



Certificate of Analysis

Productname: ACETONE

Inspection No: K09948/0124/536

Batchnumber: 23K10-T09-108244

Expiration date: 09.05.2026

Analysed according to: ČL 2017-Dopl.2019, Ph.Eur. 11.0

Original Manuf. Date: 12.10.2023

Sample Unit: 1 x 25 ml

Batch Size: 2,018 x 100 ml

Identification of producer: V00327

Batch no. of vendor: PP/2023/12377

	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	0,792		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	0,792			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	2	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

Performed by: Ludmila Stochlebová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 19.01.2024

Conclusion: **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.