Annex D: Technical Specifications for Packaging

I. Bottle Specifications for NI & UNICEF

1.0 BOTTLES

1.1 Vitamin A Soft Gelatin Capsules are to be bottled as 100 or 500 capsules per bottle

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 100 or 500 capsules. Desiccant Packs are to be included in each 100 or 500 - 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:

Red: **Vitamin A (Retinol palmitate) 200,000 IU (60 mg)**
stabilized with 40 IU Vitamin E

Blue: **Vitamin A (Retinol palmitate) 100,000 IU (30 mg)**
stabilized with 20 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.

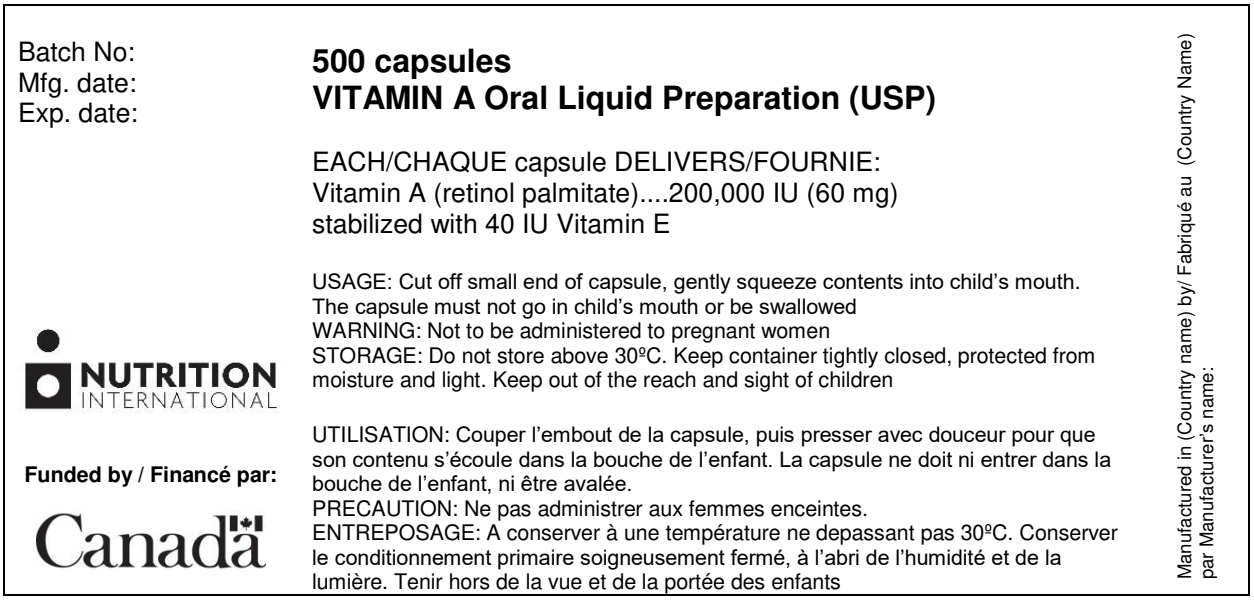
2.6 Labels must be firmly affixed to be tamper proof and to prevent detachment in tropical climates.

2.7 The label shall contain the following information:

a. Contents per bottle: 100 or 500 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 30º 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 depassant pas 30ºC. 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 **Leeza Sharma,** lsharma@nutritionintl.org prior to use.

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



III. Bottle Labels Specifications for UNICEF

3.0 BOTTLE LABELS

3.1 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.

3.2 Bilingual labels in English and French will be required.

3.3 The colours of lettering for amount of active ingredient must be:

Red: **Vitamin A (Retinol palmitate) 200,000 IU (60 mg)**
stabilized with 40 IU Vitamin E

Blue: **Vitamin A (Retinol palmitate) 100,000 IU (30 mg)**
stabilized with 20 IU Vitamin E

All other lettering on the bottle labels must be black.

