



QUALITY CONTROL DEPARTMENT
Certificate of Analysis of Finished Product

(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/FG/334/24-25

Report Date: 21-10-2024

Name of the product : FRASIX 20 Injection 2ml
Generic Name : Frusemide Injection I.P
Batch No. : FR424
Batch Size : 205000
Mfg. Date. : OCT-2024
Exp. Date. : SEP-2027
Quantity of Sample : 100Nos
Date of Sampling : 05-10-2024
Date of Commencement of analysis : 05-10-2024
Date of Completion of analysis : 19-10-2024

| TEST NAME | SPECIFICATION | OBSERVATION |
|-------------------------------|---|------------------------------|
| Description: | A clear, colourless solution. | A clear, colourless Solution |
| Identification: A.(By UV) | The final solution obtained in the assay shows three absorption Maximum at about 228 nm, 271nm, and 333nm | Complies to IP specification |
| B.Colour reaction | A violet colour is produced | Complies to IP specification |
| pH | 8.0 to 9.3 | 8.43 |
| Related substance | In the chromatogram obtained with the test solution the area of any secondary peak is not more than the area of the principal peak obtained with the reference solution (1 per cent), and sum of areas of all the secondary peaks is not more than 1.5 times the area of the peak in the chromatogram obtained with the reference solution (1.5 per cent) | Complies to IP specification |
| Extractable Volume | NLT-2.0 ml/Ampoule | 2.1 ml |
| Particulate matter | No visible particles | Complies |
| Bacterial endotoxins | NMT 3.5EU/mg of Frusemide | LT 3.5 EU/mg |
| Sterility Test | To comply as per IP | Complies |
| Assay | | |
| Each ml contains: | 9.5mg to 10.5mg | 10.10mg |
| Frusemide I.P 10 mg | (95.0 % - 105.0%) | 101.00% |

OBSERVATION: In the opinion of the undersigned the sample referred to above is of ~~Standard Quality~~ **Standard Quality** as in the act and the rules made there under for the reason given below.

REMARKS : COMPLIES AS PER IP WITH RESPECT TO THE ABOVE TESTS ONLY CARRIED OUT.

Analysed By:
Date: 21/10/2024

Checked By:
Date: 21/10/2024

Person In Charge of Testing
Date: 21/10/24

