



PRODUCT SPECIFICATION SHEET

Iron 60 mg + Folic acid 400 mcg tabs/Pac 100

Version no: 1.1

Material No: S1550030

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Revised by: AF, MCR

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1. General Description

Iron 60mg (as ferrous fumarate or ferrous sulphate) and Folic acid 400mcg tablets, bottle of 100 tablets

2. Technical Specifications

Tablets containing ferrous salt (as ferrous fumarate or ferrous sulphate preferred) equivalent to 60mg elemental iron and 400mcg folic acid, bottle of 100 tablets

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 labeled content of iron and folic acid from the tablets is dissolved in 1 hour.

3. Therapeutic Class

Antianemia

4. Standard Shelf life

24 months minimum, 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. Child-Proof Packaging

Child resistant cap on each pack/bottle is preferable.

8. Guidelines for Use

1. As per the WHO guidelines: 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 Anemia \(motherchildnutrition.org\)](#)
3. [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](#)
4. WHO Standards for Maternal and Neonatal Care 2007 a91272.pdf (who.int)

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 lsd.nutritionssupplies@unicef.org

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