PRODUCT SPECIFICATION SHEET

F-100 Therap.milk CAN 400g/CAR-24

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1. General Description

F-100 therapeutic milk diet with added vegetable fat, carbohydrates, vitamins, and minerals. It comes as powder packed in a can to prepare a liquid therapeutic diet with an energy density of approximately 100 kcal/100ml.

2. Intended use

The F-100 liquid therapeutic diet is intended for the nutritional rehabilitation phase of treatment of children with Severe Acute Malnutrition (SAM), it is intended to achieve rapid weight gain.

The specified quantity of powdered therapeutic milk is mixed with the specified quantity of water boiled and cooled down to not below 70˚C to obtain a defined quantity of liquid therapeutic diet with an energy density of approximately 100 kcal/ 100ml.

F-100 must be administered under medical supervision.
(WHO. Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva: *World Health Organization*; 2013:4)

3. Target population

Children diagnosed with SAM, in the nutritional rehabilitation phase of their treatment.

4. Technical specifications

4.1 General quality

Milk based white or pale yellowish fine powder; free from impurities, coloured particles, caking or lumps.

4.2 Ingredients

The main components of the therapeutic milk are: milk powder, refined vegetable oil, sugar, maltodextrin, milk derivate, emulsifier (e.g., lecithin), vitamin and minerals (optionally a premix can be used). For flavourings, antioxidants and other additive requirements see section 4.5.4 to 4.5.6

4.3 Nutritional composition per 100 g

Micronutrients per 100g	Macronutrients per 100 ml
Energy: 530 (520-550) kcal.	100 (95-105) kcal
Protein*: 11 (10-12) % of total energy	
14 (12-16) g	3 (2.3-3.1) g
Lipids: 53 (45-60) % of total energy	
30.5(25.8-36.3) g	5.8 (4.9-6.9) g
n-6 fatty acid: 6.5 (3 -10)% of total energy	
n-3 fatty acid: 1.5 (0.3- 2.5)% of total energy	
Carbohydrate: 36 (28-45) % of total energy	
46 (35- 65) g	9 (7 - 12) g
Lactose: 22 (21-23) g	4.2 (4.0-4.4) g maximum
Moisture content (of powder): 2.5% maximum	
Ash: 4.0% maximum	
Solubility index: 1ml maximum	
Burnt particles: 15 maximum (disc B min)	
Osmolarity (of prepared liquid): 260-320 mOsmol/L (freezing point depression)	

**All therapeutic foods approved for use in the rehabilitation of individuals with severe acute malnutrition must provide at least 50% of protein in the form of dairy protein. For the purposes of conversion from unit weight to unit energy, protein and carbohydrate are assumed to contribute 4 kcal/g and lipids 9 kcal/g.*

Minerals per 100g	Minerals per 100ml
Sodium: 290 mg maximum	55 mg
Potassium: 1100-1400 mg	210-270mg
Calcium 300 - 600 mg	55-115mg
Phosphorus*: 300 - 600 mg	55-115mg
Magnesium: 80-140 mg	15-25mg
Iron: 0.3 mg maximum	0.05mg maximum
Zinc: 11 - 14 mg	2.0-3.0mg
Copper: 1.4 - 1.8 mg	0.25-0.35mg
Selenium: 20 - 40 mcg	3.5-7.7mcg
Iodine: 70 - 140 mcg	13-27mcg

**(excluding phytate)*

Vitamins per 100g	Vitamins per 100ml
Vitamin A: 0.8 - 1.7 mg	0.15-0.32mg
Vitamin D3: 15 - 30 mcg	3.0-5.3mcg
Vitamin E: 20 - 40 mg	4.0 -6.5mg
Vitamin K: 15mcg minimum	3.0 mcg minimum
Thiamine: 0.5 mg minimum	0.1 mg minimum
Riboflavine: 1.6 mg minimum	0.3 mg minimum
Ascorbic acid: 50 mg minimum	9.6 mg minimum
Vitamin B6: 0.6 mg minimum	0.1mg minimum

