## kaliberr

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Format No.: KBPL	and the second s			
Product Name	NOR-ADR			
Generic Name	Sterile Noradrenaline Concentrate IP 0.2% w/v			
Batch No.	K06723008	A.R. No.	FP/11/23/00113	
Mfg. Date	Nov-2023	Sampling Quantity	80 Ampoules	
Exp. Date	Oct-2025	Sampling Date	18/11/2023	
Batch Size	200 Ltr	Date of Analysis	18/11/2023	
Pack Size/Type	5 x 2 ml	Date of Release	03/12/2023	
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Test	Specification	Result
Description	A clear colourless solution.	A clear colourless solution.
Identification		
By chemical Method	A strong reddish violet colour is produced	Complies
pH	3.0 to 4.6	3.7
Extractable volume	NLT 2 ml	2.0 ml
Particulate Matter ≥ 10 μm ≥ 25 μm	NMT 6000 no. of particles per container. NMT 600 no. of particles per container.	208 particles per container. 4 particles per container
Sterility	Should be sterile.	sterile.
Bacterial Endotoxins	Not more than 83.4 endotoxin Units per mg of noradrenaline	Less than 83.4 EU/mg
Assay	Not more than 0.18% and not more than 0.23 % w/v of noradrenaline Bitartrate	0.21 %
	Description Identification By chemical Method pH Extractable volume Particulate Matter ≥ 10 μm ≥ 25 μm Sterility Bacterial Endotoxins	DescriptionA clear colourless solution.IdentificationA strong reddish violet colour isBy chemicalA strong reddish violet colour isMethodproducedpH3.0 to 4.6Extractable volumeNLT 2 mlParticulate Matter ≥ 10 μm ≥ 25 μmNMT 6000 no. of particles per container. NMT 600 no. of particles per container.SterilityShould be sterile.Bacterial EndotoxinsNot more than 83.4 endotoxin Units per mg of noradrenalineAssayNot more than 0.18% and not more than

CONCLUSION: The Finish Product Sample Complies / Does not complies as per HH/IP/BP/USP Specification.

Function	Prepared By	Reviewed By	Approved By
Name	Jagvijay Yadhav	Maya Sirsat	Siddharth. Singh
Designation- Department	Executive -QC	Executive -QC	Sr. Executive-QC
Sign & Date	25/12/2023	28/12/2023	879 171121W1

