

TAMMAN TITOE



Tamman Titoe Pharma Pvt Ltd  
56-57, Sideo Pharmaceutical Complex,  
Alathur-603 110, Tamilnadu.

**QUALITY CONTROL DEPARTMENT**  
**Certificate of Analysis of Finished Product**

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

Report No: TT/FG/122/24-25  
Report Date: 11-06-2024

Name of the product : FRASIX 20 Injection 2ml  
Generic Name : Frusemide Injection I.P  
Batch No. : FR411  
Batch Size : 155000  
Mfg. Date. : MAY-2024  
Exp. Date. : APRIL-2027  
Quantity of Sample : 100Nos  
Date of Sampling : 27-05-2024  
Date of Commencement of analysis : 27-05-2024  
Date of Completion of analysis : 10-06-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description:	A clear, colourless solution.	A clear, colourless Solution
Identification: A.(By UV )  B.Colour reaction	The final solution obtained in the assay shows three absorption Maximum at about 228 nm, 271nm, and 333nm  A violet colour is produced	Complies to IP specification  Complies to IP specification
pH	8.0 to 9.3	8.41
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-4.0 ml/Ampoule	4.1 ml
Particulate matter	No visible particles	No visible particles
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	10.086mg
Frusemide I.P 10 mg	(95.0% - 105.0%)	100.86%

**OBSERVATION:** In the opinion of the undersigned the sample referred to above is of **Standard Quality** / ~~Not 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: V. S. A  
Date: 11/6/24

Checked By: *[Signature]*  
Date: 11/6/24

Person in Charge of Testing  
Date: 11/6/24