Vitamin B12: 1.6 mcg minimum	0.3 mg minimum
Folic acid: 200 mcg minimum	38 mg minimum
Niacin: 5 mg minimum	1.0 mg minimum
Pantothenic acid: 3 mg minimum	0.6 mg minimum
Biotin: 60 mcg minimum	11 mg minimum

4.4 Formulation and Starting materials

All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre removed when necessary. All ingredients and food additives shall be gluten free.
After reconstitution according to the manufacturer´s preparation instruction the product shall be a homogenous liquid that does not separate into oil/liquid phases or leave a solid sediment upon standing in a refrigerator with occasional gentle stirring. Frothing of the therapeutic milk after preparation should be minimal to enable accurate dosage measurements of the milk to each individual recipient. The product should have characteristic milk taste and smell. It shall be white as cream, shall not have rancid, pungent, or unpleasant taste or smell.

The product must provide at least 50% of protein in the form of dairy protein.
All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre removed when necessary. All ingredients and food additives shall be gluten free.
Applicable reference link for raw materials codex standards:
http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/

4.4.1 Milk

Full cream milk powder
Skimmed milk powder and/or
Whey powder (NB: may produce a bitter taste)

Applicable reference

1. CXS 207-1999 Codex Standard for Milk Powders and Cream Powder
2. CXS STAN 289-1995: Codex Standard for Whey Powders

4.4.2 Carbohydrates

Carbohydrates used shall be gluten free and readily soluble in water.
Lactose or fructose shall not be added.
Glucose or lactose polymers are the preferred sources of carbohydrate and should be pre-gelatinized (e.g., maltodextrin).

Applicable reference

1. CXS 212 -1999: Codex Standard for Sugars

4.4.3 Oil

Edible refined vegetable oil. The manufacturer shall choose judiciously the type of oil and establish specifications for oil to ensure that the specifications in finished product are met (with particular attention to requirements for omega 3 and omega 6 fatty acid content). Hydrogenated vegetable oils are not to be used.

Applicable reference

1. CXS 210 -1999: Codex Standard for Named Vegetable Oils
2. Code of Practice for the reduction of 3-Monochloroprane-1-2- DIOL Esters (3-MCPDEs) and GLYCYCIDL Esters (GEs) in Refined Oils and Food Products made with refined oils.
3. Trans-fat: CXS 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants, rev 2007

4.4.4 Vitamins and minerals

The used nutrient compounds shall comply with the criteria established in 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 https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B9-1987%252FCXG_009e_2015.pdf
Another list of acceptable vitamin compounds can be found in Annex 3 of the COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae, follow-on formulae and amending Directive 1999/21/EC. http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0141

If the manufacturer uses a mineral and vitamin premix(es), they must source it from a specialized premix manufacturer.

Vitamins and minerals shall be in such forms that they are easily absorbed by patients with SAM, who are often achlorhydric. The added minerals shall be water-soluble and shall not form insoluble components when mixed together. Iron salts are not to be added.

The liquid therapeutic diet prepared from the product according to the manufacturer´s instruction for use shall have a mineral composition that will not alter the acid-base metabolism of patients with SAM. In particular, it shall have a moderate positive non-metabolisable base sufficient to eliminate the risk of metabolic acidosis. The non-metabolisable base can be estimated using the formula:
Estimated absorbed millimoles (sodium+potasium+calcium+magnesium) minus (phosphates + chlorides) See: http://www.who.int/maternal_child_adolescent/documents/a91065/en/

Added minerals shall be in the form of water-soluble salts. Minerals used shall be in forms that are known to be bioavailable, nitrite and nitrate salts shall not be used. Recommended forms of minerals can be found in Appendix 4, Management of Severe Malnutrition a manual for senior health workers. MSMCoverI (who.int)

4.4.5 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.
https://www.fsai.ie/uploadedFiles/Reg%201334_2008.pdf

4.4.6 Antioxidants

The use of artificial antioxidants is not permitted, only natural antioxidants such as ascorbyl palmitate or mixed tocopherols may be used.

4.4.7 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.