3.4 The writing on the labels must be in indelible ink, and varnish free.

3.5 Self-adhesive, white, pharmaceutical defiberized paper (80 g/m2)

3.6 Film or UV coated for protection against humidity.

3.7 Labels must be firmly affixed to be tamper proof and to prevent detachment in tropical climates.

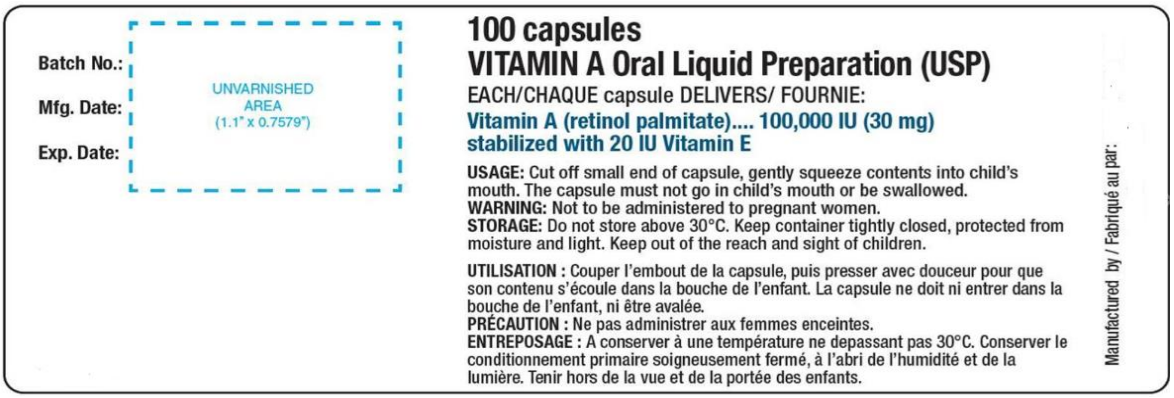
3.8 The label shall contain the following information:

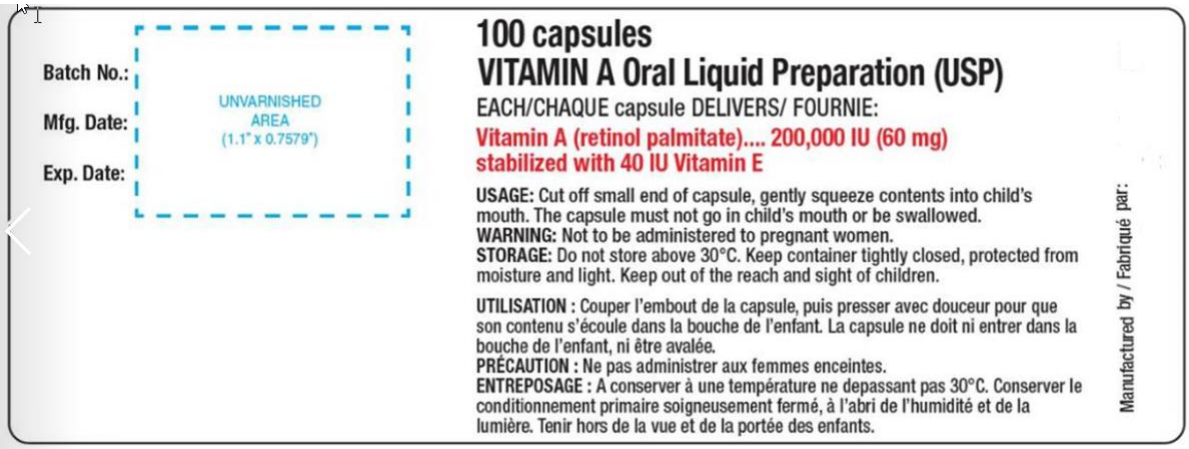
a. Contents per bottle: 100 or 500 capsules
b. The name of the product and the pharmacopoeial standard of the FPP:
"VITAMIN A Oral Liquid Preparation (USP)" in a bold, clearly visible font size.
c. The ester form in which the vitamin A is present
d. Stabilized with Vitamin E and the proportions added.
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 30º 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 depassant pas 30ºC. 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. For all products, the word "Halal" must **not** appear on any of the labels

3.9 A mock-up of the label must be pre-approved by UNICEF (to the attention of **Rajiv Kshirsagar, rkshirsagar@unicef.org** prior to use.

