Specifications

As per contractual agreement, ICRC/IFRC will appoint an inspection company that will check that the food matches compulsory analytical requirements.

Additional tests may be performed in case further quality assessment is required. This will be performed in addition to analysis performed by supplier according to his quality internal control system.

ICRC/IFRC reserves the right to control any parameter, at the supplier's premises or elsewhere, in accordance with these specifications.

On demand of the ICRC/IFRC the supplier will provide all documentation and evidence of a proper quality control.

Production process and Quality Management system:

F75 shall be manufactured referencing the formula described in the WHO document: Management of severe malnutrition: a manual for physicians and other senior health workers, World health organization, 1999 (refer to Table 7, Table 8 and Appendix 4).

All processing and drying shall be carried out in a manner that minimizes loss of nutritive value, particularly protein quality and vitamin content.

Products must be manufactured in accordance with the Codex Alimentarius and applicable references and GMPs (Good Manufacturing Practices). The producer must have a food safety policy in place and an effective food safety management system based on a Hazard Analysis and Critical Control Points (HACCP) approach. Prerequisite programs including environmental monitoring must be implemented.

Applicable standards reference:

• CAC/RCP 1-1969, Rev. 4-2003: Recommended International Code of Practice. General Principles of Food Hygiene.

• CAC/RCP 66 – 2008: Code of Hygienic Practice for Powdered Formulae for Infants and Young Children.

• ISO 22000:2005 - Food Safety Management Systems – Requirements for any Organization in the Food Chain.

• ISO/TS 22002-1:2009 – Prerequisite Programs for Food Safety. Part 1. – Food Manufacture.

The manufacturer is responsible to elaborate and implement an analytical plan of the finished product, raw materials and the processing environment. All analytical test procedures must be described in sufficient details, e.g. the sampling plan, acceptance/release criteria, analytical methods. ISO 17025 certified laboratories shall preferably be used.

Traceability:

The manufacturer should have implemented an upstream and downstream quality system allowing for every production batch to trace the composition, the raw materials used, the results of the analysis performed on raw materials, intermediate products and final product, customers, quantity produced and dispatched, customers and sites where delivered etc.

The batch size shall not exceed 150 Metric tons and/or one week of production

Therapeutic Milk F75

Product requirements		
Ingredients	**Specifications**	**Applicable Standards**
Dairy powder products	Full cream milk powder • Skimmed milk powder and/or • Whey powder (may produce bitter taste) The product must provide at least 50% of protein in the form of dairy protein.	*Codex STAN 207-1999 - Codex Standard for Milk Powders and Cream Powder and/or* *Codex STAN 289-1995: Codex Standard for Whey Powders*
Oil	- Edible refined vegetable oil - Hydrogenated vegetable oils are not to be used.	*Codex STAN 210-1999: Codex Standard for Named Vegetable Oils*
Carbohydrates (sweetener)	- Carbohydrates used shall be gluten free and readily soluble in water. - Isotonic versions, which contain maltodextrins instead of cereal flour and some of the sugar can be accepted. - Lactose shall not be added: Lactose and glucose polymers to be used.	*Codex STAN 212-1999: Codex Standard for Sugars*
Vitamins and Minerals premix	The used nutrient compounds shall comply with the criteria established Vitamins and minerals shall be in such forms that they are easily absorbed by patients with SAM. The added minerals shall be water-soluble and shall not form insoluble components when mixed together. - Iron salts are not to be added - supplied by a specialized premix supplier with full certificate of analysis	*-CAG/GL 10 – 1979 (Rev. 2008 last amendment 2015) Advisory lists of Nutrient Compounds for use in foods for Special Dietary uses for Infants and Young Children.*

	- Storage maximum temperature: 20°C - Record frequent measurements of the coefficient of the variation related to the mixing step - Added minerals shall be in the form of water soluble salts. Nitrite and nitrate salts shall not be used. Minerals used shall be in forms that are known to be biologically available.	*- Annex 3 of the COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. Vitamin and mineral compounds approved for use in infant formulae are listed on pages 22 and 23; these compounds are also acceptable for therapeutic food.*
Additives	**Specifications**	**Applicable Standards**
Flavouring	The use of artificial flavourings is not permitted, only natural flavourings may be used.	Natural flavourings are defined in CAC/GL 29-1987 General Requirements for Natural Flavourings and in Regulation of the European parliament and of the Council (EC) N° 1334/2008.
Antioxidants	The use of artificial antioxidants is not permitted, only natural antioxidants as ascorbyl palmitate or mixed tocopherols may be used.	
Other additives	Essential L-amino acids, choline, taurine, carnitine, inositol carotene and other semi-essential or biologically valuable nutrients may be added to meet the specification at levels considered to be safe for children with severe malnutrition.	