5. Shelf-life

The product shall retain the above-mentioned specifications for at least 12 months from date of manufacture when stored in dry conditions at a temperature of 30°C, supported by real time shelf-life data. Shelf-life studies shall be conducted in accordance with the UNICEF/MSF *Requirements for stability study for Therapeutic Food.*

6. Packaging

6.1 Primary packaging (canister)

All packaging material being in contact with food or intended to come in contact with food, including inks and glue shall be of food-contact grade. Product shall be packed in airtight canisters. Packaging under inert gas (nitrogen or carbon dioxide) prolongs products shelf-life and is recommended.
Packaging must be free of damage such as, but not limited to: tears, cuts, holes, and abrasions through one or more layers, leakage of any seal. The closure seal must be free of wrinkles and occluded maters.

6.1.1 Canister

Canisters should be hermetically sealed and resistant to humid and hot climates. Seal and canister integrity shall be adequate to withstand pressure changes associated with international distribution channels such as air transport. The canister shall be capped with a reusable lid to adequately close the canister and protect its content form external contamination and humidity during storage. The period when opened canister can be used shall be minimum 4 weeks.

6.1.2 Primary label (Canister)

Labels must have adequate information to permit identification, safe transport, storage and use of the product throughout its shelf life. The canister label is to be white with blue printing. (Similar to Pantone 18-4247). Labels must be self-adhesive and made from paper, e.g., pharmaceutical defiberised paper (80gsm), that is film or UV coated for protection against humidity and firmly affixed to be tamper proof and to prevent detachment in tropical climates. Type preferably by lithography directly on container/packaging.

Ink/colour: The writing on primary and secondary packs must be in indelible ink, in blue on white. The labelling shall be in English, Arabic and French, one of these languages may be replaced by a local language as requested by UNICEF.

The label shall contain the following information

-Generic name: F-100 Therapeutic Milk
-Clear statement: For the nutritional rehabilitation phase of treatment of children with Severe Acute Malnutrition, not suitable for long-term feeding of well-nourished children. Use under medical supervision.
-Applicable warnings (such as handling product leftovers, how long reconstituted diet can be kept at room temperature and in the refrigerator, use by date after opening, scoop hygiene. When to dispose the opened canister, etc.)
-Breastfeeding logo and a message: *Breastfeeding is recommended for at least the first 24 months and exclusively until 6 months*
-List of ingredients (starting materials used) in descending order quantity
-Nutritional composition per 100 g of powder and 100 ml of reconstituted diet.
-Name and address of the manufacturer and packer, or distributor, or importer, or exporter, or vendor and country of origin
-Net weight
-Batch number clearly identified and visible
-Date of manufacture
-Best before date clearly identified and visible
-Storage conditions

Additionally, to this information, the canister label shall also contain:

-Instructions for preparation of reconstituted diet, e. g.,
2 levelled scoop added to 50 ml water = XX milk (approx.)
4 levelled scoops added to 100 ml water = XX milk
-The entire content of the packaging e.g., 400 g (estimate); added to 1850 ml water = XX ml milk
-Instruction for hygienic use of the scoop.
Instruction to ‘Discard any feed that has not been consumed within two hours.

6.2 Model instruction for preparation

A pictogram schema for preparation instructions shall be included on the canister label OR as a package leaflet. The preparation instructions shall be based on the World Health Organization 2007. How to Prepare Powdered Infant Formula in Care Settings.
Safe preparation, storage and handling of powdered infant formula: guidelines (who.int)

6.3 Scoop (canister)

A scoop must be included in each F-100 canister. Scoops should be made of a food contact material and a design that is easily kept clean, blue in colour and market with the product name 'F-100' in addition to the manufacturers name. Size of a scoop must allow the reconstitution at the following proportion: 2 levelled scoops: 50 ml water, approximately 47.5-52.5 kcal/50ml). The scoops should be placed inside the canister. Scoops shall be coloured blue and marked with the product name "F-100" in addition to the manufacturer's name. (The exact powder weight in each of the vendor's scoop for the vendor's product shall be specified by the supplier in the tender offer).

6.4 Secondary packaging

Canisters shall be placed in strong, export carton boxes. Carton boxes shall be shock and puncture resistant. 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 - for example an ECT (Edge Crush test*) > 11kN/m with minimum 60% remaining with 90% humidity at the highest recommended storage temperature.

