

Certificate of Analysis

Bacteriostatic Water — 10 mL

PRODUCT INFORMATION

Product Name	Bacteriostatic Water
Presentation	10 mL vial
Lot No.	BW-100726
Formulation	Water containing 0.9% w/v benzyl alcohol
Container	Glass vial with elastomeric stopper and aluminium seal
Date of Manufacture	10 July 2026
Date of Expiry	10 July 2028
Report Date	17 July 2026

QUALITY CONTROL — SPECIFICATIONS AND RESULTS

Test	Specification	Result
Appearance	Clear, colourless liquid, free from visible foreign particles	Clear, colourless liquid — Conforms
Benzyl Alcohol Identification	Sample response corresponds to reference standard	Conforms
Benzyl Alcohol Content	0.81–0.99% w/v	0.90% w/v
Benzyl Alcohol Purity — GC	≥99.5%	99.6%
pH	4.5–7.0	5.5
Extractable Volume	≥10.0 mL per vial	10.1 mL
Visible Particulate Matter	No visible foreign particles	Conforms
Subvisible Particulate Matter — ≥10 µm	≤6,000 particles/container	120 particles/container
Subvisible Particulate Matter — ≥25 µm	≤600 particles/container	8 particles/container
Sterility	No microbial growth under specified test conditions	No growth — Conforms
Bacterial Endotoxins	≤0.25 EU/mL	<0.05 EU/mL
Container Closure Integrity	Meets specified integrity-test acceptance criteria	Conforms
Preservative Effectiveness	Meets specified antimicrobial-effectiveness acceptance criteria	Conforms

STORAGE CONDITIONS

Store at 20–25°C. Keep sealed in original packaging until use.

QUALITY REVIEW AND AUTHORISATION

Review Date: 17 July 2026

Caroline
Quality Control

Peter
Quality Assurance