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





IV. Desiccant Pack Specifications

4.0 GENERAL:

4.1 Desiccant Packs are to be included in each 100 or 500-capsule container of Vitamin A Soft Gelatin Capsules manufactured for Nutrition International.

4.2 PURPOSE OF THE DESICCANT PACKS:

4.3 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.

4.4 PERFORMANCE:

4.5 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.

4.6 PRODUCT SPECIFICATION:

4.7 Sufficient B-type or wide pore spherical synthetic amorphous silica (silicon dioxide, Si02) 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.

4.8 PACKAGING OF THE PRODUCT:

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

OR

4.10 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 dessicant 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.

V. Specifications for Packing; Pallets & Boxes; Pallet & Box Labels

For UNICEF supply, the secondary packaging for vitamin A soft gelatin capsules must comply with the current UNICEF Warehouse Packing Technical Standards and Specifications.
https://www.unicef.org/supply/files/CPH_WH_only_packing_specifications_April_2017.pdf

5.0 GENERAL REQUIREMENTS

5.1 Contractors who do not comply with the packing requirements for deliveries to the UNICEF Warehouse, Copenhagen, Denmark, as outlined herein shall be invoiced the extra cost of re-work fees on arrival at UNICEF Supply Division. The current recovery fee structure is available on the UNICEF website (http://www.unicef.org/supply/files/UNICEF_Re-Work_fees.pdf)

5.2 UNICEF also reserves the right to reject non-compliant shipments. All additional costs in relation to the rejection of the shipment shall be borne by the manufacturer.

5.3 No carton may contain items from more than one manufacturing batch.

5.4 If the goods are batch managed, each pallet/carton shall contain one batch only.

5.5 Case identification as requested on the order must be mentioned on all invoices.

5.6 The packing (e.g. bottles, caps, boxes, labels) must be of a sturdy export quality and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions, and high humidity – i.e. not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of 40°C (tropical conditions).

5.7 The packaging unit must be strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing.

5.8 All wood packaging, including pallets and boxes, utilized in any shipment, must have undergone the treatment, marking and documentation required to meet the specifications described in ISPM No. 15: Guidelines for Regulating Wood Packaging Material in International Trade, available at www.ippc.int.

5.9 All paper-pulp used for cardboard and corrugated boxes must be of virgin base materials.

5.10 Deliveries to any destination other than the UNICEF Warehouse, Copenhagen, Denmark, must be packed and palletized in the most cost-effective way to minimize freight costs.

5.11 **Packing List:** All markings must be reflected in the packing list to be completed at time of shipment. The packing list shall indicate weights and volumes, description of the goods, manufacturing batch number, quantity per batch, expiry date and UNICEF's P.O. reference (680*) and material numbers (S78*) and cross-reference to the carton numbers. One copy of the packing list must be included with the shipment and another copy shall accompany the shipping documents.

