



American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Dobutacan 5ml Injection (Dobutamine Hydrochloride USP 250 mg/5ml)		
Batch No.	25AR027	A.R. No.	AFP25029
Batch Size	50100 Amps.	Sample Quantity	60 Nos
Mfg. Date	09/2025	Date of Testing	28/09/2025
Exp. Date	08/2027	Date of Release	14/10/2025
Reference Batch No	25AR027	MFG. Lic. No.	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	Description	A clear, colourless liquid.	Clear and colorless liquid.
2.	Identification	The <i>RF</i> value of the principal spot of the <i>Sample solution</i> corresponds to that of the <i>Standard solution</i> .	Complies
3.	pH	2.5 to 5.5	4.54
4.	Extractable Volume	NLT 5.0 ml	5.0 ml
5.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
6.	Bacterial Endotoxins	NMT 2.08 EU/mg	Less than 2.08 EU/mg
7.	Sterility	Should be complies	Sterile
8.	Assay: Each ml contains Dobutamine Hydrochloride IP Eq. to Dobutamine 50 mg	90.0 to 110.0 % (45.0 to 55.0 mg)	101.15 % (50.5770 mg)



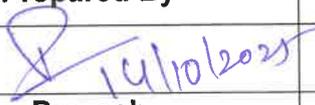
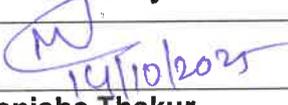
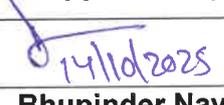
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Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 14/10/2025	 14/10/2025	 14/10/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

