



## Certificate of Analysis

**Productname:** FORMALDEHYDE SOLUTION 35%

**Inspection No:** J07557/0922/536  
**Batchnumber:** 22E24-T01-097535  
**Expiration date:** 09.05.2024  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 9.5.2022

**Sample Unit:** 1 x 10 ml  
**Batch Size:** 129 x 1 l

**Identification of producer:** V01009  
**Batch no. of vendor:** 2212905810

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Density	Conform	1,088	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	35,4	%	Assay	Fagron CZ
TESTS					
Appearance of solution	Colourless	Conform			Fagron CZ
Acidity	<=0,4	0,02	ml		Fagron CZ
Methanol	9,0 - 15,0	10,9	%(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	35,4	%		Fagron CZ

Quality: Excipient

**Performed by:** Pavla Šlázarová

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

**Date:** 14.09.2022

**Conclusion:** APPROVED

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

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