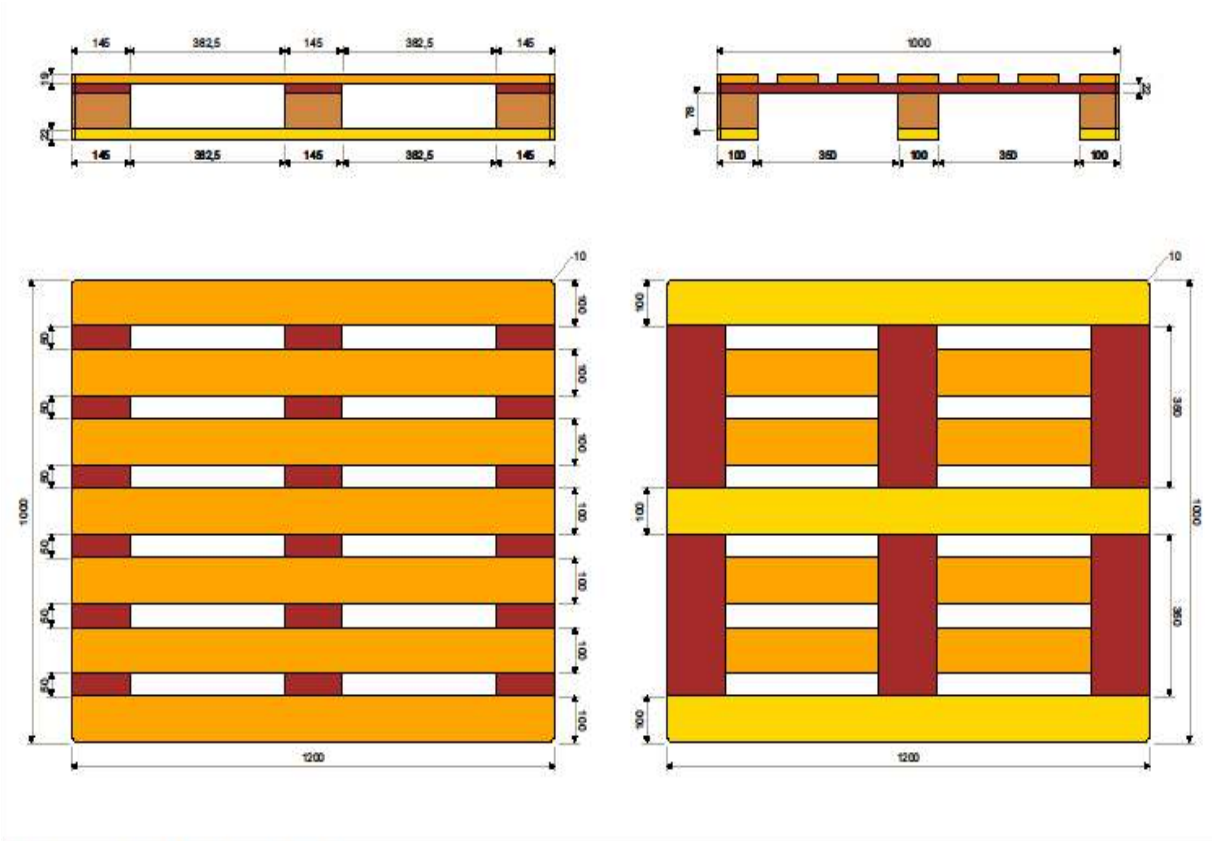
5.12 PALLET SPECIFICATIONS

5.13 All deliveries to the UNICEF Warehouse, Copenhagen, Denmark, must be on non-returnable pallets.

5.14 A detailed packing list including material number and description, quantity and batch number, shall be attached to both short sides of minimum the first pallet of the shipment.

5.15 Below are details of the **acceptable** pallet types:

5.15.1 1200 x 1000 mm (Preferred size), One Way Pallet, Heat treatment according to ISPM 15



Nails/Joint:

Deck board/Block	2 pcs. 3.1/85 mm ring nail
Deck board/Stringer board	2 pcs. 2.5/45 mm round nail (diamond shaped)
Bottom board/Block	2 pcs. 3.1/75 mm ring nail

Tolerances:

