



PRODUCT SPECIFICATION SHEET

Ferrous sulphate 25 mg/ml, oral solution,
30 ml bottle

Version no: 3.1

Material No: S1550180

Author: DK

Revised by: AF, MCR

Date: 11.10.2022

1. General Description

Ferrous Sulphate Oral Solution 125mg/ml (eq. to 25 mg elemental iron/ml) 30 ml bottle.

2. Technical Specifications

Ferrous Sulphate Oral Solution 125mg/ml equivalent to 25mg of elemental iron per ml, 30 ml dropper bottle.

Oral liquid is preferably packed with a dropper bottle, graduated measuring device, or syringe which is enclosed or attached to the bottle.

Acceptable pharmacopoeias

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

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. Dispensing Instructions

Dispense in original container. Do not repack or decant.

7. Packaging and labelling

A Patient Information Leaflet should be attached or enclosed in a box with each bottle.

Refer to UNICEF Technical requirements for pharmaceutical products [5 \(unicef.org\)](#)

8. Guideline for Use

1. Guideline: Daily iron supplementation in infants and children. Geneva: World Health Organization; 2016
http://apps.who.int/iris/bitstream/10665/204712/1/9789241549523_eng.pdf?ua=1&ua=1
2. Guidelines for the Use of Iron Supplements to Prevent and Treat Iron Deficiency Anemia; 1998
https://www.who.int/nutrition/publications/micronutrients/guidelines_for_Iron_supplementation.pdf?ua=1
3. Enteral iron supplementation in preterm and low birth weight infants
https://www.who.int/elena/titles/review_summaries/iron-infants/en/

9. Storage and transportation

Do not transport and store in temperatures above 30 degrees

10. 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](#)