1. General Description

Micronutrient film coated tablets, for pregnant and lactating women in a blister pack of 30.

Each tablet or capsule is preferably as small as possible.

2. Technical specifications

Each tablet contains

- Vitamin A (retinol): 800 RE
- Vitamin E (T.E): 10 mg
- Vitamin D (cholecalciferol): 200 I.U. (5 mcg)
- Vitamin B1 (thiamine): 1.4 mg
- Vitamin B2 (riboflavin): 1.4 mg
- Niacin (nicotinamide): 18 mg
- Vitamin B6 (pyridoxine): 1.9 mg
- Vitamin B12 (cyanocobalamin): 2.6 mcg
- Folic Acid: 400 mcg
- Vitamin C: 70 mg
- Iron: 30 mg
- Zinc: 15 mg
- Copper: 2 mg
- Selenium: 65 mcg
- Iodine: 150 mcg

API shall comply with one of the following Pharmacopoeias:

- BP, Ph. Eur., Ph. Int., USP

FPP tablets shall comply with the following monograph: Oil- and Water-Soluble Vitamins with Minerals Tablets, USP (most recent version) and applicable General Notices and Requirements or equivalent.

Dissolution test should be included in the product specification as per USP, BP or Eur.Ph. Unless otherwise specified in the individual monograph, the requirements are met if not less than 75% of the labelled content of iron and folic acid from the tablets is dissolved in 1 hour.

3. Therapeutic Class

Nutritional product, vitamins, and minerals.

4. Standard Shelf life
24 months minimum, preferably 36 months.

5. **Dispensing Instructions**

Dispense in original container. Do not repack.

6. **Packaging and labelling**

A Patient Information Leaflet should be attached or enclosed in a box with each pack. Refer to *UNICEF Technical Requirements for Pharmaceutical Products* [5](unicef.org)

Label and leaflet to be in English or French. A local language may be required. (see Appendix)

7. **Component of a kit**

   No

8. **Guidelines for Use**

1. WHO recommendations on antenatal care for a positive pregnancy experience. World Health Organization 2016
   [http://apps.who.int/iris/bitstream/10665/250796/1/9789241549912-eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/250796/1/9789241549912-eng.pdf?ua=1)

2. Nutritional interventions update: multiple micronutrient supplements during pregnancy ([who.int](who.int))

9. **Items supplied with**

   Consumer leaflet

10. **Items required, but not supplied:**

    N/A

11. **Shelf life**

    24 months minimum, preferably 36 months

12. **Stability data requirements**

    Zone IV b as per ICH guidelines

13. **Storage and transportation**

    Do not store or transport above 30 °C; transport between 15-25 degrees, store in tightly closed original container, protect from moisture.

14. **Material Safety Data Sheet Information (MSDS)**

    Keep out of reach and sight of children
Useful Resources

1. Minimum stability testing reporting requirements (guidance) for stability reports - Nutritional supplements (Tablets & oral solutions)
2. Interagency finished pharmaceutical product questionnaire
3. Technical questionnaire for pharmaceutical manufacturers
4. Technical Requirements for Pharmaceutical and Nutrition Products

Appendix

Generic label artwork of MMS-blister pack box

FOR MORE INFORMATION

CPHHQ-SD - Nutrition Supplies | sd.nutritionsupplies@unicef.org

Technical resources for nutrition products | UNICEF Supply Division