Other, specify		

■ Is production capacity figures based on one or more shifts? (Tick in appropriate box)

☐ 1

☐ 2

☐ 3

☐ Other, (please specify): [Click or tap here to enter text.](#)

5. PRODUCTS

5.1 Product licences

☐ Please enclose a list of all products manufactured by your company and authorised for sale on the domestic market (country of origin). Comments (if any): [Click or tap here to enter text.](#)

☐ For each licensed product, please categorise as follows:

- The product is marketed on the domestic market.
- The product is licensed but not marketed on the domestic market.
- The licence is for export only

☐ Kindly also list licences for each product held in other countries:
[Click or tap here to enter text.](#)

☐ Please indicate how much in percentage your export is of the total production:
[Click or tap here to enter text.](#)

☐ Please also list the name of any contract manufacturer, when a product is not fully manufactured by your company.
[Click or tap here to enter text.](#)

☐ If possible, please attach an indicative price list. Comments (if any):
[Click or tap here to enter text.](#)

5.2. Documentation

☐ The following product documentation must upon request be available for all products offered to NI:

- Product composition - master formula
- Batch manufacturing record
- Starting materials specification
- Finished product specification
- Validation report
- Stability report
- Packaging and labelling specifications
- Annual Product Review
-

Please indicate if this documentation is NOT available for any of the products on the list, point

5.1. [Click or tap here to enter text.](#)

5.3. Starting materials:

☐ Indicate approved starting material sources for the company's major products and indicate if approved DMFs or Certificates of suitability of the Monograph of the European Pharmacopoeia are available:

[Click or tap here to enter text.](#)

☐ How is it ensured that Active Pharmaceutical Ingredients (APIs) are manufactured in accordance with GMP?

☐

6. GMP INSPECTION

- Can NI or any other representative designated by NI perform an inspection of the Manufacturing site? ☐ Yes ☐ No

- Can the National Drug Regulatory Authority participate as observers in the audit? ☐ Yes ☐ No

- Please attach a Site Master File (PIC-S format). If not attached please indicate why it is not attached:

Click or tap here to enter text.

- May NI share the inspection report with its partners WHO Geneva, MSF France, ICRC Geneva and PIC-S member states upon request? (Your company will be notified in case the report is shared.) ☐ Yes ☐ No

7. OTHER INFORMATION

Please provide a contact person that can be reached by NI

Name: Click or tap here to enter text.

Position in Company: Click or tap here to enter text.

Email: Click or tap here to enter text.

Add any other information: Click or tap here to enter text.

I hereby certify that the information given in this questionnaire and the attachments is correct.

Name: Click or tap here to enter text.

Title: Click or tap here to enter text.

Date: Click or tap here to enter text.

Signature:

NI PHARMACEUTICAL PRODUCT QUESTIONNAIRE

Note for the applicant: Please fill one form separately for each finished pharmaceutical product (FPP) item offered (e.g. Item 1a, 1b, etc). Note that the information in this questionnaire will be shared confidentially amongst NI for procurement purposes. All sections and fields in the template that would be applicable should be completed. If the field does not apply, indicate "not applicable" in the appropriate area with an accompanying explanatory note.

I. Finished Pharmaceutical Product (FPP) Identification

Active Pharmaceutical Ingredient(s) – use the approved international non-proprietary name (INN):

-

▪ Generic name of the product:

▪ Brand/trade name (if any):

▪ Dosage form:

☐ Tablets ☐ Capsules ☐ Injectable ☐ Syrups/oral liquids ☐ Soft-gel

☐ Other (please specify):

▪ Strength per dosage unit:

▪ Route of administration:

☐ Oral ☐ I.M. ☐ I.V. ☐ S.C.

☐ Other (please specify):

▪ Description and composition of primary packaging materials¹, container size, closure system and number of dosage units per pack:

▪ Description and composition of secondary packaging materials and number of units per secondary pack:

Please attach:

→ The formulation of the product (complete qualitative and quantitative composition including active ingredient(s), overages if any and excipients) and state the function of each component.

→ A flow diagram and description of the steps involved in the manufacturing and control process (showing where materials enter the process as well as identifying critical steps and points at which process controls are conducted.)

→ The specifications for primary packaging (including specific tests and analytical methods).

¹ In direct contact with the FPP.

II. Manufacturer identification

- Name, address and link with the product of company submitting the technical dossier:

Name of company submitting technical dossier	Physical and Mailing address	Contact person name, telephone, fax, email and website details	Link with the product (e.g. marketing license holder, distributor/wholesaler, manufacturer, other)

- Name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing should be provided in the table below.
Note: For a mixture of an API with an excipient, the blending of the API with the excipient is considered to be the first step in the manufacture of the final product and, therefore, the mixture does not fall under the definition of an API. Sites for such manufacturing steps should be listed in this section.