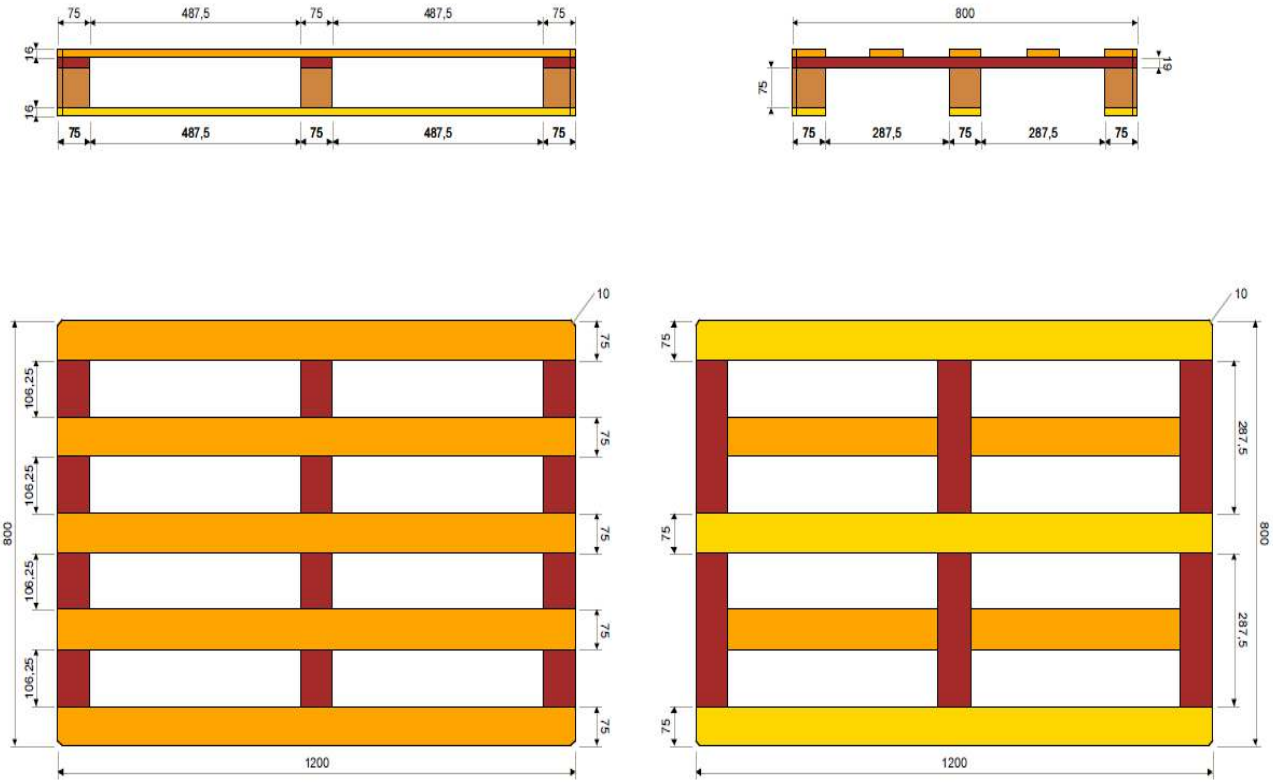
Pallet length	-0/+3 mm
Pallet width	-0/+3 mm
Board length	-0/+3 mm
Board width	-3/+3 mm
Board thickness	-0/+1 mm
Block length	-3/+3 mm
Block width	-3/+3 mm
Block height	-0/+2 mm
Entry height	Min. 100 mm

Wood:

Moisture content	<20 %
Wanes	<15 mm
Single knot	<1/3 of width
Sum of knots	<1/2 of width

Insect holes and rot are NOT allowed
Heat treatment: According to ISPM 15

5.15.2 1200 x 800 mm, One Way Pallet (Euro) as per UIC 435-2 , Heat treatment according to ISPM 15



Nails/Joint:

Deck board/Block	2 pcs. 3.1/85 mm ring nail
Deck board/Stringer board	2 pcs. 2.5/45 mm round nail (diamond shaped)
Bottom board/Block	2 pcs. 3.1/75 mm ring nail

Tolerances:

Pallet length	-0/+3 mm
Pallet width	-0/+3 mm
Board length	-0/+3 mm
Board width	-3/+3 mm
Board thickness	-0/+1 mm
Block length	-3/+3 mm
Block width	-3/+3 mm
Block height	-0/+2 mm
Entry height	Min. 97 mm

Wood:
Moisture content <20 %
Wanes <15 mm
Single knot <1/3 of width
Sum of knots <1/2 of width
Insect holes and rot are NOT allowed
Heat treatment: According to ISPM 15

5.16 Below are details of **<u>unacceptable</u>** pallet types and pallet characteristics:

5.16.1 Inka pallet

5.16.2 Plastic pallets

5.16.3 China pallets

5.16.4 Any other pallet type

5.16.5 Pallets manufactured from other materials than solid wood are **NOT** acceptable; (such as wood chip, MDF board, ply wood or carton).

