



CERTIFICATE OF ANALYSIS

Issued by an ISO/IEC 17025-accredited laboratory · raw data appended (page 2)

PASS

QC released for dispatch



Scan to verify

Bacteriostatic Water — 10ml

Sterile Water 0.9% Benzyl Alcohol

1. PRODUCT IDENTIFICATION

Synonym	Sterile Water 0.9% Benzyl Alcohol	Label claim	10ml
Sequence / structure	—	Lot / Batch	ZX260512-467 / B34930
Mol. formula	H ₂ O	Manufacture date	19 May 2026
Mol. weight	18.02 g/mol	Date of analysis	27 May 2026
CAS number	7732-18-5	Storage	2–8 °C, dark
Salt form	Free base / N/A		

2. ANALYTICAL TEST RESULTS

Test	Method	Specification	Result	Verdict
Appearance	Visual	Clear colourless solution	Clear, colourless particle-free solution	PASS
Benzyl alcohol	GC	0.90% w/v (±10%)	0.89% w/v	PASS
pH	Potentiometric (USP <791>)	4.5–7.0	5.2	PASS
Sterility	USP <71>	Sterile, no growth	No growth	PASS
Bacterial endotoxin	LAL (USP <85>)	< 0.25 EU/mL	0.15 EU/mL	PASS
Particulate matter	USP <788>	Conforms	Conforms	PASS

CONCLUSION

All tested parameters CONFORM to the acceptance specifications. The batch is of high chromatographic purity (≥ 98%) with an impurity profile, identity and residual/contaminant results meeting pharmaceutical-grade quality requirements. Material released. Supporting RP-HPLC chromatogram and ESI-MS spectrum are appended on page 2.

DHR.

Dr. Huang Rui

Analyst · 27 May 2026 · Zhongxi Research Institute

DLX.

Dr. Lin Xia (QC Manager)

Approved by · 27 May 2026 · Zhongxi Research Institute



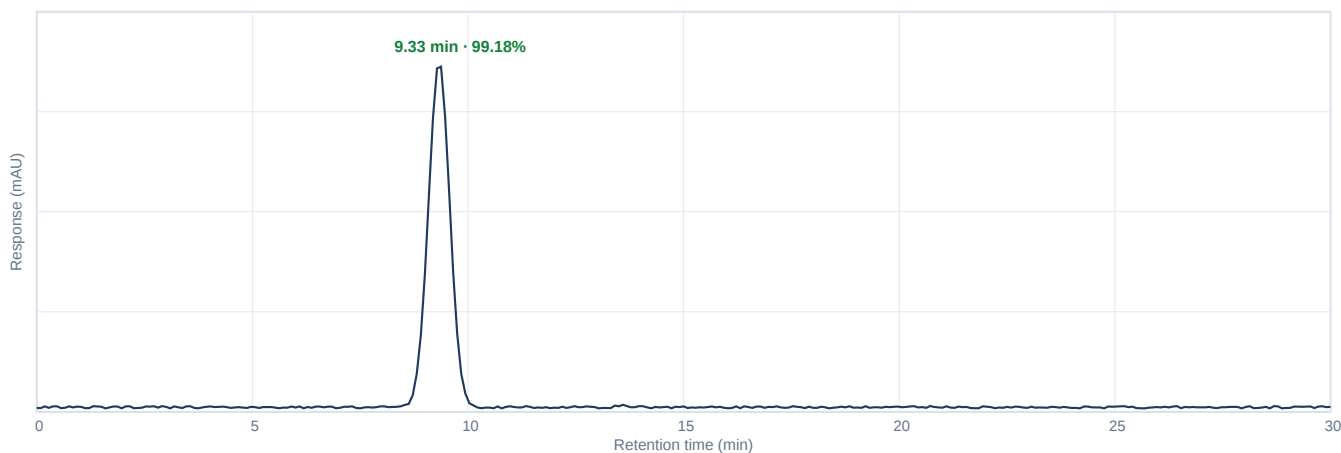
APPENDIX — ANALYTICAL RAW DATA

Bacteriostatic Water 10ml · Lot ZX260512-467 · Cert. ZXR-COA-2026-70378



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Figure 1. RP-HPLC Chromatogram — benzyl alcohol assay (UV 257 nm)



Peak #	RT (min)	Area (μV·s)	Area %	Assignment
1	9.33	1045511	99.18	Benzyl alcohol
2	13.55	4313	0.41	Impurity / related substance
3	20.48	2718	0.27	Impurity / related substance
4	5.18	1197	0.11	Impurity / related substance
5	16.95	297	0.03	Impurity / related substance

Figure 2. Identity confirmation (MS not applicable to this product class)

MS not applicable for this product class.

Interpretation

This product is a sterile bacteriostatic solution. Identity and strength are established by GC assay of benzyl alcohol and compendial physicochemical tests (page 1); mass spectrometry is not applicable. The trace below is the benzyl-alcohol assay chromatogram.

Methods — RP-HPLC: Zorbax SB-C18 4.6×250 mm, 5 μm; 40% MeCN / 60% water isocratic; 1.0 mL/min; 30 °C; UV 257 nm (benzyl alcohol chromophore). pH: USP <791>. Sterility: USP <71>. Endotoxin: LAL kinetic chromogenic. Particulates: USP <788>.