



Certificate of Analysis

Productname: ACETONE

Inspection No: H10237/1220/536
Batchnumber: 20J22-T01-084211
Expiration date: 14.08.2023
Analysed according to: ČL 2017-Dopl.2019,Ph.Eur.10.0
Original Manuf. Date: 14.8.2020

Sample Unit: 1 x 25 ml
Batch Size: 195 x 5 l

Identification of producer: V00327
Batch no. of vendor: PP/2020/10129

	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	2	g/l		Fagron CZ
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Mgr. Kateřina Jokešová, QC
 PharmDr. Ivana Urbánková, QA

Date: 11.01.2021

Conclusion: APPROVED

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