

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:

Products must be manufactured in accordance with Codex Alimentarius applicable references, in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene recommended by the Codex Alimentarius Commission (CAC/RCP 1-1969), and other relevant Codes of Hygienic Practice and Codes of Practice. All producers must have Good Manufacturing Practice (GMPs) and Good Hygiene Practices (GHPs), a food safety policy in place and a complete quality management system based on a Hazard Analysis and Critical Control Points (HACCP) approach to food safety. Other standards and food safety approaches such as ISO, GMP and HACCP (Annex 5 of the U.S. Department of Health and Human Services, and FDA 199 Food Code) are highly recommended. Pharmaceutical companies manufacturing this product must comply with a Quality Management System commensurate with Good Manufacturing Practice (GMP) according to WHO (Technical Report Series 961).

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, etc.

Product requirements

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|--|--|--|---------------------------------|-------------------|
| Applicable standards Reference | Joint Statement by the World Health Organization, the World Food Programme and the United Nations Children's Fund – Preventing and controlling micronutrient deficiencies in populations affected by an emergency – Multiple vitamin and mineral supplements for pregnant and lactating women, and for children aged 6 to 59 months http://www.who.int/nutrition/publications/WHO_WFP_UNICEFstatement.pdf | | | |
| | HF-TAG programmatic Guidance brief on use of micronutrients powders (MNP) for home fortification | | | |
| | HF-TAG Quality Manual on Micronutrient powders | | | |
| | WFP specification for MNP Version 16.0, Date : 25/02/2016 | | | |
| | Unicef supply catalogue | | | |
| Codex Guidelines for Vitamin and mineral food supplements CAC/GL 55 | | | | |
| Ingredients | | | | |
| Carrier must be Corn maltodextrin with a DE 11-14 and max 5% loss on drying Anticaking agent must be Tri-calcium phosphate or silicon dioxide with adequate particle size | | | | |
| General Requirements | | | | |
| Physical and organoleptic characteristics | Parameter | Recommended level | Reference methods or equivalent | |
| | Taste | Neutral, addition of the MNP must not significantly change the taste, color or texture of the food | | |
| | Texture | Powder must be homogeneous, stable and dry, powder must be easy to mix uniformly with ant semi-solid or solid food eaten | | |
| Vitamins and Minerals | | | | |
| <ul style="list-style-type: none"> - All ingredients in the finished product should be appropriately formulated and demonstrated to have overcome or significantly minimized any potential problems of bioavailability, stability and acceptability. - For all nutrients of the formulation, mixing and particle size must ensure that from one sachet to another, the maximum coefficient of variation is 20% | | | | |
| | Unit | Min | Max | Method |
| Vitamin A (as dry CWS vitamin A acetate or palmitate) | RE µg | 400 | 640 | HPLC |
| Vitamin C (as ascorbic acid or sodium ascorbate) | µg | 30 | 45 | HPLC/Titration |
| Vitamin D3 (as dry CWS Cholecalciferol) | | 5 | 8 | HPLC |
| Vitamin E TE mg (as Dry vitamin acetate) | mg | 5 | 6 | HPLC |
| Vitamin B1 (as Thiamine mononitrate) | mg | 0.5 | 0.8 | HPLC/Microbiology |
| Vitamin B2 (as Riboflavin fine powder or riboflavin -5-phosphate) | mg | 0.5 | 0.8 | HPLC/Microbiology |
| Vitamin B6 (as Pyridoxine hydrochloride) | mg | 0.5 | 0.8 | HPLC |
| Vitamin B12 (as 1% or 0.1% Cyanocobalamin on a carrier) µg | µg | 0.9 | 1.4 | HPLC/Microbiology |
| Niacin (as Niacinamide) | mg | 6 | 8 | HPLC |
| Folic Acid | µg | 90 | 140 | HPLC |
| Iodine (as Potassium iodide) | µg | 90 | 130 | ICP-MS/HPLC |
| Iron (as coated Ferrous fumarate or as Ferric pyrophosphate micronized + NaFe EDTA*) | mg | 10 | 14 | ICP-MS |
| Zinc (as Zinc sulphate, or zinc gluconate) | mg | 4.0 | 5.6 | ICP-MS |
| Copper (as Copper gluconate or copper sulphate) | mg | 0.56 | 0.70 | ICP-MS |
| Selenium (as Sodium selenate or sodium selenite anhydrous or selenomethionine) | µg | 17 | 24 | ICP-MS |
| Contaminants | | | | |
| MNPs shall be free from objectionable matter. It shall not contain any poisonous or deleterious substances, including microbial contaminants, anti-nutritional factors, heavy metals or pesticides in amounts that may represent a hazard to health | | | | |
| Microbiology | | | | |
| The product should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997). | | | | |
| Microbiology | Mesophilic Aerobic Bacteria | <1000 cfu per g | ICC No 125 //AACC 42-11 | |
| | Salmonella | 0 cfu per 50g | AACC 42-25B | |
| | E. Coli | <10 cfu per g | AOAC 991.14 | |

