



PRODUCT SPECIFICATIONS SHEET

Therapeutic Complex of Vitamins and Minerals (CMV)

Material No: S0000238

Version 1.2

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1. General Description

Use to prepare phase 1 milk (F-75) and enriched high energy milk (F-100). Therapeutic complex of vitamins and minerals (CMV) is used for a nutritional fortification for making therapeutic foods in the dietetic treatment of severe acute malnutrition. Therapeutic CMV is packed in 800g metal tin, in carton of 6 tins. Each tin contains one levelled measuring scoop to weigh 6.8 g of CMV.

1.1 Indications

The composition of therapeutic CMV complies with the WHO recommendations for mineral and vitamin enrichment in the dietetic treatment of Severe Acute Malnutrition.

It must only be used in the treatment of Severe Acute Malnutrition, therefore under medical supervision.

2. Technical Specifications

2.1 Raw Materials

All materials used shall be of food or pharmaceutical grade and their selection and approval must take into consideration origin, transport, storage, processing, handling and the intended use of the finished product.

2.2 Vitamins and minerals

Vitamins and minerals used in the product shall meet criteria as stated in food chemical codex (FCC). Vitamin and mineral sources may also be required to meet Halal and Kosher requirements.

For specifications regarding identity and purity of a substance relating to arsenic or heavy metals, CMV shall meet criteria as stated in food chemical codex (FCC).

Applicable reference

1. Codex Alimentarius: Advisory list of mineral salts and vitamins intended for infants and for young children CAC/GL 10 – 1979
2. Food chemical codex (FCC) standard 1.3.4 Identity and Purity

3. WHO/1999 Management of severe malnutrition: a manual for physicians and other senior health workers.

3. Composition per 6.8 g (1 levelled measuring spoon) of Therapeutic CMV includes the following

Vitamins

Vitamin A	3000 µg (as dry CWS Vitamin A acetate or palmitate beadlets)
Vitamin C	200 mg (as sodium or calcium ascorbate)
Vitamin D	60 µg (2400 IU) (as Cholecalciferol)
Vitamin E	44 mg TE (as d or dl-alpha tocopheryl acetate)
Vitamin K	80 µg (as Phytonadione)
Vitamin B1	1.4 mg (as Thiamine mononitrate)
Vitamin B2	4 mg (as Riboflavin or riboflavin -5-phosphate)
Vitamin B3	20 mg (as Nicotinamide)
Vitamin B5	6 mg (as Pantothenic acid)
Vitamin B6	1.4 mg (as Pyridoxine hydrochloride)
Vitamin B7	0.2 mg (as Biotin)
Vitamin B9	700 µg (as Folic acid)
Vitamin B12	2 µg (as Cyanocobalamin on a carrier)

Minerals

Potassium	2340 mg
Magnesium	146 mg
Zinc	40 mg (as Zinc sulphate, or gluconate)
Copper	5.7 mg (as Copper gluconate or sulphate)
Iron	0 mg
Iodine	154 µg (as Potassium iodide, or potassium iodate)
Selenium	94 µg (as Sodium selenate or selenite or selenomethionine)

4. Packaging

Therapeutic CMV is packed in 800 g. containers, ensuring physical and chemical stability of the powder (being an effective barrier to light, moisture, oxygen, bacteria, volatiles, etc. as appropriate), as well as protecting the product from mechanical trauma – protection from damage during transit, distribution and storage and maintaining product integrity until its in-use phase is completed, or the expiry date stated on the label has passed.

5. Standard shelf life

24 months (minimum)

Shelf-life studies shall demonstrate the product has levels of all nutrients within specification at 24 months, in Zone IVb climatic conditions (temperatures of 30 degrees Celsius and 75% RH) as the product destinations will be delivered to countries with hot and humid climates.

6. Storage conditions

Do not store above 30 °C

Store in original packaging, in a cool dry place; protect from moisture.

Keep out of reach and sight of children.

As defined by the manufacturer, no refrigeration needed. The therapeutic C.M.V is affected by humidity so the lid must be closed firmly after each use.

7. Safety

CMV shall be free from any objectionable foreign 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, and with microbiological limits as detailed below:

7.1 Microbiological criteria

Total CFU	max 10 ³ /g.
Yeast/molds	max 10 ² /g.
<i>Salmonella</i> sp	negative in 50 g
<i>Bacillus cereus</i>	max 10/g
Enterobacteriaceae	negative in 10 g
<i>Clostridium perfringes</i>	Absence/g

7.2 Contaminants

Heavy metals, residual solvents and other contaminant level need to meet the limits as set out by the current USP, BP Ph. Eu or Ph.Int. See example of limits of heavy metals below

Element	PDE* (µg/day)
Arsenic (inorganic)	15 µg/day
Cadmium	5 µg/day
Lead	10 µg/day
Mercury (total)	15 µg/day
Methylmercury (as Hg)	2 µg/day

Individual Components limit based on maximum daily intake of 10 g dietary supplements

Arsenic (inorganic)	1.5µg/g
Cadmium	0.5µg/g
Lead	0.5µg/g
Mercury (total)	1.5µg/g
Methylmercury (as Hg)	0.2µg/g

*Permitted daily exposure.

Applicable Reference

1. USP 2021, Microbial Enumeration Tests - Nutritional and Dietary Supplements
2. USP 2232 Elemental Contaminants in Dietary Supplements
3. USP 233 Elemental Impurities, general chapter
4. USP Residual solvents <467> in USP and NF Articles

8. Dispensing and instructions for use

The composition of the therapeutic CMV complies with the recommendations for mineral and vitamin enrichment in the dietetic treatment of severe malnutrition.

It can be used to prepare phase 1 milk (F-75) and enriched high energy milk (F-100).

9. Uniformity of measurement 1 leveled measuring scoop

The 1 leveled measuring scoop is used to measure 6.8 g CMV on average. The weight of CMV from the measurement of leveled scoop may vary from 6.35 g to 7.0 g CMV.

10. Item supplied with

One levelled measuring scoop to measure 6.8 g CMW

11. Storage, Transportation, and handling instructions:

Cool dry place, away from direct sunlight, under 30 degrees Celsius

12. Material safety data sheet information (MSDS): N/A

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

FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies lsd.nutritionssupplies@unicef.org

[Technical resources for nutrition products | UNICEF Supply Division](#)