5.17 Contractors shall send their pallet specifications to NI and UNICEF for approval prior to any shipment to **UNICEF Warehouse, Copenhagen, Denmark**. The specification must be sent to the attention of **Leeza Sharma, lsharma@nutritionintl.org** for any NI contract related shipments; **and UNICEF Procurement Services, psid@unicef.org** for any UNICEF contract related shipments for approval prior to use.

5.18 SPECIFICATIONS FOR CARTONS/ BOXES

5.19 Export cartons

a. Design

Box style	Full-overlap slotted container (FOSC)
FEFCE/ESBO Code	0203 modified as described below
Closure	Outside flap, glued and stitched
Flute designation	BC double wall
Structural instructions	Meeting inner flaps. All corners of long side flaps are chamfered 25x25 mm.

b. Quality and standards

Edge Compression Test (ECT)	≥ 17 kN/m	(EN ISO 3037)
Bursting strength (Mullen)	≥ 2200 kPa	(EN ISO 2759)
Water absorptiveness (Cobb 1800)	< 155 g/m^2	(EN ISO 535)
Bending stiffness	MD: ≥ 44000 Nmm CD: ≥ 19500 Nmm	(EN ISO 5628)

c. Quality instructions

- Min. 60% of resulting box strength must be maintained in tropical conditions, i.e. 40°C and 90 % R.H.
- Box compression test (BCT) must be provided.

5.20 Inner cartons

a. Design

Box style	Regular slotted container (RSC)
FEFCE/ESBO Code	0201 modified as described below
Closure	Inside flap, glued
Flute designation	C single wall
Structural instructions	All corners of short side flaps (inner flaps) are chamfered 10 x 20 mm (10 mm on top edge).

b. Quality and standards

Edge Compression Test (ECT)	≥ 6,1 kN/m	(EN ISO 3037)
Bursting strength (Mullen)	≥ 1680 kPa	(EN ISO 27597)
Water absorptiveness (Cobb 1800)	< 155 g/m2	(EN ISO 535)
Bending stiffness	MD: N/A, CD: N/A	(EN ISO 5628)

c. Quality instructions

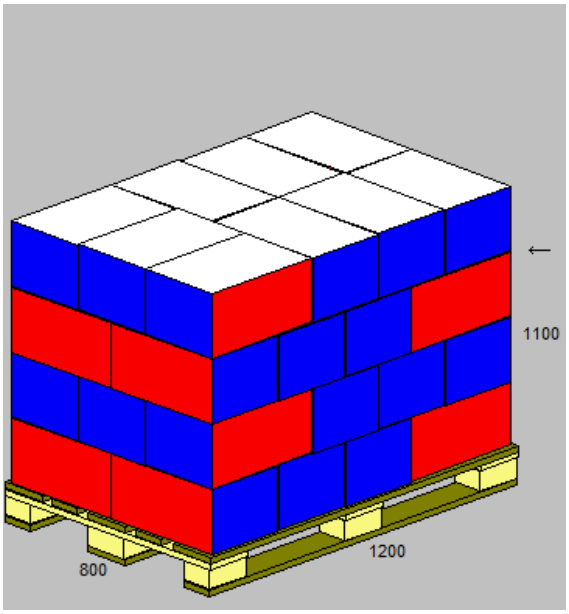
- Min. 60% of resulting box strength must be maintained in tropical conditions, i.e. 40°C