Macronutrients						
Parameter	Unit	Min	Max	Unit	Min	Max
Energy	Kcal/100ml	72	77	Kcal	435	465
Protein	g/100ml reconstituted diet	0.7	1.4	% of total energy	4.1	7.6
Lipids	g/100ml reconstituted diet	2	5	% of total energy	25	35
Carbohydrates - calculated	g/100ml reconstituted diet	10	15	% of total energy	55	70
Ash Content	%	3.2	4			
Moisture Content			4.0 %			
Solubility index	ml		1			
Burnt Particles	(disc B minimum)		15			
Osmolarity	mOsmol/L (freezing point depression)	280	333			

Minerals			
Nutrient	Unit	Minimum	Maximum
Sodium	mg/100ml reconstituted diet		<17.3
Potassium	mg/100ml reconstituted diet	130	165
Calcium	mg/100ml reconstituted diet	50	105
Phosphorus	mg/100ml reconstituted diet	50	105
Magnesium	mg/100ml reconstituted diet	8.5	11
Iron	mg/100ml reconstituted diet		<0.1
Zinc	mg/100ml reconstituted diet	1.9	3.2
Copper	mg/100ml reconstituted diet	0.25	0.32
Selenium	µg/100ml reconstituted diet	3.5	7
Iodine	µg/100ml reconstituted diet	12.3	24.5
NB : Ration Ca : P : between 1 and 1,5			

Vitamins			
Nutrient	Unit	Minimum	Maximum
Vitamin A	mg/100ml reconstituted diet	0.1	0.3
Vitamin D3	µg/100ml reconstituted diet	2.5	5.0
Vitamin E (d-alpha tocopherol)	mg/100ml reconstituted diet	3.5	4.4
Vitamin K	µg/100ml reconstituted diet	2.5	5.3
Vitamin C Ascorbic acid	mg/100ml reconstituted diet	>8.8	
Vitamin B1 Thiamine	mg/100ml reconstituted diet	>0.1	
Vitamin B2 Riboflavin	mg/100ml reconstituted diet	>0.3	
Vitamin B3 Niacin	mg/100ml reconstituted diet	>0.9	
Vitamin B5 Pantothenic acid	mg/100ml reconstituted diet	>0.5	
Vitamin B6 Pyridoxine	mg/100ml reconstituted diet	>0.1	
Vitamin B7 Biotin	µg /100ml reconstituted diet	>10.5	
Vitamin B9 Folic acid	µg/100ml reconstituted diet	>35	
Vitamin B12 Cobalamin	µg/100ml reconstituted diet	>0.3	

Shelflife	
The product shall retain the above mentioned specifications for at least 18 months from date of manufacture when stored in dry temperatures between 30 and 40 °C	A real time shelf life study at 30°C or an accelerated shelf life study at 40°C shall be initiated on each new formulation to confirm that: - Food remains within the range defined in the above **Erreur ! Source du renvoi introuvable.** of the final product

Microbiology		
"Microbiological safety of Ready-to-use Lipid Based therapeutic and supplementary Foods- Technical meeting" summary report released on March 6th 2013, FAO and WHO. *CAC/GL 21, 1997, the Principles for the Establishment and Application of Microbiological Criteria for Foods (revision scheduled for 2013).* *CAC/GL 63-2007: Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* **Microbiological criteria** The batch shall not be released if there is a failure to meet the criteria related to Salmonella and Enterobacteriaceae defined below. *In the Microbiological plans defined below* - n: number of sampling units to be taken - c: maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan - m: a microbiological limit in a 2-class plan, separates good quality from defective quality or, in a 3-class plan separates good quality from marginally acceptable quality - M: a microbiological limit in a 3-class plan, separates from marginally acceptable quality to defective quality - p: define the plan (2 or 3 class plan)		
Salmonella	Max level: 0/25g following a 2-class plan - n = 60 - p = 2; - c=0; - m = 0/25g (e.g. absent in 25g) maximum allowable number of defective sample: 0 out of the 60 samples tested	ISO 6579 **NOTE**: No composite sample. Maximum pooling authorized is 4 pooled samples of 375g (25g from 15 sachets), only if the laboratory method has been validated and accredited for that method
C.Sakazakii	Max level: 0/10g following a 2-class plan - n = 30 - p = 2;	Method ISO/TS 22964 **NOTE**: No composite sample. One pooled sample of 300g (10g from

	- c=0; - m = 0/10g (e.g. absent in 10g) maximum allowable number of defective sample: 0 out of the 30 samples tested	30 units) authorized, only if the laboratory method has been validated and accredited for that method.
Enterobacteriaceae at 30 degree	Max level : ≤10cfu/g following a 2-class plan - n = 10 - p =2 - c= 2 - m ≤10cfu/g maximum allowable number of defective sample: 0 out of the 10 samples tested	For ISO 21528-1: One pooled sample of 300g (10g from 30 units) authorized, only if the laboratory method has been validated and accredited. In case of positive result, another test using the ISO 21528-2 is mandatory (no composite sample, no pooled samples authorized for ISO 21528-2.
Mesophilic Aerobic Bacteria	Max level : ≤500cfu/g following a 3-class plan - n = 5 - p =3 - c= 2 - m ≤500cfu/g - M ≤5000cfu/g The lot can be released if : - Each of the 5 samples analysed has a level of Enterobacteriaceae which is ≤500 cfu/g - Maximum 2 samples analysed has a level of Mesophyllic bacteria which is ≤5000 cfu/g. The rest of each sample analysed have a level of Enterobacteriaceae which is ≤500 cfu/g.	Method ISO 4833 No composite sample. No pooled samples