Name of each manufacturer, including contractors	Actual address of production or manufacturing site(s) involved, including block(s) and unit(s) rather than administrative offices	Telephone, Fax and email contact details	List all activities relevant to this manufacturer / site or facility (e.g. manufacturing, packaging, labeling, testing)	Reference of manufacturing site license by the National Drug Regulatory Authority, issuing and expiry dates

- For each site listed above:

- Please attach a copy of the site license issued by the National Drug Regulatory Authority authorizing the manufacturer /manufacturing site(s) to perform activities listed in the table above (e.g. manufacture, package, label, test and/or sell pharmaceutical products) to be submitted for each site involved in the manufacturing process of the finished product.
- Please also attach a copy of the most recent site inspection report from the National Drug Regulatory Authority (note: to be submitted for each site involved in the manufacturing process of the finished product).

- Please provide the date of the last GMP inspection carried out for each finished product manufacturing site listed above performed by one or more internationally recognized authority that is a member or a partner of the Pharmaceutical Inspection Scheme (PIC/S).

Name of Manufacturer/ Contract Manufacturer (if any) and manufacturing site inspected	Name of inspection agency	Date of inspection	Outcome of inspection

- For each site involved in the manufacturing process of the finished product:
→ Please attach a copy of the GMP certificate(s) and/or valid inspection report of each finished product manufacturing site from the last inspection/audit demonstrating compliance of the manufacturing process with international GMP Standards for Pharmaceutical Products performed by one or more internationally recognized authority that is a member or a partner of the Pharmaceutical Inspection Scheme (PIC/S).

III. Regulatory situation (licensing status)

▪ Product registration in the country of manufacture

- ☐ Product registered and currently marketed in the country of manufacture.

License n°:

Valid until:

Issued by (please name agency):

Country:

- ☐ Product registered for marketing in the country of manufacturing but not currently marketed.

License n°:

Valid until:

Issued by (please name agency):

Country:

☐ Product registered for export only.

License n°:

Valid until:

Issued by (please name agency):

Country:

☐ Product not registered in country of manufacture (please clarify):

→ Please provide copies of all product registration licenses that apply.

▪ **Certificate of Pharmaceutical Product (CPP)**

☐ CPP has been obtained.

Reference n°:

Valid until:

Issued by (please name agency):

Country:

→ Please attach CPP according to the WHO Certification Scheme - WHO Technical Report Series No. 863 (earlier version is not acceptable) or equivalent document.

☐ CPP has not been obtained (please state reason):

→ Please attach equivalent document (if any)

▪ **Product registration in other countries**

List other countries where the product is registered and is currently marketed (for each country, please provide registration number, issuing agency and validity period):

IV. Finished Product Specification

- Indicate finished product specification reference:

☐ USP (please specify edition and publication date):

☐ Ph. Int. (please specify edition and publication date):

☐ Other (please specify):

☐ In-house (number and date):

- Indicate any additional specifications to those in the pharmacopoeia referred to above (e.g. dissolution, syringeability):

- Indicate analytical procedures and source of reference standard or materials used by the FPP manufacturer for testing the vitamin A.

Please attach:

→ A copy of the finished product specifications dated and signed by authorized personnel. If different from official pharmacopoeia validated analytical methods should be included as well as equivalence report.

→ A copy of the certificate of analysis for the 3 last batches released. The CoAs should include batch number, batch size, API source, specification reference for testing parameters and microbiological testing.

→ Please attach a copy of the sample preparation method with instructions to be used in the lab prior to analytical procedure. Unless modified, it is not necessary to also provide copies of the officially recognized analytical procedure.

- Do you have equipment to measure soft gel capsule hardness?

☐ Yes ☐ No

If yes,

→ Please attach validated method used by your company to measure capsule hardness.

Have the manufacturing methods for each standard production batch size been validated?

☐ Yes ☐ No

If no, please clarify:

- Indicate the batch number, batch size and manufacturing date of the validated standard production batch:

Has the finished product previously received Halal product certification by an internationally recognized certifying agency such as the Islamic Food and Nutrition Council of America (IFANCA) to meet Islamic Halal requirements?

☐ Yes ☐ No

If yes, please provide the name of the issuing agency:

→ Please attach a copy of the Halal finished product certificate.

