



Certificate of Analysis

Productname: FORMALDEHYDE SOLUTION 35%

Inspection No: J10633/0223/536
Batchnumber: 22I29-T04-100263
Expiration date: 06.09.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 6.9.2022

Sample Unit: 1 x 10 ml
Batch Size: 31 x 1 l

Identification of producer: V01009
Batch no. of vendor: 2224905811

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Density	Conform	1,090	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	36,2	%	Assay	Fagron CZ
TESTS					
Appearance of solution	Colourless	Conform			Fagron CZ
Acidity	<=0,4	0,13	ml		Fagron CZ
Methanol	9,0 - 15,0	11,9	%(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	36,2	%		Fagron CZ

Quality: Excipient

Performed by: Pavla Šlázarová

Responsible: Ing. Pavel Mišák, QC
 MVDr. Zdenka Borská, QP

Date: 15.12.2022

Conclusion: APPROVED

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

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