Contaminants		
CAC/RCP 49-2001: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals. *CODEX STAN 228-2001: General Methods of Analysis for Contaminants.* *CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food and Feed.* *CODEX STAN 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods.* *COMMISION REGULATION (EU) No 594/2012 of July 2012 amending Regulation (EC) 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non-dioxin like PCBs and melamine in food stuffs*		
Pesticides	Carbamates < 10ppb Organochlorine < 10 ppb Organophosphorus < 10 ppb Pyrethroid < 10 ppb	*CODEX STAN 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods*
Heavy metals	Lead <0.01 mg/kg	*CODEX STAN 228-2001: General Methods of Analysis for Contaminants.* *CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food and Feed.*
Radioactivity		*Only ingredients certified free of radioactivity can be used. If the limits are not defined, the value must not exceed 370bq/kg max (Cs 134&Cs137)*
Melamine	must not exceed 0.15mg/kg in the reconstituted form	*CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food.*
Mycotoxins Ochratoxin A Aflatoxin B1 Aflatoxin M1 Palutin Deoxynivalenol	 <0.5ppb <0.1ppb <0.025ppb <10ppb <200ppb	*CAC/RCP 49-2001 Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.* *CODEX STAN 228-2001: General Methods of Analysis for Contaminants.* *CODEX STAN 193-1995: Codex*

Zearalenone Fumonisins	<20ppb <200ppb	*General Standard for Contaminants and Toxins in Food.*
Other contaminants		*The product should be free from residues of hormones, antibiotics and pharmacologically active substance*
Packaging		
Primary package	F75 Ready to use Therapeutic Milk shall be packaged in properly sealed, safe, food grade sanitised packaging materials. The product when marketed shall be packaged in well-sealed packaging materials in order to prevent spoilage or contamination of the product. The packaging material used for F75 Ready to use Therapeutic Milk shall be a 200 mL Tetra Pak® having the following requirements: ▪ lightproof, ▪ gas proof, ▪ mechanically strong, ▪ non-toxic ▪ not impart any off-flavour to the milk, ▪ able to withstand aseptic packaging pre-treatment procedure, and ▪ able to allow hermetic sealing. F75 Ready to use Therapeutic Milk shall be packaged aseptically into sterile packaging material and sealed hermetically.F75 Ready to use Therapeutic Milk packages shall be not deformed, creased, dented or have crushed corners	
Secondary package	Shock, puncturing resistant, strong export cartons for single units package. Cartons shall be of a sturdy quality and provide protection of the goods for carriage by air, sea and/or road to final destination worldwide,	

	including remote locations under adverse climatic and storage conditions, and high humidity
Inside containers	Slip sheet or plywood shall be used to provide maximum stacking strength. Pallets with appropriate stacking configuration could also be used.
Leaflet	Each carton must contain a leaflet in English (and other language as per contract) including the protocol and instructions for use, and should mention reconstitution, serving, storage of the reconstituted diet

Labelling

Codex STAN 146-1985 : General standards for the labelling of and claims for pre-packaged foods for special dietary uses

Codex STAN 1-1985 : General standard for labelling of pre-packaged foods

	Single Unit	**Inside leaflet**	**Outside box**
Commercial name	Shall be kept simple		
Product Name	Generic name: F-75 Therapeutic Milk		
Target use	A clear statement: *For initial phase* (or *Phase 1*) *of treatment of Children with Severe Acute Malnutrition* Reference to the WHO manual: Management of severe malnutrition: a manual for physicians and other senior health workers, *World Health Organization*, 1999		
Breastfeeding logo and a message:	*Breastfeeding is recommended for at least the first 24 months and exclusively until 6 months*		
Preparation instructions	Instruction for hygienic handling of left overs of Therapeutic milk		
Net Weight and gross weight Number of packaging per carton	200ml	-	filled by manufacturer
Nutrients content Per 100 mL of reconstituted diet	-	Nutritional composition	
Ingredient list	filled by manufacturer (raw materials used) in descending order quantity)		-
Storage instruction	" Best stored below XX degrees, in dry and hygienic conditions"		

Manufacturer name	Produced by: filled by manufacturer		
Manufacturer address	filled by manufacturer, including country of origin		
Manufacturer batch/lot number	filled by manufacturer	-	filled by manufacturer
Production date	filled by manufacturer	-	filled by manufacturer
Best before Date	filled by manufacturer	-	filled by manufacturer
Other	-	"not for sale or exchange" "Contains no ingredients of animal origin besides dairy products"	
Donor and logo	-	as per contractual agreement	
Colour coding	-		
Beneficiary feedback hotline (if required in the contractual agreement)	filled by manufacturer	-	filled by manufacturer