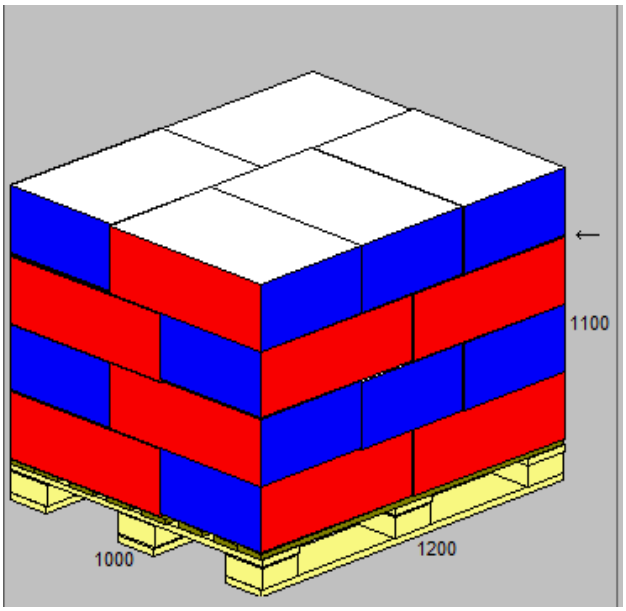
and 90 % R.H.

- Box compression test (BCT) must be provided.

5.21 Carton stacking

1.1.1 The maximum height is **110 cm including** the pallet.
1.1.2 The maximum weight of the cargo including the pallet is **950 kg**
1.1.3 The cartons shall be cross stacked on the pallets whenever possible.
1.1.4 No overhang is allowed.





5.22 Cargo

5.22.1 The pallets/cartons shall contain only one material.
5.22.2 For batch managed materials, e.g. pharmaceuticals and medical devices, the cartons/pallets shall contain only 1 single batch.

5.23 Wrapping

5.23.1 The cargo on the pallets shall be shrink-wrapped.
5.23.2 The shrink-wrapping shall allow the pallet to be handled by fork-lift.
5.23.3 Loose foil ends are not tolerated.
5.23.4 Pallets must not be wrapped together.

5.24 Strapping

5.24.1 As an alternative to shrink-wrapping, the cargo can be fixed with straps of polypropylene.
5.24.2 Steel straps are not acceptable.
5.24.3 The cargo shall be fixed with at least 4 straps, 2 on the pallet's short side and 2 on its long side.

5.25 IDENTIFICATION MARKINGS

5.26 The **pallets**, cases, and all **outer and inner** cartons must be clearly marked with the following information:

5.26.1 Purchase order number (optional for inner cartons);
5.26.2 UNICEF material number*;
5.26.3 Description of contents;
5.26.4 Quantity per carton;
5.26.5 Gross Weight;
5.26.6 Cubic Measurement;
5.26.7 Batch Number Reference;
5.26.8 IMCO classification (if applicable);
5.26.9 Manufacturing date;
5.26.10 Expiration date.

5.27 The size of the markings and labels must not exceed A5 (210 x 148 mm).

* **UNICEF material number should be written in one complete sequence, i.e. no hyphens:**

Capsule Type	UNICEF Material Number
200,000 IU Vitamin A Soft Gelatin Capsules – 500 count bottles	S7800002
100,000 IU- Vitamin A Soft Gelatin Capsules – 500 count bottles	S7800001
200,000 IU- Vitamin A Soft Gelatin Capsules – 100 count bottles	To be provided at time of contract
100,000 IU- Vitamin A Soft Gelatin Capsules – 100 count bottles	S7800003

5.28 BARCODE LABEL STANDARD

5.29 All **pallets and outer** cartons shall be barcode labelled with the below details using encoding type GS1-128. The markings shall be in both text format and contained in a barcode label. The use of any other standard will cause the shipment to be returned to the Contractor for replacement. All costs associated with the return of the shipment(s) and replacement of the labels will be at the Contractor's cost.

