ANALYTON™ LABS

AN-2026-00018

Issued 2026-08-11

Certificate of analysis

Issued by ANALYTON LABS, analytical testing laboratory, under ANALYTON GC 1.1.

BATCH ID AMENDED 2026-10-29

REPORT FIELD OMITTED 2026-10-29

Client	Molequa
Sample	Bacteriostatic water, 0.9 % benzyl alcohol, vial labelled 3 ml
Batch number	MQ-BAC-WATER-202608
Matrix	Bacteriostatic water for injection

Sample received	2026-08-04
Analysis	2026-08-05 to 2026-08-10
Date of issue	2026-08-11
Determinations performed	20

CONFORMS TO SPECIFICATION

All 17 determinations judged against a specification are within it. 3 further determinations are reported without a specification.

SUMMARY OF RESULTS

DETERMINATION	METHOD	RESULT	SPECIFICATION
Appearance	Visual, USP <790>, black and white background, 2000 lx, 5 s	**Clear, colourless solution free of visible particles; faint aromatic odour of benzyl alcohol**	Clear, colourless, free of visible particles PASS
Identity of benzyl alcohol	GC-MS (EI, 70 eV) and LC-HRMS (ESI+)	**Retention time 12.90 min matches the standard within 0.05 min; EI spectrum m/z 108 (M+•), 107, 79, 77, NIST library match 96 %; LC-HRMS [M+H]+ 109.0648, deviation 0.0 ppm, [M+Na]+ 131.047**	Theoretical monoisotopic 108.0575 Da from C7H8O; [M+H]+ 109.0648 PASS
Benzyl alcohol content	GC-FID, DB-624, internal standard 2-phenylethanol; five-point calibration 0.5 to 1.5 % w/v, r² 0.9998	**0.91 ± 0.02 % w/v (9.1 mg/ml), 101 % of the labelled 0.9 % (k = 2)**	90 to 110 % of label (0.81 to 0.99 % w/v) PASS

DETERMINATION	METHOD	RESULT	SPECIFICATION
Related substances of benzyl alcohol	GC-FID; LOD 0.003 %, LOQ 0.01 %, reporting threshold 0.01 % relative to benzyl alcohol	**Benzaldehyde 0.030 % (RRT 0.85, ± 0.004 %), i.e. 2.7 µg/ml; dibenzyl ether 0.020 % (RRT 1.62); cyclohexylmethanol < 0.01 % (RRT 0.93); total 0.05 %**	Ph. Eur. 0256, parenteral grade: benzaldehyde <= 0.05 %, cyclohexylmethanol <= 0.10 %, any other <= 0.10 %, total <= 0.3 % PASS
Deliverable volume	Gravimetric, USP <697>, density 0.9975 g/ml at 20 °C	**3.15 ml (five vials 3.10 to 3.20 ml)**	Not less than 3.0 ml from each vial PASS
Benzyl alcohol per vial	Calculated from content and deliverable volume	**28.7 mg per vial (9.1 mg/ml × 3.15 ml) against 27 mg for the labelled 0.9 % in 3 ml, i.e. 106 %; each withdrawn millilitre carries 9.1 mg regardless of overfill**	90 to 110 % PASS
pH	Potentiometric, USP <791>, 25 °C, KCl bridge for low ionic strength	**5.6 ± 0.1**	4.5 to 7.0 (USP Bacteriostatic Water for Injection) PASS
Osmolality	Freezing point depression, USP <785>	**85 ± 3 mOsm/kg (calculated 83 for 9.0 g/l benzyl alcohol); the solution is hypotonic and is not an isotonic vehicle**	Report only
Conductivity	USP <645>, 25 °C	**1.1 ± 0.1 µS/cm**	<= 1.3 µS/cm (stage 1) PASS
Total organic carbon	USP <643>	**Not applicable: benzyl alcohol itself contributes 7.4 mg of carbon per ml, so the test would measure the preservative and not contamination**	Report only
Density and balance	Oscillating U-tube, USP <841>, 20 °C	**0.9975 ± 0.0005 g/ml; 9.1 mg/ml benzyl alcohol + 988.4 mg/ml water = 997.5 mg/ml, consistent with the density; no other solute (conductivity 1.1 µS/cm)**	Report only