| | | | |
|--|--|-----------------------|-------------------------|
| | Yeasts and Moulds | <100 cfu per g max | ICC No 146 //AACC 42-50 |
| | Staphylococcus aureus | <10 cfu per g | ISO 21528-2 |
| Contaminants: | The product shall not contain any contaminants and toxins in amounts which may represent a hazard to health. | | |
| Packaging | <p>The product covered by the provisions of this specification must be packed in appropriate food grade packing which safeguard the hygienic, nutritional, technological, and organoleptic qualities of the product.</p> <p>Sachet foil to include an aluminum layer to protect against UV light and humidity. In addition :</p> <ul style="list-style-type: none"> - Foil used to produce sachets shall have the following composition PET12/Al 8/ PE45 or equivalent and adequate barrier properties to protect product from moisture, light and oxygen - Inside Box shall be made of paperboard - Outside box shall be made of corrugated fiberboard. Cartons are of 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. Each carton must contain a leaflet in English (and if relevant, in another language according to the destination) | | |
| Sachet Weight | Sachet net weight : average sachets weight must be between 0.95g and 1.05g with a maximum coefficient of variance of 5% | | |
| Marking: | The marking should comply with CODEX STAN 1-1985, to be marked with non-toxic ink, to remain readable after minimum 10 handlings. | | |
| Marking Primary Packaging | <p>Name of the Product : "Micronutrient Powder – Children 6-59 months" or local appropriate name as per contractual agreement;</p> <p>Nutrient contents</p> <p>Preparation instruction : "one sachet per child per day", "mix with food before consumption" together with a generic pictogram that shows how the powder is sprinkled onto a bowl of food:</p> <p>Net weight : 30x1g</p> <p>Name of the supplier + Address</p> <p>Batch number</p> <p>Manufacturing date</p> <p>Best used before:</p> <p>Storage instructions: "best stored below 25°C in dry and hygienic conditions", "store away from children"</p> <p>Any additional marking as per contractual agreement «not for sale or exchange»</p> | | |
| Leaflet | <p>Each carton should contain a leaflet. The following information should appear on the leaflet :</p> <ul style="list-style-type: none"> - Name and address of manufacturer including country of origin - Composition : all ingredients listed in order of descending quantities - Information of allergens and ingredient of animal origin - Storage conditions - Protocol and instruction for use | | |
| Marking Secondary packaging Carton boxes | <p>Name of the Product : "Micronutrient Powder – Children 6-59 months" or local appropriate name as per contractual agreement;</p> <p>Ingrédient list</p> <p>Nutrients contents (nutrients + amount)</p> <p>Net content : 200 x 30 x 1g (6kg)</p> <p>Name of the supplier + Address</p> <p>Batch number</p> <p>Manufacturing date</p> <p>Best used before:</p> <p>Storage instructions: "best stored below 25°C in dry and hygienic conditions", "store away from children"</p> <p>Any additional marking as per contractual agreement «not for sale or exchange» Each carton should contain a leaflet</p> | | |
| Minimum documentation required To be established by an independent official body | Certificate of inspection. | | |
| | Certificate of origin, including manufacturing date. | | |
| | Health Certificate or Phytosanitary Certificate. | | |
| | Weight and Quality Certificate. | | |
| | Non radioactivity Certificate. | | |
| | Fumigation Certificate (when required). | | |
| Non GMO certificate | | | |