



Certificate of Analysis

Productname: FORMALDEHYDE SOLUTION 35%

Inspection No: K08637/1223/536
Batchnumber: 23J23-T11-109408
Expiration date: 03.10.2025
Analysed according to: ČL 2017, Ph.Eur.11.0
Original Manuf. Date: 3.10.2023

Sample Unit: 1 x 10 ml
Batch Size: 59 x 1 l

Identification of producer: V01009
Batch no. of vendor: 2327605813

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Density	Conform	1,089	g/cm3		Fagron CZ
IDENTIFICATION					
Identification A	Violet	Conform			Fagron CZ
Identification B	Red	Conform			Fagron CZ
Identification C	Grey precipitate, silver mirror	Conform			Fagron CZ
Identification D	34,5 - 38,0	37,1	%	Assay	Fagron CZ
TESTS					
Appearance of solution	Colourless	Conform			Fagron CZ
Acidity	<=0,4	0,1	ml		Fagron CZ
Methanol	9,0 - 15,0	13,0	%(V/V)		Contract Lab
Sulfated ash	<=0,1	0,0	%		Fagron CZ
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer
ASSAY					
Formaldehyde	34,5 - 38,0	37,1	%		Fagron CZ

Quality: Excipient

Performed by: Ludmila Burianová

Responsible: Mgr. Zdeňka Šinclová, QC
 MVDr. Zdenka Borská, QP

Date: 04.12.2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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