



CLIENT & SAMPLE INFORMATION

Client	N/A	Analysis Date	04/27/2026
Lot / Batch	DVB038	Product Name	Bacteriostatic Water
Preservative	Benzyl Alcohol 0.9%	Container	Glass Vial

This Certificate of Analysis certifies that the bacteriostatic water sample listed herein was tested for preservative content, sterility, and physicochemical properties in accordance with applicable USP/EP methods.

BENZYL ALCOHOL ASSAY (GC)

Parameter	Specification	Result	Status	Parameter	Specification	Result	Status
Appearance (Color)	Colorless	Colorless	PASS	GC Impurity 1	$\leq 0.50\%$	$< 0.01\%$	PASS
Appearance (Form)	Liquid	Liquid	PASS	GC Impurity 2	$\leq 0.50\%$	ND	PASS
Benzyl Alcohol Content	0.9% +/- 10%	0.90%	PASS	Refractive Index (20C)	1.540 - 1.542	1.541	PASS
Purity (GC)	$\geq 99.5\%$	99.9%	PASS	Overall Determination			PASS

Reference: CAS 100-51-6 | C_7H_8O | MW 108.14 g/mol | Method: Gas Chromatography per USP <621>

ADDITIONAL QUALITY SCREENS

PH ANALYSIS		ENDOTOXIN SCREEN		STERILITY / MICROBIAL SCREEN	
Method	USP <791>	Method	LAL (USP <85>)	Method	Rapid Sterility
Specification	4.5 - 7.0	Limit	≤ 0.5 EU/mL	Specification	No Growth
Result	5.5	Result	< 0.10 EU/mL	Incubation	3 days
Status	PASS	Status	PASS	Result	No Growth
				Fungi	Not Detected
				Status	PASS

TESTING METHODOLOGY SUMMARY

Benzyl Alcohol Assay (GC)

The preservative content was quantified using Gas Chromatography per USP <621>. This method separates and measures benzyl alcohol concentration to verify the 0.9% w/v specification. Sample preparation involves dilution in appropriate solvent, followed by injection into the GC system equipped with a flame ionization detector (FID). Peak area is compared against certified reference standards to determine concentration. Impurity profiles are simultaneously assessed to ensure product purity meets pharmacopeial requirements.