5.29.1 The height of the barcode shall be minimum 15 mm.
5.29.2 The size of the markings and labels must not exceed A5 (210 x 148 mm).
5.29.3 Inner cartons shall also be barcode labelled.
5.29.4 The pallet barcode label shall be placed at each of the two short sides of the pallet, outside the shrink-wrapping, if any, at the top right corner

5.30 Only the following identifiers (listed in brackets) in relation to barcode labelling shall be used. Where alternative is indicated, only one of these shall be used.

(400)	UNICEF Purchase order number
(93)	Material number
(37)	Quantity
(10)	Batch number
(11)	Manufacturing date
(12)	Expiration date

5.31 The date format shall follow one of the following standard: DDMMYYYY
5.32 The default marking for days (DD) is the last day of the month, e.g., expiry July 2019 should be 31072019 on the barcode.
5.33 The quantity on both carton and pallet labels should reflect the quantity of the buying unit
5.34 Contractors shall send a sample of a barcode label to NI for approval prior to any NI related shipment to UNICEF Warehouse, Copenhagen, Denmark. The sample barcode label must be submitted to the attention of Leeza Sharma at lsharma@nutritionintl.org, for approval prior to use.

5.35 PALLET BARCODE LABEL SPECIFICATIONS

Barcode standard:	GS1-128*, only.*
Dimensions of labels:	*4" x 7" (10 cm x 18 cm)*
Background colour:	*White*
Lettering:	*Black*
Bar Codes (dates):	*Use following format only: DDMMYYYY (31.10.2019)*
Identifiers:	*This number in the brackets is an identifier according to* GS1-128*. Use only the identifiers indicated.*
Font & font size:	*Should fit appropriately on label. Minimum size: one half inch.*
Material number:	*Should be without hyphens (ex: S7800001)*
Note:	*Manufacturing date & expiration date format: DDMMYYYY (31.07.2019)*

Figure 1: Sample Pallet Label

SHIP TO: **UNICEF Supply Division**	
UNICEF P.O. No.: (write in)	**IIIIIIIIIIIIIIIII** (400)xxxxxxxx
UNICEF Material No.: (write in)	**IIIIIIIIIIIIIIIII** (93)xxxxxxxx
Quantity of bottles: (write in)	**IIIIIIIIIIIIIIIII** (37)xxxx
Batch Number: (write in)	**IIIIIIIIIIIIIIIII** (10)xxxxxx
Manufacturing Date: (write in)	**IIIIIIIIIIIIIIIII** (11)xxxxxx
Expiration Date: (write in)	**IIIIIIIIIIIIIIIII** (12)xxxxxx
Pallet No.:	

5.36 BOX BARCODE LABEL SPECIFICATIONS

Barcode standard:	GS1-128*, only.*
Dimensions of labels:	*4" x 7" (10 cm x 18 cm)*
Background colour:	*White*
Lettering:	*Black*
Bar Codes (dates):	*Use following format only: DDMMYYYY (31.07.2019)*
Identifiers:	*The number in the brackets is an identifier according to* GS1-128*. Use only the identifiers indicated.*
Font & font size:	*Should fit appropriately on label. Minimum size: one half inch.*
Material number:	*Should be without hyphens (ex: S7800001)*
Note:	*Manufacturing date & expiration date format: DDMMYYYY (31.07.2019)*

Figure 2: Sample Box Label

Vitamin A (Retinol) **200,000 IU – 500 capsules** **NI Project No.: 10-XXXX-XXXXX-XX**	
UNICEF P.O. No.: (write in)	IIIIIIIIIIIIIIIII (400)xxxxxxxx
UNICEF Material No.: (write in)	IIIIIIIIIIIIIIIII (93)xxxxxxxx
Quantity of bottles: (write in)	IIIIIIIIIIIIIIIII (37)xxxx
Batch Number: (write in)	IIIIIIIIIIIIIIIII (10)xxxxxx
Manufacturing Date: (write in)	IIIIIIIIIIIIIIIII (11)xxxxxx
Expiration Date: (write in)	IIIIIIIIIIIIIIIII (12)xxxxxx

Figures 3 & 4: Example: Use of specifications provided to indicate format only