Micronutrient Initiative

unicef

MI-UNICEF Joint 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 MI and UNICEF 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) if any:

- Generic name of the product:

- Trade (proprietary) name (if any):

- Dosage form:

  ☐ Tablets ☐ Capsules ☐ Injectable ☐ Syrups/oral liquids

  ☐ Other *(please specify):*

- Strength per dosage unit:

- Route of administration:

  ☐ Oral ☐ I.M. ☐ I.V. ☐ S.C.

  ☐ Other *(please specify):*

- Description and materials used for primary packaging[1] container size (quantity of dosage-form units per container) and closure system:

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

Please provide:

→ *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. Please also indicate the standard for each ingredient (e.g. BP, USP, in-house):* ***Checklist item A.***

→ *A flow diagram and brief narrative describing the manufacturing and control processes of this product with relevant parameters:* ***Checklist item B.***

→ *The specifications for primary packaging (including specific tests and analytical methods):* ***Checklist item C.***

[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 the technical dossier	Physical and Mailing address	Contact person name, telephone number, fax, email and website details	Link with the product (e.g. marketing license holder, distributer/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 provide 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:* ***Checklist item D***.
  - → *Please also provide 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):* ***Checklist item E***.

III. Regulatory (licensing) status

- 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 provide 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):* ***Checklist item F.***

- ***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:* ***Checklist item G.***

▪ ***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):*

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

☐ CPP has been obtained.

Reference n°:

Valid until:

Issued by (*please name agency*):

Country:

☐ If CPP cannot be obtained from the national medicines regulatory authority, please state the reason and send an equivalent document if any:

→ *Please attach CPP according to the WHO Certification Scheme - WHO Technical Report Series No. 863 (an earlier version is not acceptable) or all product licenses that apply:* ***Checklist item H.***

IV. Finished Product Specification

- Indicate finished product specification standard:

  ☐ USP (*please specify edition and publication date*):

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

  ☐ In-house (*number and year documented*):

  ☐ Other *(please specify):*

- 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 provide:

→ *Copies of the release and shelf life specifications for the FPP dated and signed by authorized personnel. If analytical methods are in-house, different from the official pharmacopoeia, provide copies of validated analytical methods and analytical validation data: All should be included under:* ***Checklist item I.***

→ *A copy of the certificate of analysis for the 3 last batches released:* ***Checklist item J.***

→ *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 provide copies of the officially recognized analytical procedure:* ***Checklist item K***

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

☐ Yes ☐ No

If yes,

→ *Please provide validated method used by your company to measure capsule hardness:* ***Checklist item L***

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

☐ Yes ☐ No

If no, please clarify:

If yes, please provide details of validation status in the table below:

Batch size of the validated standard production batch: (minimum, maximum size)	
Batch numbers of the validated batches:	
Manufacturing dates of the validated batches:	
Reference number for the process validation report:	
If the processes are yet to be validated, the reference number for the process validation protocol should be indicated:	

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:* ***Checklist item M***.

V. Stability of Finished Product

- **Is 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/Light/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/Light/Duration)	
Number of batches:	
Batch sizes:	
Study start date:	
Study end date:	

Please provide:
→ Copies of the stability testing protocol and reports for accelerated and long-term stability testing meeting the minimum information requirements and presented in the appropriate format (see EOI, Annex 1): ***Checklist item N***
→ If applicable, a written commitment (signed and dated) to continue long-term testing over the shelf-life period: ***Checklist item O***.

- 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 of any ongoing stability data for this product:* ***Checklist item P.***

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 climatic zone:

☐ Zone I
☐ Zone II
☐ Zone III
☐ Zone IV a
☐ Zone IV b
☐ 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

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:* ***Checklist item Q***.

VII. Therapeutic Equivalence

- Therapeutic Equivalence studies are:

☐ **Demonstrated**

☐ **Not demonstrated**, please explain why:

☐ **Not relevant**, please explain why:

→ *If demonstrated, please provide relevant study protocol and report:* ***Checklist item R.***

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 last 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:* ***Checklist item S.***

2.2 Specifications

- 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 from the API manufacturer and a copy of the FPP manufacturer internal API specifications if different from official pharmacopoeia, validated analytical methods should be included:* ***Checklist item T.***

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:* ***Checklist item U.***
→ *Please attach a copy of the certificate of analysis of the API from the Finished Pharmaceutical Product manufacturer:* ***Checklist item V.***

2.4 *Suitability* of monograph

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

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

If yes, Certificate N°: ☐

→ *Please attach a copy of the CEP (including any annexes). 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:* ***Checklist item W.***

☐ 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:* ***Checklist item X.***

- Is the gelatin supplied to the finished product manufacturer certified to be Halal 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 gelatin certificate for the gelatin manufacturer(s):* ***Checklist item Y.***

3.2 Certificate of Analysis

→ *Please attach a copy of the certificate(s) of analysis of the gelatin from the gelatin manufacturer:* ***Checklist item Z***
→ *Please attach a copy of the certificate(s) of analysis of the Finished Pharmaceutical Product manufacturer:* ***Checklist item AA.***

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):* ***Checklist item AB.***

☐ 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:

(If the product is marketed in the country of origin, select the appropriate box below):

☐ 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 offered will be identical in all aspects of manufacturing and quality to that proposed in Expression of Interest No. 12-01-0014, 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.

If any changes occur to the information after the submission of this product questionnaire, the manufacturer/supplier undertakes to notify MI and UNICEF of the relevant update as soon as possible.

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), state the function of each component and also indicate the standard for each ingredient (e.g. BP, USP, in-house).
- ☐ **B.** A flow diagram and brief narrative describing the manufacturing and control processes of this product with relevant parameters.
- ☐ **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 all product licenses that apply.
- ☐ **I.** Release and shelf life specifications for the FPP, dated and signed by authorized personnel. If analytical methods are in-house, different from the official pharmacopoeia, provide a copy of validated analytical methods and analytical validation data.
- ☐ **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.