DETERMINATION	METHOD	RESULT	SPECIFICATION
Inorganic impurities of the water	Ion chromatography; oxidisable substances by permanganate	**Nitrate < 0.2 ppm, chloride < 0.5 ppm, sulfate < 0.5 ppm, ammonium < 0.1 ppm; oxidisable substances: the pink colour persists**	Ph. Eur. Water for injections: nitrate <= 0.2 ppm, ammonium <= 0.2 ppm PASS
Bacterial endotoxins	Kinetic chromogenic LAL, USP <85>, undiluted sample	**< 0.005 EU/ml (LOQ 0.005 EU/ml); 0.9 % benzyl alcohol does not interfere**	<= 0.25 EU/ml (USP Bacteriostatic Water for Injection) PASS
Sterility	Membrane filtration with 3 × 100 ml rinse to neutralise benzyl alcohol, USP <71>; 20 vials; fluid thioglycollate 30 to 35 °C and soya bean casein digest 20 to 25 °C	**No growth after 14 days**	No growth PASS
Antimicrobial effectiveness	USP <51>, category 1 (parenteral), inoculum 10^5 to 10^6 CFU/ml	**S. aureus 3.4 log reduction at 7 d and > 4.0 at 14 d; P. aeruginosa 3.6 and > 4.0; E. coli 3.8 and > 4.0; C. albicans 1.2 log at 14 d; A. brasiliensis 0.6 log at 14 d; no increase to 28 d. Benzyl alcohol is weak against moulds, which is why the number is reported**	Bacteria >= 1.0 log at 7 d, >= 3.0 log at 14 d, no increase to 28 d; yeast and mould no increase from the initial count PASS
Residual solvents and volatile impurities	Headspace GC, USP <467>	**Benzene < 0.5 ppm (LOQ 0.5 ppm; precursor of benzyl alcohol); toluene < 1 ppm; methanol, ethanol and acetone each < 10 ppm**	ICH Q3C: benzene <= 2 ppm (Class 1), toluene <= 890 ppm, methanol <= 3000, ethanol and acetone <= 5000 ppm PASS
Elemental impurities	ICP-MS, direct introduction of the solution, USP <233>	**Cd, Pb < 0.05 µg/l; As, Hg, Co, V < 0.10 µg/l; Ni 0.30 µg/l; for information Al 2.0 µg/l (type I glass) and Fe 1.5 µg/l**	ICH Q3D(R2) Class 1 and 2A, parenteral PDE per 3 ml daily: Cd 667, Pb 1667, As 5000, Hg 1000, Co 1667, V 3333, Ni 6667 µg/l PASS
Sub-visible particles	Light obscuration, USP <788>, mean of 5 vials	**>= 10 µm 140 per vial; >= 25 µm 6 per vial**	<= 6000 and <= 600 per container PASS

DETERMINATION	METHOD	RESULT	SPECIFICATION
Container closure integrity	Vacuum decay, USP <1207>	**0 of 10 vials leaking; bromobutyl stopper, aluminium seal, flip-off cap**	0 leaking PASS
Compound screening	GC-MS full scan m/z 35 to 400 and LC-HRMS m/z 100 to 1000, both polarities, against reference standards	**Other preservatives (methylparaben, propylparaben, phenol, m-cresol, chlorobutanol), ethanol, glycerol, propylene glycol and phthalates (DEHP from the closure): none above 1 µg/ml; no sodium chloride (conductivity), so this is not saline**	Nothing above 1 µg/ml outside the declared composition PASS



SIGNATURE

NAME O. Noga

ROLE Head Laboratory Technician

DATE 2026-08-11



The sample

Sample	Bacteriostatic water, 0.9 % benzyl alcohol, vial labelled 3 ml
Batch number	MQ-BAC-WATER-202608
Matrix	Bacteriostatic water for injection
Received	2026-08-04
Analysis	2026-08-05 to 2026-08-10
Condition on receipt	Seal intact, flip-off cap present, solution clear and colourless, no visible particles
Storage before analysis	20 to 25 degrees Celsius, dark, upright, until first portion taken

