

Certificate of Analysis

Productname: **ACETONE**

Inspection No: 106467/0921/536
 Batchnumber: **21E06-T03-089547**
 Expiration date: 25.01.2024
 Analysed according to: ČL 2017-Dopl.2019,Ph.Eur.10.0
 Original Manuf. Date: 25.1.2021

Sample Unit: 1 x 25 ml
 Batch Size: 300 x 5 l

Identification of producer: V00327
 Batch no. of vendor: PP/2021/03618

	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	Conform	% (V/V)		Contract Lab
Impurity B	<=0,05	Conform	% (V/V)		Contract Lab
Impurity C	<=2	Conform	µl/l		Contract Lab
Any other impurity	<=0,05	Conform	% (V/V)		Contract Lab
Matter insoluble in water	Conform	Conform			Fagron CZ
Residue on evaporation	<=50	0,0	µg/g		Fagron CZ
Water	<=3	2	g/l		Fagron CZ
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Performed by: Lucie Kubáňová DiS.

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

Date: 27.09.2021

Conclusion: **APPROVED**

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