American Remedies Healthcare Pvt. Ltd.

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	**Dobutacan Injection (Dobutamine Hydrochloride IP 250 mg/5ml)**		
Batch No.	26AR107	**A.R. No.**	AFP260119
Batch Size	50900 Ampoules	**Sample Quantity**	60 Amps.
Mfg. Date	09/2026	**Date of Testing**	28/09/2026
Exp. Date	08/2028	**Date of Release**	14/10/2026
Reference Batch No	26AR107	**MFG. Lic. No.**	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	**Description**	A clear, colourless liquid filled in amber colour ampoule.	Clear and colorless liquid filled in amber colour ampoule.
2.	**Identification**	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).	Complies
3.	**pH**	2.5 to 5.5	4.76
4.	**Extractable Volume**	NLT 5.0 ml	5.0 ml
5.	**Related Substances** **Any other Impurity** **Total Impurities**	 NMT 0.5% NMT 1.0%	 Not Detected Not Detected
6.	**Particulate Matter**	Injections that are solutions, when examined under suitable conditions of visibility, are clear andpractically free from particles that can be observed on visual inspection by the unaided eye.	Complies
7.	**Bacterial Endotoxins**	NMT 10.0 EU/mg	Less than 10.0 EU/mg
8.	**Sterility**	Should be Sterile	Sterile
9.	**Assay:** **Each ml contains** **Dobutamine Hydrochloride IP** **Eq. to Dobutamine 50 mg**	 47.5 to 52.5 mg (95.0 to 105.0%)	 49.70 mg (99.40%)

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

	Prepared By	Checked By	Approved By
Sign/Date	Saini 14/10/2026	14/10/2026	14/10/2026
Name	**Diksha Saini**	**Vinay Kumar**	**Bhupinder Navet**
Designation	**Officer QC**	**Sr.Executive-QC**	**Head-QC**

Name: Bhupinder Navet
Designation: Head QC
Qualification: M. Pharma
Registration No: 12-DVI-103
Pt BD Sharma University of Health Sciences, Rohtak

AMERICAN REMEDIES HEALTHCARE PVT. LTD. QUALITY CONTROL MANAGER