



## Certificate of Analysis

**Productname:** ACETONE

**Inspection No:** J03226/0322/536

**Batchnumber:** 22B01-T08-093463

**Expiration date:** 13.10.2024

**Analysed according to:** ČL 2017-Dopl.2019,Ph.Eur.10.0

**Original Manuf. Date:** 31.10.2021

**Sample Unit:** 1 x 25 ml

**Batch Size:** 682 x 1 l

**Identification of producer:** V00327

**Batch no. of vendor:** PP/2021/12975

	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	0,791		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	0,791			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	µl/l		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	µg/g		Fagron CZ
Water	<=3	1	g/l		Contract Lab
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Quality: Excipient

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
	Kontrolní laboratoř č. 536	<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521

**Performed by:** Mgr. Zdeňka Šinclová

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

**Date:** 12.04.2022

**Conclusion:** **APPROVED**

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