



PRODUCT SPECIFICATION SHEET

Iron 60 mg and Folic acid 2800 mcg tab/PAC-100

Version no: 3

Material No: S1550009

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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 2800mcg tablets, bottle of 100 tablets

2. Technical Specifications

Tablets containing ferrous salt (as ferrous fumarate or ferrous sulphate preferred) equivalent to 60 mg elemental iron and 2800 mcg folic acid in a bottle of 100 tablets. The tablets should be pink coloured. PANTONE colour PMS 9284C. Natural colours are preferable. Tablet should be coated.

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

Antianaemia

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 shall be attached or enclosed in a box with each pack. Refer to *UNICEF Technical requirements for pharmaceutical products 5* ([unicef.org](http://www.unicef.org)) Label and leaflet to be in Arabic, English and French

Child-Proof Packaging

Child resistant cap on each pack/bottle is preferred.

7. Guideline for Use

As per the WHO guidelines

1. WHO Recommendations on Adolescent Health Guidelines approved by the WHO Guideline review committee. AUGUST 2017
<http://apps.who.int/iris/bitstream/handle/10665/259628/WHO-MCA-17.09-eng.pdf;jsessionid=2B8F62ECEB4D7B68501CA1921CD30850?sequence=1>
2. 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>
3. [Guidelines for the Use of Iron Supplements to Prevent and Treat Iron Deficiency Anemia \(motherchildnutrition.org\)](http://www.motherchildnutrition.org)

8. Storage and Transportation

Do not store or transport above 30 degrees

9. Material Safety data sheet information (MSDS): needs to be provided

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](#)