Bacterial endotoxins

PRINCIPLE

Lysate from the amoebocytes of the horseshoe crab is activated by bacterial endotoxin through a protease cascade, which cleaves a chromogenic substrate. The rate at which colour develops is proportional to endotoxin concentration, and the onset time is read against a standard curve prepared from control standard endotoxin.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Standard curve correlation coefficient	not less than 0.980 in absolute value	0.9994
Positive product control recovery	50 to 200 per cent	99 %
Negative control	below the lowest standard	no onset
Dilution used	at or below the maximum valid dilution	undiluted

BACTERIAL ENDOTOXINS · PASS

< 0.005 EU/ml (LOQ 0.005 EU/ml); 0.9 % benzyl alcohol does not interfere

Against <= 0.25 EU/ml (USP Bacteriostatic Water for Injection)

Sterility

PRINCIPLE

The contents are transferred under aseptic conditions to fluid thioglycollate medium and to soya bean casein digest medium, and incubated for fourteen days at the temperatures each medium requires. Growth in either medium is a failure.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Growth promotion of each medium	confirmed with the compendial challenge organisms	all media passed
Method suitability against the product	confirmed, no inhibition	growth within 5 days after rinsing, product present; inoculum below 100 CFU
Negative control	no growth for the full incubation	no growth
Incubation	not fewer than 14 days	14 days

STERILITY · PASS

No growth after 14 days

Against No growth

Residual solvents

PRINCIPLE

A weighed portion is equilibrated in a sealed vial and the vapour above the sample is sampled and separated by gas chromatography, with detection by mass spectrometry or flame ionisation. Sampling the headspace rather than the solution keeps involatile matrix out of the instrument.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Resolution between the two closest eluting solvents	not less than 1.0	4.1, benzene from toluene
Signal to noise at the limit of quantitation	not less than 10 to 1	22 to 1 for benzene at 0.5 ppm
Repeatability of the standard	not more than 15 per cent relative standard deviation	3.8 %
System blank	no interfering peak at any target retention time	no interfering peak

RESIDUAL SOLVENTS AND VOLATILE IMPURITIES · PASS

Benzene < 0.5 ppm (LOQ 0.5 ppm; precursor of benzyl alcohol); toluene < 1 ppm; methanol, ethanol and acetone each < 10 ppm

Against ICH Q3C: benzene <= 2 ppm (Class 1), toluene <= 890 ppm, methanol <= 3000, ethanol and acetone <= 5000 ppm

Compound screening

PRINCIPLE

The sample is acquired in both positive and negative ionisation and the detected features are compared against reference standards held by the laboratory and against a spectral library, with confirmation by retention time and fragmentation where a standard is available.

SYSTEM SUITABILITY APPLIED

CRITERION	REQUIREMENT	ACHIEVED
Reference standards injected in the same sequence	confirmed for every reported identification	11 injected in the same sequence
Mass accuracy	within 5 ppm	within 3 ppm (LC-HRMS)
Both polarities acquired	confirmed	acquired (LC-HRMS); EI for GC-MS
Solvent blank between injections	no carryover above the reporting threshold	no carry-over above 0.01 %

COMPOUND SCREENING · PASS

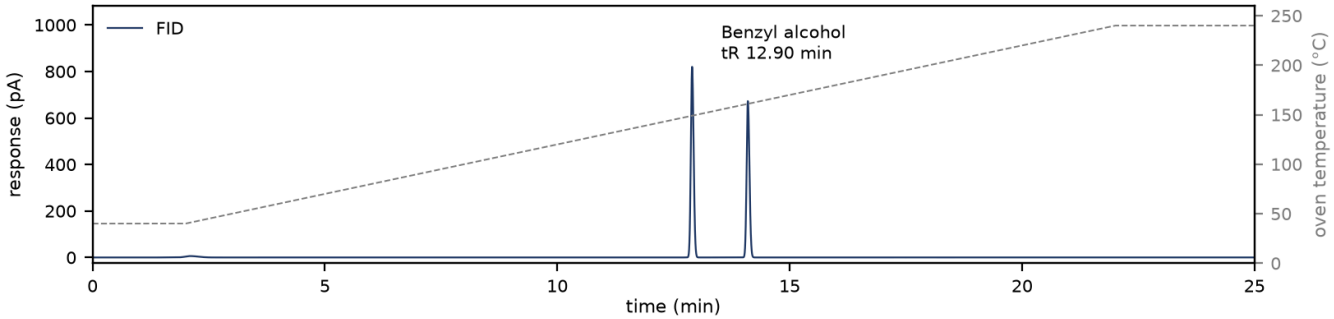
Other preservatives (methylparaben, propylparaben, phenol, m-cresol, chlorobutanol), ethanol, glycerol, propylene glycol and phthalates (DEHP from the closure): none above 1 µg/ml; no sodium chloride (conductivity), so this is not saline