V. Stability of Finished Product

▪ **Stability testing data available:**

☐ Yes ☐ No

If yes, summarize information in table below (where relevant):

Satisfactory accelerated testing at (state the months)	
Type and material of packaging	
Conditions: (Temperature/ Relative Humidity/Duration)	
Number of batches	
Batch sizes	
Study start date	
Study end date	
Satisfactory long-term testing at (state the months)	
Type and material of packaging	
Conditions: (Temperature/ Relative Humidity/Duration)	
Number of batches	
Batch sizes	
Study start date	
Study end date	

Please attach:

→ Copies of the stability testing protocol and reports for 3 batches for accelerated and long-term conditions meeting the minimum information requirements and presented in the appropriate format (see RFP, Annex C). The reports should include batch number, batch size, API source, specification reference for testing parameters and microbiological testing.

→ If applicable, a written commitment (signed and dated) to continue long-term testing over the shelf-life period.

▪ Was the stability testing done on a product of the same formulation, with API from the same source, manufactured at the same site and packaged in the same container closure system as the product that will be supplied?

☐ Yes ☐ No

If no, describe the differences:

▪ Do you have on-going stability data for this product?

☐ Yes ☐ No

If yes:

→ Please also include a status report.

If no, please indicate plans for any future study:

▪ **Shelf-life**

Guaranteed shelf life (based on existing stability study data):

Maximum possible shelf life:

Shelf life as it appears on the packaging:

Shelf life after primary package is open or product is reconstituted:

▪ **Storage conditions**

Specific storage conditions for this product as they appear on the packaging and based on stability studies (temperature, light, humidity etc):

Product suitable for use in:

- ☐ Zone I
☐ Zone II
☐ Zone III

- ☐ Zone IVa
☐ Zone IVb
☐ Other (specify):

VI. Samples for Technical Evaluation

- You are required to please provide a sample of the finished product(s) offered. Product sample provided:

☐ Yes ☐ No

Please refer to the RFP for person and address to mail the samples. Manufacturers are responsible for any charges associated with shipping the samples.

If you cannot submit any of the above with the questionnaire, please state why not and when you will do so:

▪ Shelf-life on the sample:

▪ Storage condition on the sample:

▪ Patient information leaflet available (Y/N):

▪ Language on the label and/or PIL:

- The product sample provided conforms in all forms to the product offered and as it will be supplied on purchase:

☐ Yes ☐ No (please clarify):

→ Please attach a certificate of analysis relevant to the sample provided.

VII. Therapeutic Equivalence

Therapeutic Equivalence studies are:

- ☐ **Not relevant**, please explain why:
- ☐ **Not demonstrated**, please explain why:
- ☐ **Demonstrated**

→ If demonstrated, please provide relevant study protocol and report

VIII. Active Pharmaceutical Ingredient(s) (APIs) and Excipient Manufacturers

Note for the applicant: For vitamin A soft gelatin capsule manufacturers, this question should be completed to include information pertaining to the vitamin A, vitamin E and the Gelatin manufacturers. In this section, be sure to provide information for each manufacturer of the active pharmaceutical ingredient and the gelatin who supply the finished product manufacturer.

1. API and Gelatin Manufacturers

Name of API (use INN if any) /Excipient	Name of manufacturer (please list all alternative sources, if any)	Actual address of production or manufacturing site(s) involved, including block(s) and unit(s) rather than administrative offices	Reference of manufacturing license by the National Drug Regulatory Authority, issuing and expiry dates	If applicable, certificate No. of suitability to the Ph. Eur. or registration No. of the open part of the Drug Master File

2. API Manufacturers only

2.1 GMP certification

Please provide the date of the last inspection/audit for each API manufacturing site listed in table above performed by one or more internationally recognized authority that is a member or a partner of the Pharmaceutical Inspection Scheme (PIC/S).

Name of Manufacturer/ manufacturing site inspected	Name of inspection agency	Date of inspection	Outcome of inspection

For each API manufacturing/ intermediate manufacturing site listed above,

→ Please attach a copy of the GMP certificate(s) and/or valid inspection report(s) from the last inspection demonstrating compliance of the API manufacturer with international GMP Standards for Pharmaceutical Products.

2.2 Specifications

- API Specifications and standard test methods exist for this API?

☐ Yes ☐ No

- API specifications:

☐ BP (please specify edition and publication date):

☐ USP (please specify edition and publication date):

☐ Ph. Eur. (please specify edition and publication date):

☐ Ph. Int. (please specify edition and publication date):

☐ Other (please specify):

☐ In-house (please specify):

→ Please attach a copy of the API specifications dated and signed by authorized personnel. If different from official pharmacopoeia, validated analytical methods should be included.

2.3 Certificate of Analysis

→ Please attach a copy of the certificate of analysis of the last production batches of API from the API manufacturer.

