



PRODUCT SPECIFICATION SHEET

Version no: 3

Material No: S1551005

Author: DK

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Folic acid 5 mg tabs/PAC-1000

1. General Description

Folic acid 5 mg tabs, bottle of 1000 tablets

2. Technical Specifications

Each uncoated tablet contains 5mg folic acid, preferably pack of 1000 tablets

Acceptable pharmacopoeias

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

Dissolution test for folic acid is required as per USP or BP

3. Therapeutic Class

Antianaemia

4. 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 \(unicef.org\)](https://www.unicef.org/5)
Label and leaflet to be in Arabic, English and French

7. Guideline 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. WHO Standards for Maternal and Neonatal Care 2007 [a91272.pdf \(who.int\)](#)

8. 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.nutritionsupplies@unicef.org

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