Against Nothing above 1 µg/ml outside the declared composition

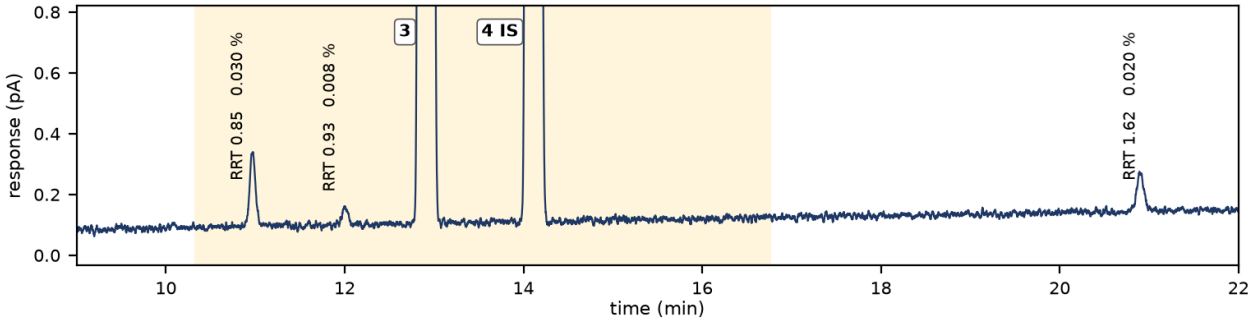
Benzyl alcohol 0.9 %, 3 ml · GC-FID assay

Column DB-624 (6 % cyanopropylphenyl / 94 % dimethylpolysiloxane), 30 m × 0.32 mm, 1.8 µm; carrier He 2.0 ml/min; injector 220 °C, split 1:20, 1 µl; oven 40 °C for 2 min, 10 °C/min to 240 °C, hold 3 min (25 min); FID 260 °C. Sample: bacteriostatic water diluted 1:1 with internal-standard solution (2-phenylethanol 9.0 mg/ml in water); calibration 5 points 0.5 to 1.5 % w/v benzyl alcohol, r² = 0.9998.

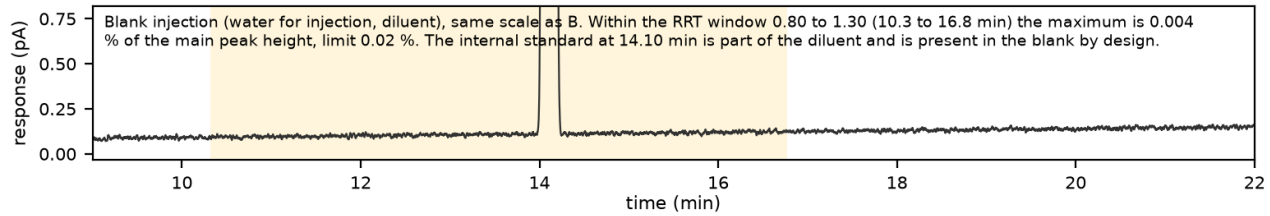
A. Full trace 0 to 25 min, full scale



B. Expanded view 0 to 0.1 % of the main peak height (0.8 pA); main peak Benzyl alcohol tR 12.90 min off scale; impurities above the 0.01 % reporting threshold, numbered as in the table; yellow band = RRT window 0.80 to 1.30



C. Blank injection before the sequence



D. Peak table and system suitability

Peak	tR (min)	RRT	Area (%)	Height (pA)	EI-MS m/z	Assignment
1	10.96	0.85	0.030	0.25	106, 105, 77	benzaldehyde (oxidation product)
2	12.00	0.93	0.008	0.07	96, 81, 67 (trace)	cyclohexylmethanol (below LOQ, not reported)
3	12.90	1.00	99.950	820		Benzyl alcohol (main peak)
4	14.10	1.09	n/a (IS)	672	122, 91, 92	2-phenylethanol (internal standard, 4.5 mg/ml after dilution)
5	20.90	1.62	0.020	0.12	198, 107, 91, 79	dibenzyl ether (synthesis by-product)