→ Please attach a copy of the certificate of analysis of the API from the Finished Pharmaceutical Product manufacturer.

2.4 Suitability of monograph

For this API, are you in possession of the following information?

- ☐ Certificate of suitability to the European Pharmacopoeia (CEP):

Certificate N°:

→ Please attach a copy of the CEP (including any annexes). Note: A written commitment noting that the applicant will inform NI and UNICEF in the event that the CEP is withdrawn should accompany the CEP.

- ☐ The open part of Drug Master File (DMF) registered in:

Country:

Registration N°:

- ☐ A Technical File:

2.5 Approval Process

- Do you have internal procedure for approving/accepting API manufacturers? ☐ Yes ☐ No

If yes:

- Do you audit your API manufacturers? ☐ Yes ☐ No

If yes:

Please specify the frequency at which you audit your API manufacturers:

3. Gelatin Manufacturers only

3.1 Specifications

- Specifications and standard test methods exist for the Gelatin?

☐ Yes ☐ No

- Gelatin specifications:

☐ BP (please specify edition and publication date):

☐ USP (please specify edition and publication date):

☐ Ph. Eur. (please specify edition and publication date):

☐ Ph. Int. (please specify edition and publication date):

☐ Other (please specify):

☐ In-house (please specify):

→ Please attach a copy of the Gelatin specifications dated and signed by authorized personnel. If different from official pharmacopoeia, validated analytical methods should be included.

- Is the gelatin supplied to the finished product manufacturer certified to be Halal by a internationally recognized certifying agency such as the Islamic Food and Nutrition Council of America (IFANCA) to meet Islamic Halal requirements?

☐ Yes ☐ No

If yes, please provide the name of the issuing agency:

→ Please attach a copy of the Halal gelatin certificate for the gelatin manufacturer(s).

3.2 Certificate of Analysis

- Please attach a copy of the certificate(s) of analysis of the gelatin from the gelatin manufacturer.
→ Please attach a copy of the certificate(s) of analysis of the Finished Pharmaceutical Product manufacturer.

3.3 Suitability of monograph

For gelatin, are you in possession of the following information?

- ☐ Certificate of suitability to the European Pharmacopoeia (CEP):

Certificate N°:

→ Please attach a copy of the CEP (including any annexes).

- ☐ The open part of Drug Master File (DMF) registered in:

Country:

Registration N°:

- ☐ A Technical File:

3.4 Approval Process

- Do you have an internal procedure for approving/accepting gelatin manufacturers? ☐ Yes ☐ No

If yes:

Do you audit your gelatin manufacturers?

☐ Yes ☐ No

If yes:

Please specify the frequency at which you audit your gelatin manufactures:

4. All other Excipient Manufacturers

- Do you have an internal procedure for approving/accepting all other excipient manufacturers?

☐ Yes ☐ No

If no:

Please list the excipients for which you don't have an internal procedure for approving/accepting manufacturers:

Do you audit your other excipient manufacturers?

☐ Yes ☐ No

If yes:

Please specify the frequency at which you audit your other excipient manufacturers:

IX. Commitment

I (Full Name), _____, certify that:

- ☐ The product offered is identical in all aspects of manufacturing and quality to that registered and marketed in/the country of origin (name of country) _____ Ref No _____, including formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information.

AND/OR

- ☐ The product supplied will be identical to that offered in this RFP in all aspects of manufacturing and quality including formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information.

Explain any exceptions:

Signature

Date

X. Authorization

I, the undersigned certify that the information provided above is accurate, correct, complete, up to date and true at the time of submission.

The manufacturer/supplier undertakes to notify NI of any changes that occur to the information after the submission of this product questionnaire.

Full Name:

Full title/ position in company:

Company name:

Signature

Date

Company seal/ stamp:

Annex 1: List of documents provided

Note to the applicant: Please include a copy of this checklist together with the submission of the PPQ and attach all necessary documents as per below to enable objective evaluation of your product. Indicate the reference letter as specified for each document listed below in the top right corner of each document submitted. If more than one document is submitted, please use numbers (e.g. A-1, A-2, etc). This checklist may not be exhaustive.

