



Specification

1.00987.0000 Benzyl alcohol special grade (benzaldehyde $\leq 0.05\%$) EMPROVE®
EXPERT Ph Eur, BP, JP, NF

	Specification	
Assay (GC)	98.0 - 100.5	%
Identity (IR)	conforms	
Appearance of solution (nephelometric)	conforms	
Clarity of solution	conforms	
Color of solution	conforms	
Acidity	conforms	
Refractive index (n 20/D)	1.538 - 1.541	
Density (d 20 °C/20 °C)	1.043 - 1.049	
Peroxide value	≤ 5.0	
Related substances (GC) (Benzaldehyde (Impurity A))	≤ 0.05	%
Related substances (GC) (Cyclohexylmethanol (Impurity B))	≤ 0.10	%
Related substances (GC) (Sum of peaks with a relative retention less than that of benzyl alcohol)	≤ 0.02	%
Related substances (GC) (Sum of peaks with a relative retention greater than that of benzyl alcohol)	≤ 0.20	%
Related substances (GC) (disregard limit)	≤ 0.0001	%
Benzene (GC)	≤ 0.0002	%
Chlorobenzene (GC)	≤ 0.01	%
Toluene (GC)	≤ 0.01	%
Other residual solvents (ICH Q3C)	excluded by manufacturing process	
Evaporation residue	≤ 0.050	%
Water	≤ 0.1	%
Bacterial endotoxins	≤ 2.5	I.U./ml
Total aerobic microbial count (TAMC)	≤ 100	CFU/g
Total combined yeasts/moulds count (TYMC)	≤ 10	CFU/g
Bile-tolerant gram-negative bacteria (absent in 1 g)	passes test	
Candida albicans (absent in 1 g)	passes test	
Escherichia coli (absent in 1 g)	passes test	
Pseudomonas aeruginosa (absent in 1 g)	passes test	
Salmonella (absent in 10 g)	passes test	
Staphylococcus aureus (absent in 1 g)	passes test	

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental impurities).
Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).

Conforms to Ph Eur, BP, JP, NF

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Jeannette David

Responsible laboratory manager quality control

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