Applicable reference

1. Recommended guideline for food hygiene in rooms where the therapeutic milk is prepared and stored ISO/TS 22002-1:2013 – Prerequisite programs for food safety. Part 3. – Catering
2. World Health Organization 2007 Safe preparation, storage and handling of powdered infant formula: guidelines. "World Health Organization in collaboration with Food and Agriculture Organization of the United Nations."

6.5 Secondary packaging Label

Carton label shall contain these information

-Generic name: F-100 Therapeutic Milk (or Therapeutic formula F-100)
-A clear statement: For rehabilitation phase (or Phase 2) of treatment of Children with Severe Acute Malnutrition
- Any applicable warnings
-Name and address of the manufacturer or packer, or distributor, or importer, or exporter, or vendor and country of origin
- Gross weight
- Number of canisters per carton
- Batch number clearly identified and printed out
- Date of manufacture

- Use by date clearly identified and printed out
- Storage conditions and maximum stacking height (e.g., 2 meters maximum)
- An image indicating that boxes should not be stood on:

6.6 Palletisation

Cartons shall be securely closed, stacked (cross stacked if possible, to maximize stacking strength) on one-way pallets and wrapped with stretch/shrink. Please see UNICEF supply division Packing Specifications (non-CPH destinations)
https://www.unicef.org/supply/documents/packing-packaging-and-labelling-specifications-non-copenhagen-destinations

7. Processing requirements

7.1 General

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 CAC/RCP 66 – 2008: Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. untitled (fao.org), and CAC/RCP 1-1969, Rev. 4-2003: Recommended International Code of Practice. General Principles of Food Hygiene. http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXP_001e.pdf other applicable codex 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 programs must be implemented.

Applicable reference

1. FAO/WHO Expert Meeting on Enterobacter sakazakii and Other Microorganisms in Powdered Infant Formula. Enterobacter sakazakii and other microorganisms in powdered infant formula: meeting report http://www.fao.org/3/a-y5502e.pdf
2. ICMSF (International Commission on Microbiological Specifications for Foods). 1986. Microorganisms in foods 2. Sampling for microbiological analysis: Principles and specific applications. 2nd ed.Toronto: University of Toronto Press. ICMSF: https://www.icmsf.org/publications/software-downloads/
3. ISO 22000:2005 - Food Safety Management Systems – Requirements for any Organization in the Food Chain.
4. ISO/TS 22002-1:2009 – Prerequisite Programs for Food Safety. Part 1. – Food Manufacture.

The manufacturer must elaborate and implement an analytical test plan of the finished product, starting 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. Refer to section 9 for the minimum analyses to be performed for each batch.

7.2 Process validation

The coefficient of variation shall be as low as possible, and always <5%. For calculator refer to WFP method:
http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator

7.3 Traceability

A complete traceability system must be in place. For every batch number, the manufacturer must be able to identify full history of the finished products (composition, sources and batches of starting materials used, processing parameters, analytical results, quantity produced and dispatched, customers and sites where delivered).

7.4 Batch Size

The batch size shall be defined as one bulk mix.

8. Product Safety

Therapeutic milk shall be free from objectionable matter. It shall not contain any toxic substances originating from microorganisms or any other poisonous or deleterious substances, including anti-nutritional factors, heavy metals or pesticide residues in amounts that may represent a hazard to health. It shall not contain detectable levels of residues of antibiotics or other veterinary drugs used in animal husbandry.

8.1 Microbiological criteria

Manufacturers are responsible for ensuring the compliance of finished products with the microbiological criteria as specified. In regard to limitations of the end-product testing the compliance shall be ensured through the design of an appropriate food safety control system and verification of the effectiveness of the applied control measures through appropriate auditing methods, including review of monitoring records, deviations and assuring that critical control points (CCPs) are kept under control and good hygienic practices (GHPs) are adhered to. These activities can be supplemented, as necessary, by appropriately documented microbiological sampling and analysis plans. The microbiological testing shall include, as appropriate, analysis of samples taken from raw materials, environment, production line and finished product. Environmental samples shall be taken from both: the points considered as most likely to cause product contamination and being most contaminated.
Where results of monitoring the control measures and surveillance or verification indicate that the product batch, lot or consignment, or its part is unsafe (not in compliance with the set microbiological criteria), it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

8.1.1 Food Safety Criteria

The criteria set out in Annex 1 *Code of Hygienic Practice for powdered formulae for Infants and Young Children CAC/RCP 66-2008*[3] using ISO 6579 and ISO 22964 or other validated methods applied to the finished product (powder form) after primary packing completed or anytime thereafter up to the point when the primary packaging is opened. The batch shall not be released if there is a failure to meet these criteria.

