

Certificate of Analysis

Productname: ACETONE

Inspection No: I04592/0621/536
Batchnumber: 21E06-T03-087100
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: 138 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: 08.07.2021

Conclusion: APPROVED

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