



Specification

1.04002.1000 Formaldehyde solution about 37% stabilized with about 10% methanol
Ph Eur, BP, USP

	Specification	
Assay (iodometric)	36.5 - 38.0	%
Identity	conforms	
Color	passes test	
Appearance of solution	passes test	
Acidity (Ph Eur, BP)	passes test	
Acidity (according to USP)	passes test	
Free acid (as HCOOH)	≤ 0.03	%
Density (d 20 °C/ 4 °C)	1.08 - 1.09	g/ml
Chloride (Cl)	≤ 0.001	%
Heavy metals (as Pb)	≤ 0.0005	%
Fe (Iron)	≤ 0.0005	%
Methanol (GC)	9.0 - 11.0	%
Methanol (GC)	12.3 - 15.0	% (v/v)
Other residual solvents (ICH Q3C)	...excluded by production process	
Sulfated ash	≤ 0.1	%

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 (*).

Corresponds to Ph Eur, BP, USP

Dr. Reiner Vogt

Responsible laboratory manager quality control

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