



Certificate of Analysis

Productname: ACETONE

Inspection No: L02618/0424/536
Batchnumber: 24C05-T02-110226
Expiration date: 25.10.2026
Analysed according to: ČL 2023, Ph. Eur. 11.0
Original Manuf. Date: 16.1.2024

Sample Unit: 1 x 25 ml
Batch Size: 1,300 x 100 ml

Identification of producer: V02026
Batch no. of vendor: PP/2024/00214

	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	0,793		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	0,793			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

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: QC Fagron a.s. (CZ)

Responsible: Mgr. Barbora Vránová, QC
MVDr. Zdenka Borská, QA/ QP

Date: 17.04.2024

Conclusion: **APPROVED**

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