

Certificate of Analysis Finished Product

Title	:		
Product Name	TORSICAN Injection	A.R. No.	NL/FP/24/044
Generic Name	Torse mide Injection 10mg/ml	Sampled qty.	45 Ampoules
Batch No.	A23640B	Sampled by	Vineet
Batch Size	30,000 Ampoules	Sampled on	26/04/2024
Mfg. Date	03/2024	Date of Testing	26/04/2024
Exp. Date	02/2026	Date of Release	12/05/2024

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in clear glass ampoule.	A clear colourless solution filled in clear glass ampoule.
2.	Identification (By HPLC)	In the assay, the principle peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.	Complies
3.	Nominal fill volume	NLT-2 ml	2.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml
5.	pH	9.0 to 11.0	9.43
6.	Particulate matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/ Ampoules NMT-600/ Ampoules The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	104/Ampoules 2/Ampoules Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT 17.5 EU/mg of Torsemide.	Less than 17.5 EU/mg of Torsemide.
9.	Assay: Each ml contains:		

Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Torsemide	IP	10 mg	10.065 mg	100.65%	90.0% to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not-complies as per IP/BP/USP/IHS.

Analysis by *S* Checked by *W* Approved by *[Signature]*