Applicable reference

1. FAO/WHO Expert Meeting on Enterobacter sakazakii and Other Microorganisms in Powdered Infant Formula. Enterobacter sakazakii and other microorganisms in powdered infant formula: meeting report http://www.fao.org/3/a-y5502e.pdf
2. ICMSF (International Commission on Microbiological Specifications for Foods). 1986. Microorganisms in foods 2. Sampling for microbiological analysis: Principles and specific applications. 2nd ed.Toronto: University of Toronto Press. ICMSF: https://www.icmsf.org/publications/software-downloads/

1) NOTE: No composite sample. Maximum pooling authorized is 4 pooled samples of 375g (25g from 15 units), only if the laboratory method has been validated and accredited for that method.
2) NOTE: No composite sample. One pooled sample of 300g (10g from 30 units) authorized, only if the laboratory method has been validated and accredited for that method.

8.1.2 Food hygiene criteria

The safe production of these products is dependent on maintaining a high level of hygiene control. The criteria for process hygiene as set out in *Code of Hygienic Practice for powdered formulae for Infants and Young Children CAC/RCP 66-2008*[3] are intended to be used by the manufacturer as a means of ongoing assessment of its hygiene programs. As such these tests are not intended to be used for assessing the safety of a specific batch of product, but instead are intended to be used for verification of the hygiene programs.

1) NOTE: No composite sample. No pooled samples.
2) NOTE: 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.

9. Chemical and other Safety

9.1 Contaminants

Nitrates < 200mg NO_3/kg
Nitrites < 2mg NO_2/kg
Aluminium < 0.6mg/kg
Melamine < 1mg/kg

Mycotoxins (as per Codex standard when applicable for the starting materials used)

Ochratoxin A <0.5ppb
Aflatoxin B1 <0.1ppb
Aflatoxin M1 <0.025ppb
Palutin <10ppb
Deoxynivalenol <200ppb
Zearalenone <20ppb
Fumonisins <200ppb

Applicable reference

1. CAC/RCP 49-2001 Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.
2. CXS 228-2001: General Methods of Analysis for Contaminants.
3. CXS 193-1995: Codex General Standard for Contaminants and Toxins in Food.

9.1.1 Pesticides

In general, pesticide levels must be below 10 ppb. Verifying pesticide levels are below accepted limits is the responsibility of the manufacturer.

Carbamates <10 ppb
Organochlorines<10 ppb
Organophosphates <10 ppb
Pyrethroids <10 ppb

The maximum residue levels of specific pesticides or their metabolites in therapeutic milk powder set in below shall not be exceed:

Substance and Maximum residue level (mg/kg)
Cadusafos: 0.006
Demeton-S-methyl/demeton-S.methyl sulfone/
oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl) 0.006
Ethoprophos 0.008
Fipronil (sum of fipronil and fipronil-deslfinyl, expressed as finpronil) 0.004
Propineb/propylenethiourea (sum of propined and propylenethiourea) 0.006

The following pesticides shall not be used in the agricultural production intended for the production of therapeutic formulae:

Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone, expressed as disulfoton)
Fensulfotion (sum o fensulfothion, its oxygen analogue and their sulfone, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation

Haloxfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
Hexachlorobenzene
Nitrofen
Ometholate
Terbufos (sum of terbufos, ist sulfoxide and sulfone, expressed as terbufos)
Aldrin and dieldrin, expressed as dieldrin, Endrin

Applicable reference

1. CXS 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods

9.1.2 Heavy metals*

Verifying that heavy metal levels are below accepted limits is the responsibility of the manufacturer. Examples of heavy metals that must be controlled include, but are not limited to:

