



Certificate of Analysis

Productname: ACETONE

Inspection No: J03229/0322/536

Batchnumber: 22B01-T08-093466

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: 2,440 x 100 ml

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

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

Performed by: Mgr. Zdeňka Šinclová

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 12.04.2022

Conclusion: **APPROVED**

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