



## Certificate of Analysis

**Productname:** ACETONE

**Inspection No:** K03592/0723/536

**Sample Unit:** 1 x 25 ml

**Batchnumber:** 23E04-T07-103770

**Batch Size:** 197 x 5 l

**Expiration date:** 13.01.2026

**Analysed according to:** ČL 2017-Dopl.2019, Ph.Eur. 11.0

**Original Manuf. Date:** 13.1.2023

**Identification of producer:** V00327

**Batch no. of vendor:** PP/2023/05009

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Volatile, clear, colourless liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	0,790 - 0,793	0,792		Relative density	Fagron CZ
Identification B	Conform	Conform		Defined discoloration	Fagron CZ
Identification C	Conform	Conform		Defined discoloration	Fagron CZ
TESTS					
Appearance of solution	Clear, colourless	Conform		50% V/V	Fagron CZ
Acidity or alkalinity	<=0,5	Conform			Fagron CZ
Relative density	0,790 - 0,793	0,792			Fagron CZ
Reducing substances	Conform	Conform			Fagron CZ
Related substances	Conform	Conform		GC	Contract Lab
Impurity A	<=0,05	<0,05	% (V/V)		Contract Lab
Impurity B	<=0,05	<0,05	% (V/V)		Contract Lab
Impurity C	<=2	<2	ppm (V/V)		Contract Lab
Any other impurity	<=0,05	<0,05	% (V/V)		Contract Lab
Matter insoluble in water	Conform	Conform			Fagron CZ
Residue on evaporation	<=50	0,0	ppm		Fagron CZ
Water	<=3	1	g/l		Contract Lab
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

Quality: Excipient

**Performed by:** Ludmila Burianová

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

**Date:** 21.07.2023

**Conclusion:** **APPROVED**

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