



PRODUCT SPECIFICATION SHEET

Iron 60 mg + Folic acid 400 mcg tabs/Pac-10x10

Version no: 2.1

Material No: S1550005

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1. General Description

Iron 60 mg (as ferrous fumarate or ferrous sulphate) and folic acid 400 mcg tablets, blister of 10x10 tablets

2. Technical specifications

Tablets containing ferrous salt (as ferrous fumarate or ferrous sulphate preferred) equivalent to 60-65 mg elemental iron and 400 mcg folic acid in a blister pack of 100 tablets: 10 tablets per blister tray.

Acceptable pharmacopoeias

- British Pharmacopoeia (BP)
- United States Pharmacopoeia (USP)
- European Pharmacopoeia (Ph.Eur.)
- International Pharmacopoeia (Ph.Int)

Dissolution test should be included in the product specification (for both active ingredients) 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

Antianemia

4. Standard Shelf life

Minimum 24 months, preferably 36 months

5. Stability data requirements

Zone IVb as per ICH guidelines

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 Arabic, English and French

7. Guideline 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>
2. Guidelines for the Use of Iron Supplements to Prevent and Treat Iron Deficiency Anaemia
[WHO | Guidelines for the use of iron supplements to prevent and treat iron deficiency anemia](#)
3. Prevention of neural tube defects: Integrated Management of Pregnancy and Childbirth
http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/neural_tube_defects.pdf

8. Storage and transportation

Do not store or transport above 30 degrees

9. Material safety data sheet information (MSDS): Required

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

FOR MORE INFORMATION

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

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

