

CERTIFICATE OF ANALYSIS

Product Name	Frasix 20		
Generic Name	Frusemide injection IP 10mg/ml, 2ml	Product Code	FS
Batch No	FSA24009	Batch size	400 Liters
Mfg. Date	MAR.2024	Exp. Date	FEB.2027
Date of sampling	27/03/2024	Completed Date	18/04/2024
A.R. No	RLS/FP/240078	Specification No:	FPS012

Sl. No.	Tests	Method	Specification	Results
1	Description	IP/IH	A clear, colourless or almost colourless solution filled in USP type I, 2ml amber ampoule.	A clear, colourless solution filled in USP type-I, 2ml amber ampoule with red ring.
2	Identification A	IP	Absorption maxima at about 228nm, 271nm and 333nm.	Complies
	Identification B	IP	A red-violet colour is produced	Complies
3	pH	IP	NLT 8.0 and NMT 9.3	8.89
4	Extractable volume	IP	NLT 2.0 ml	2.0 ml
5	Particulate matter:	IP	Clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies
6	Related substance	IP	Area of secondary peak: NMT 1 %	0.078%
			Sum of all the secondary peaks: NMT 1.5 %.	0.132%
7	Assay (each ml of solution contains 10 mg Frusemide)	IP	NLT 95.0% and NMT 105.0% (9.5 mg to 10.5 mg)	100.7 % (10.070 mg/ml)
8	BET	IP	NMT 3.5 EU/ mg	Less than 1.72 EU/mg
9	Sterility	IP	Should be sterile	Sterile

Remarks: The material complies as per IP and In-house specification.

	Analysed by	Checked by	Approved by
Signature	<u>PSH</u>	<u>CA</u>	<u>Yadavamat</u>
Date	18/04/2024	18/04/2024	18/04/2024