

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555 Email: rdtlguwahati@cdsco.nic.in



FORM 13

(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

1. Name of Inspector from whom received

: SARAH LALDINTLUANGI

ASSISTANT DIRECTOR (FOOD & DRUGS)

Sr. CMO OFFICE, SERCHHIP-796181, SERCHHIP

Serial No. and date of Inspector's memorandum

: 002/IPA/2024

Date 25/11/2024

Number of Sample

: Nil

Date of receipt

: 26-DEC-2024

Names of drugs purporting to be contained in the sample : IRON & FOLIC ACID TABLETS IP

| SSTANDARD CONTROL | | | | | | | | | |
|--------------------------|-----------------------|-----------|--------------------|-------------|--|--|--|--|--|
| Lab. Sample No. | | -V | Date of Mfg. & Exp | Marketed By | Mfg. By | | | | |
| LSD/GUW/2025- 26/0034 | GUW/LS/2025- 26/32 | SMR-30603 | 06/2023 05/2025 | NA | M/s. SUDARSHAN Pharmaceuticals Pvt. Ltd. 17B/18A, Sector-F, Industrial Area, Sanwer Road, Indore-452015. | | | | |

Condition of seals on

[the packet or on portion of sample or container]

Seals were intact & identical to the Specimen impression of the seal received from Drugs Inspector

7. Result of test or analysis with protocols or test or analysis applied

Date of Testing: From 25-Mar-2025 To 07-Apr-2025

COMPOSITION

Each sugar coated tablet contains:

Dried Ferrous Sulphate IP 200 mg. (eq to Ferrous Elemental Iron 60mg)

Folic Acid IP

0.5 mg.

Protocol Applied: I.P. 2022

| Sr No. Test Name | | Result | Limits | | |
|-------------------------|----------------|--|----------------|--|--|
| 1 | Description | Red colour, round, bi-convex, sugar coated tablet in blister pack. | | | |
| 2 | Identification | Gives positive test for Ferrous Sulphate & Folic Acid. | | | |
| 3 | Average weight | 0.3617 gm. | NA | | |
| 4 | Disintegration | Complies (Time taken for Disintegration: 46 minutes 18 seconds). | NMT 60 minutes | | |
| 5 Uniformity of content | | Complies (for Folic Acid). | NA | | |

Assay

| Sr.No Ingredient Name | | Found | Claim | % of claim | Limits | Procedure Method |
|-----------------------|---|-----------------|---------------|------------|---------------|------------------|
| 4) - (| Dried Ferrous Sulphate (eq. to Ferrous Elemental Iron | 62.02 mg/Tablet | 60 mg/Tablet | 103.366 | 90 % to 110 % | I.P. 2022 |
| 2 | Folic Acid | 0.67 mg/Tablet | 0.5 mg/Tablet | 134 | NLT 90 % | I.P. 2022 |

In the opinion of the under signed the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules thereunder for the reasons given below:-

The sample conforms to I.P. with respect to the above tests only.

Date: 07-APR-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

R.D.T.L., Guwahati-22