Arsenic <0.052mg/kg
Cadmium <0.112mg/kg
Lead <0.2mg/kg
Mercury<0.037mg/kg
Tin <105mg/kg

**Based on 5 kg child with SAM and PTWI, CXS 193- 1995 General Standard for Contaminants and Toxins in Food and feed.*

9.1.3 Hydrocarbons

Benzo[a]pyrene <1ppb

9.1.4 Radioactivity

Radioactive contamination can occur when using milk powder derived from cows that have eaten contaminated feed. This risk is managed by using certified radioactivity free milk products. The nuclear radiation level shall meet the values valid in the area of consumption. If limits are not defined, the value must not exceed 370Bq/kg (Cs 134 & Cs136).
The product and its components shall not be treated by ionizing radiation.

9.1.5 GMO (Genetically Modified Organisms)

UNICEF requires the information regarding the presence/absence of GMO to be declared.

9.1.6 Other contaminants

The product shall meet the codex CXS 72 – 1981 requirements for other contaminants (residues of hormones, antibiotics, and pharmacologically active substances.)

10. Minimum requirement for release of F 100 Powder

Certificate of Analysis (CoA) is required for every batch supplied against UNICEF Supply Division Purchase Orders. It shall be forwarded prior to its shipment. The manufacturer is expected to perform the necessary finish product analysis in order to prove that the batch complies with the specification. In case vitamin and mineral premix is used it may be adequate to test for tracers as indicated above. In case single addition of vitamins and minerals are used, then individual analysis of each component is expected.

A Certificate of Analysis must be provided for each batch.
The principal tests listed below must be performed in order to check if the quality of F-100 meets above requirements. Additional analyses shall be defined in case of further quality assessment.
List of the minimum tests results for Certificate of Analysis and reference data are listed below:

Microbiological food safety criteria set in 7.1.2 and food hygiene criteria set in 7.1.3.

Nutrient values per 100g

Energy: 520-550 kcal
Protein: 10-12 % total energy
Lipids: 45-60 % total energy
Ash: 4.0 % maximum
Moisture: 2.5 % maximum
Vitamin C : 50mg minimum
Vitamin A: 0.8-1.7 mg RE
Potassium: 1100-1400 mg
Sodium: <290mg maximum
Iron: <0.3mg

Actual value of powders bulk density in ml/100g
Burnt particules : 15mg maximum (disc B minimum)
Solubility index. 1 ml maximum (ISO 8156:2005)
Osmolarity (of prepared liquid): 260-320 mOsmol/L (freezing point depression)

The manufacturer shall conduct at least one complete finished product analysis annually in order to verify that the finished product is manufactured according to this specification.

Items to be Supplied with

Supplier shall provide one blue scoop inside each canister
Supplier should indicate items required, but not supplied: thermometer, measuring jug, feeding cup, feeding spoon in their leaflet or label

Shelf life

Unopened canisters should have a minimum 12-month shelf life from the date of manufacture. Supplier must indicate storage and transport temperature conditions. Do not store above 30 °C is preferred.
Supplier should indicate shelf life of opened canister e.g., Use within 4 weeks after opening, keep in original container, Do not store above 30°C; protect from direct sunlight, protect from moisture.
Supplier should indicate instruction for use for reconstituted milk: Use within 2hrs if at room temperature or 24 hours if stored in the refrigerator
Supplier must include other important instructions e.g., Protect from direct sunlight

Storage and Transport conditions

Supplier should indicate storage and transport instructions: Do not store above 30°C; protect from direct sunlight, protect from moisture.

Material safety data sheet information (MSDS): N/A
Packaging and labelling: preparation instructions included on the label or in a leaflet
Supplier shall provide weight of carton, around: 11-14kg/ carton
Supplier shall provide gross volume of carton, around: 0.03476-0.04640 m3 / carton

Useful Resources

1. Contaminants Reference Table
2. Stability study template for Nutritional Products
3. Interagency Requirements for stability study
4. Interagency Specialised Food Manufacturer Quality Questionnaire.
5. Interagency Specialised food Product Questionnaire
6. Technical Requirements for Nutritional Products