



# MOREPEN LABORATORIES LIMITED

## QUALITY CONTROL DEPARTMENT

### CERTIFICATE OF ANALYSIS

(The Drug & Cosmetic Act 1940 and the rules there under)

|                |                                           |                  |                            |
|----------------|-------------------------------------------|------------------|----------------------------|
| Name of Sample | FRASIX 40                                 |                  |                            |
| Generic Name   | Frusemide Tablets IP 40 mg                | A.R No.          | FP3/240240                 |
| Batch No       | E4C0251B                                  | Mfg. Lic No.     | MNB/96/6                   |
| Batch Size     | 1.00 Lac                                  | Reference No     | SPC/FP/E/0129/01           |
| Mfg. Date      | Mar. 2024                                 | Mfg. By          | Morepen Laboratories Ltd.  |
| Exp. Date      | Feb. 2026                                 | Marketed By      | Healing Pharma             |
| Sampled By     | Abhishek                                  | Date of Sampling | 06 <sup>th</sup> Apr. 2024 |
| Spl. Qty.      | 80 Tablets                                | Date of Release  | 10 <sup>th</sup> Apr. 2024 |
| Address        | Plot no. 12 B, Sector 2, Parwanoo. (H.P.) |                  |                            |

| S. No. | TESTS                                        | SPECIFICATIONS/LIMITS                                                                                  | OBSERVATIONS                                                                                   |
|--------|----------------------------------------------|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| 1      | Description                                  | White colored round flat faced uncoated tablets plain on both side, packed in alu-PVC blister.         | White colored round flat faced uncoated tablets plain on both side, packed in alu-PVC blister. |
| 2      | Identification                               | (A) Maxima at about 228 nm, 271 nm and 333 nm<br>(B) A green color produced should change to deep red. | Complies<br>Complies                                                                           |
| 3      | Average Weight                               | 140.0 mg $\pm$ 3.0 %<br>(135.80 mg – 144.20 mg)                                                        | 139.23 mg                                                                                      |
| 4      | Uniformity of Weight                         | Average Weight $\pm$ 7.5 %<br>(129.50 mg – 150.50 mg)                                                  | 136.4 mg – 145.0 mg                                                                            |
| 5      | Diameter                                     | 7.00 mm $\pm$ 0.2 mm<br>(6.80 mm – 7.20 mm)                                                            | 7.01 mm – 7.07 mm                                                                              |
| 6      | Thickness                                    | 2.60 mm $\pm$ 0.2 mm<br>(2.40 mm – 2.80 mm)                                                            | 2.65 mm – 2.73 mm                                                                              |
| 7      | Hardness                                     | Not less than 2.0 kg/cm <sup>2</sup>                                                                   | 3.1 kg/cm <sup>2</sup> – 4.2 kg/cm <sup>2</sup>                                                |
| 8      | Friability                                   | Not more than 1.0 % w/w                                                                                | 0.15 %                                                                                         |
| 9      | Dissolution                                  | Not less than 70 % (Q.) of the labeled of Frusemide                                                    | Min.: 96.8 % – Max.: 99.7 %                                                                    |
| 10     | Related substances                           |                                                                                                        |                                                                                                |
|        | Any other individual impurity                | Not more than 1.0 %                                                                                    | 0.002%                                                                                         |
|        | Sum of all other impurities                  | Not more than 1.5 %                                                                                    | 0.003 %                                                                                        |
| 11     | Assay                                        |                                                                                                        |                                                                                                |
|        | Each uncoated tablet on an average contains: |                                                                                                        |                                                                                                |
|        | Frusemide IP .....40 mg                      | 36.00 mg – 44.00 mg<br>(90.0 % - 110.0 %)                                                              | 39.44 mg<br>(98.6 %)                                                                           |

Remarks: In the opinion of the undersigned, the sample referred to above is of Standard / not of standard quality as per IP/BP/USP In-house Specification w.r.t. above test only.

|             |                |             |             |
|-------------|----------------|-------------|-------------|
|             | Analysed By    | Checked By  | Approved By |
| Name        | Praveen Thakur | Pratibha    | Sgt. Yadav  |
| Sign/Date   | 10/04/24       | 10/04/2024  | 10/04/24    |
| Designation | Chemist        | Sr. Chemist | Sr. Manager |

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