- ☐ **A.** The formulation of the product (complete qualitative and quantitative composition including active ingredient(s), overages if any and excipients) and state the function of each component –
- ☐ **B.** A flow diagram and description of the steps involved in the manufacturing and control process (showing where materials enter the process as well as identifying critical steps and points at which process controls are conducted).
- ☐ **C.** The specifications for primary packaging (including specific tests and analytical methods).
- ☐ **D.** Site license issued by the National Drug Regulatory Authority authorizing the manufacturer/manufacturing sites to perform activities listed in the table under Section II (e.g. manufacture, package, label, test and/or sell pharmaceutical products) to be submitted for each site involved in the manufacturing process of the finished product.
- ☐ **E.** Most recent site inspection report from the National Drug Regulatory Authority (to be submitted for each site involved in the manufacturing process of the finished product).
- ☐ **F.** GMP certificate(s) and/or valid inspection report of each finished product manufacturing site from the last inspection/audit demonstrating compliance of the manufacturing process with international GMP Standards for Pharmaceutical Products performed by one or more internationally recognized authority that is a member or a partner of the Pharmaceutical Inspection Scheme (PIC/S).
- ☐ **G.** Product registration license(s) that apply.
- ☐ **H.** Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme- WHO Technical Report Series No. 863 (earlier version is not acceptable) or equivalent document.
- ☐ **I.** Finished product specifications dated & signed by authorized personnel. If different from official pharmacopoeia validated analytical methods should be included as well as equivalence report.
- ☐ **J.** Certificates of analysis for the 3 last batches released.
- ☐ **K.** Sample preparation method with instructions to be used in the lab prior to analytical procedure. Unless modified it is not necessary to also provide copies of the officially recognized analytical procedure.
- ☐ **L.** Validated method used by your company to measure capsule hardness.
- ☐ **M.** Halal finished product certificate for the FPP manufacturer.
- ☐ **N.** Stability testing protocol and reports for accelerated and long-term conditions meeting the minimum information requirements and presented in appropriate format (see EOI Annex 1).
- ☐ **O.** A written commitment (signed and dated) to continue long-term testing over the shelf-life period (if applicable).
- ☐ **P.** A status report if any ongoing stability study.

- ☐ **Q.** A sample of the finished product(s) offered together with a certificate of analysis relevant to sample provided.
- ☐ **R.** Therapeutic Equivalence study protocol and report (if demonstrated).
- ☐ **S.** GMP certificate(s) and/or valid inspection report(s) from the last inspection demonstrating compliance of the API manufacturer with international GMP Standards for Pharmaceutical Products.
- ☐ **T.** API specifications dated and signed by authorized personnel. If different from official pharmacopoeia, validated analytical methods should be included.
- ☐ **U.** Certificate(s) of analysis of the last production batches of API from the API manufacturer.
- ☐ **V.** Certificate(s) of analysis of the last production batches of API from the Finished Product manufacturer.
- ☐ **W.** Certificate of suitability to the European Pharmacopoeia (CEP) (including any annexes) for the API. Note: A written commitment noting that the applicant will inform MI and UNICEF in the event that the CEP is withdrawn should accompany the CEP.
- ☐ **X.** Gelatin specifications dated & signed by authorized personnel. If different from official pharmacopoeia, validated analytical methods should be included.
- ☐ **Y.** Halal gelatin product certificate for the gelatin manufacturer(s).
- ☐ **Z.** Certificate(s) of analysis of the gelatin from the gelatin manufacturer(s).
- ☐ **AA.** Certificate(s) of analysis of the gelatin from the Finished Product manufacturer.
- ☐ **AB.** Certificate of suitability to the European Pharmacopoeia (CEP) (including any annexes) for gelatin.

Annex K: Risk Assessment Register									
Instructions:									
Please complete this Risk Assessment Register to identify the risks associated with sourcing,manufacturing,supplying, and managing the Vitamin A Soft Gelatin Capsule product. Please identify as many risks as possible related to each category type.									
RISK REGISTER						DATE LAST UPDATED:			
No.	RISK IDENTIFICATION	Risk Category	RISK RATING (P x I)			RISK IMPACT	RISK RESPONSE	RISK ACTION	RISK OWNER
			Probability	Incidence	Score				
	(Identify as many risks as you can related to each category)	(Pick a category from the Dropdown Menu)	1-Least likely to happen 5-Almost likely to happen	Incidence Threat : 1 - Insignificant (Problem handled by day-to-day process) 2 - Minor (Some disruption possible) 3 - Moderate (Significant time, resources required) 4 - Major (Operations severely affected) 5 - Catastrophic Business survival is at risk				Agreed actions to minimize probability of risk from occurring or to minimize consequences should the risk occur	Risk owner is the individual who has the most impact over its result. Choosing the risk owner thus usually includes considering the source of risk and determining the individual/group who is best placed to comprehend and apply what needs to be done. Risk action plan owners are held responsible for managing the risk through the agreed plan and have the authority to make sure tasks are completed or take the action required.
1					0				
2					0				
3					0				
4					0				
5					0				
6					0				
7					0				
8					0				
9					0				
10					0				