Benzyl alcohol 0.91 % w/v (9.1 mg/ml, 101 % of the 0.9 % label; limit 90 to 110 %) · related substances relative to benzyl alcohol: benzaldehyde 0.030 % (≤ 0.05 %), dibenzyl ether 0.020 % (≤ 0.10 %), total 0.05 % (≤ 0.3 %)

System suitability (USP <621>): resolution benzaldehyde / benzyl alcohol = 19 (≥ 2.0); tailing factor T = 1.1 (0.8 to 1.5); theoretical plates N = 254,000 (≥ 50,000, peak width at half height 0.06 min); S/N at 0.01 % = 14 (≥ 10); area ratio RSD of 6 standard injections (benzyl alcohol / IS) = 0.6 % (≤ 2.0 %); spike recovery 99.4 % (98 to 102 %).

Integration: reporting threshold 0.01 % relative to benzyl alcohol, LOD 0.003 %, LOQ 0.01 %; noise 0.03 pA peak to peak within ± 1 min of the main peak; baseline rise 0.1 pA over the temperature programme (column bleed); the water/air peak at 2.1 min is present in the blank and is not integrated. Cyclohexylmethanol at RRT 0.93 is below LOQ and is shown for information only.

Detector FID (USP Benzyl Alcohol monograph uses GC): linear carbon response, internal standard corrects injection volume; identity confirmed by GC-MS (EI, 70 eV) in a separate run: benzyl alcohol tR match ± 0.05 min, m/z 108 (M+•), 107, 79, 77, library match 96 %.

GC-FID RECORD OF THE SAME SAMPLE, SEQUENCE OF 2026-08-06: BENZYL ALCOHOL ASSAY WITH INTERNAL STANDARD 2-PHENYLETHANOL AND RELATED SUBSTANCES, DB-624 30 M × 0.32 MM 1.8 MM, 40 TO 240 °C; IDENTITY BY GC-MS (EI) IN A SEPARATE RUN. THE

COMPOUND SCREEN ITSELF WAS ACQUIRED BY GC-MS FULL SCAN AND LC-HRMS IN BOTH POLARITIES

Controls carried in the same sequence

Blank	Water for injection with internal standard injected before the sequence; within RRT 0.80 to 1.30 no peak above 0.02 % of the benzyl alcohol height (maximum 0.004 %) apart from the internal standard
Reference standard	USP Benzyl Alcohol RS (primary) injected at the start and end of the sequence; area ratio difference 0.3 %, retention time within 0.05 min; a commercial USP bacteriostatic water run as control sample within 2 % of its previous value

What these results do not establish

Each determination on this report answers one question. The limits below are the questions it does not answer, and every one of them is a mistake made routinely and in good faith by someone reading a certificate.

Bacterial endotoxins
Bacterial endotoxin is not sterility. A sample can be free of endotoxin and carry viable organisms, and it can be sterile and still pyrogenic. The two are separate determinations because they are separate properties.

Sterility
Sterility applies to the units tested, not to the batch they came from. It cannot be extrapolated to a container that was not sampled, and it is not a statement about pyrogens.

Residual solvents and volatile impurities
Residual solvents are reported for the solvents in the panel, at the limits stated. A solvent not in the panel was not looked for, and its absence from this report is not evidence of its absence from the sample.

Compound screening
A screen is bounded by the reference standards held on the day it was run. A compound for which no standard was available cannot be identified by it, and its absence from the result is not evidence of its absence from the sample.

NOT PERFORMED

Particulate matter by microscopy (USP <788> method 2)	light obscuration was applied
Extractables and leachables from the stopper	only a phthalate screen was run
In-use stability after the first puncture	the 28-day claim was not verified
Rabbit pyrogen test	replaced by the LAL test
Deliverable volume over repeated withdrawals and dissolved oxygen	not measured

Verify this certificate against the register



SCAN TO VERIFY

Scan the code, or open `https://analyton.com/verify/` and enter the report number with this key:

6S6QH3RABS

The register returns every result on this report, the date of issue and the current status.