



# SWAPNROOP DRUGS & PHARMACEUTICALS

Address: Plot No:D-187/16, Five Star Shendra MIDC, Shendra,

Aurangabad-431154, Maharashtra, India.

Tel: +91 8767062101 Email: enquiry@sdp.org.in

Website: www.sdp.org.in

## CERTIFICATE OF ANALYSIS

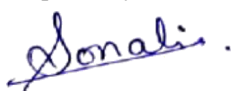
|                       |                |                         |                                   |
|-----------------------|----------------|-------------------------|-----------------------------------|
| <b>Product Name</b>   | FAMOTIDINE USP | <b>CAS No:</b>          | 76824-35-6                        |
| <b>Batch No.</b>      | 2605001        | <b>Manufactured by</b>  | Swapnroop Drugs & Pharmaceuticals |
| <b>Date of Mfg.</b>   | MAY-2026       | <b>Date of Analysis</b> | 20/05/2026                        |
| <b>Batch Quantity</b> | -              | <b>Retest Date</b>      | APR-2031                          |

| Sr No | Test                                                              | Acceptance Criteria                                                                                                                                                                                                  | Results                  |
|-------|-------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| 1     | Description                                                       | White to pale yellowish-white crystalline powder.                                                                                                                                                                    | WHITE CRYSTALLINE POWDER |
| 2     | Solubility                                                        | Freely soluble in dimethyl formamide, glacial acetic acid, slightly soluble in methanol, very slightly soluble in water, practically insoluble in acetone, in alcohol, in chloroform, in ether and in ethyl acetate. | Complies                 |
| 3     | Spectroscopic Identification Test <197> <197A>, <197K>, or <197M> | The infrared spectrum of sample should be concordant to that of working standard/ reference standard.                                                                                                                | Complies                 |
| 4     | Organic impurities by HPLC <621><br>Famotidine related compound D | Not more than 0.3 % w/w                                                                                                                                                                                              | 0.02 %                   |
| 5     | Organic impurities by HPLC <621><br>Famotidine related compound C | Not more than 0.3 % w/w                                                                                                                                                                                              | 0.02 %                   |
| 6     | Organic impurities by HPLC <621><br>Famotidine cyanoamidine       | Not more than 0.2 % w/w                                                                                                                                                                                              | 0.05 %                   |
| 7     | Organic impurities by HPLC <621><br>Famotidine related compound F | Not more than 0.1 % w/w                                                                                                                                                                                              | NOT DETECTED             |
| 8     | Organic impurities by HPLC <621><br>Famotidine amidine            | Not more than 0.2 % w/w                                                                                                                                                                                              | NOT DETECTED             |
| 9     | Organic impurities by HPLC <621><br>Famotidine related compound B | Not more than 0.3 % w/w                                                                                                                                                                                              | NOT DETECTED             |
| 10    | Organic impurities by HPLC <621><br>Famotidine related compound E | Not more than 0.3 % w/w                                                                                                                                                                                              | 0.03 %                   |
| 11    | Organic impurities by HPLC <621><br>Any other individual impurity | Not more than 0.10 % w/w                                                                                                                                                                                             | 0.02 %                   |
| 12    | Organic impurities by HPLC <621><br>Total impurities              | Not more than 1.0 % w/w                                                                                                                                                                                              | 0.16 %                   |

| Sr No | Test                                                | Acceptance Criteria                                  | Results                  |
|-------|-----------------------------------------------------|------------------------------------------------------|--------------------------|
| 13    | Assay (on dry basis by Potentiometry) (% w/w) <541> | Not less than 98.5% W/W and Not more than 101.0% W/W | 99.54 %                  |
| 14    | Loss on drying <731>                                | Not more than 0.5 %                                  | 0.24 %                   |
| 15    | Residue on ignition <281>                           | Not more than 0.1 %                                  | 0.035 %                  |
| 16    | Residual solvents (in ppm) <467> Methanol           | NMT 3000 ppm                                         | 224 ppm                  |
| 17    | Residual solvents (in ppm) <467> Acetone            | NMT 5000 ppm                                         | BELOW LOQ (LOQ = 20 ppm) |
| 18    | Residual solvents (in ppm) <467> IPA                | NMT 5000 ppm                                         | BELOW LOQ (LOQ = 15 ppm) |
| 19    | Bulk density (In house) Untapped                    | 0.25 ± 0.1 g/mL                                      | 0.27g/mL                 |
| 20    | Bulk density (In house) Tapped                      | 0.35 ± 0.1 g/mL                                      | 0.33g/mL                 |

**Storage:** Store in air tight container below room Temperature

**Conclusion:** Product Complies as per above Specifications

|                                                                                                                                                |                                                                                                                                               |                                                                                                                                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Prepared By</b><br><br>Sonali Nirmal<br>Date: 23/05/2026 | <b>Checked by</b><br><br>Dadarao Kakde<br>Date: 23/05/2026 | <b>Approved By</b><br><br>Nayna Nehete<br>Date: 23/05/2026 |
|------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|

