

## **Certificate of Analysis**

Productname: Acidum phosphoricum concentr.

 Inspection No:
 K03008/0723/536
 Sample Unit:
 1 x 25 ml

 Batchnumber:
 22C04-T09-103765
 Batch Size:
 7 x 100 ml

**Expiration date:** 30.11.2026

Analysed according to: ČL 2017-Dopl.2021,Ph.Eur.10.5

Original Manuf. Date: 15.11.2021

Identification of producer: V01486
Batch no. of vendor: K53916863

|                                      | Requirement                                   | Result  | Unit | Standard remark        | Insp. Site    |
|--------------------------------------|---|---------|------|------------------------|---------------|
|                                      |   |         |      |                        |               |
| CHARACTERS                           |   |         |      |                        |               |
| Appearance                           | Clear, colourless, syrupy liquid, corrosive.  | Conform |      |                        | Contract Lab  |
| Solubility                           | Conform                                       | Conform |      |                        | Contract Lab  |
| Relative density                     | About 1,7                                     | 1,695   |      |                        | Contract Lab  |
| IDENTIFICATION                       | ,   | ,       |      |                        |               |
| Identification A                     | Conform                                       | Conform |      | Strongly acid solution | Contract Lab  |
| Identification B                     | Yellow  | Conform |      | Phosphate              | Contract Lab  |
| TESTS                                |   |         |      |                        |               |
| Appearance of solution               | Clear and colourless                          | Conform |      |                        | Contract Lab  |
| Substances precipitated with ammonia | Conform                                       | Conform |      |                        | Contract Lab  |
| Hypophosphorous acid and phosphorou  | Conform                                       | Conform |      |                        | Contract Lab  |
| Chlorides                            | <=50  | <50     | μg/g |                        | Contract Lab  |
| Sulfates                             | <=100   | <100    | μg/g |                        | Contract Lab  |
| Iron                                 | <=50  | <50     | μg/g |                        | Contract Lab  |
| TSE/BSE                              | No contamination with TSE/BSE-risk materials. | Conform |      |                        | Data Producer |
| Residual solvents                    | CPMP/ICH/82 260/2006                          | Conform |      |                        | Data Producer |
| Metallic residues                    | ICH Q3D on elemental impurities               | Conform |      |                        | Data Producer |
| ASSAY                                |   |         |      |                        |               |
| Phosphoric acid                      | 84,0- 90,0                                    | 85,2    | %    |                        | Contract Lab  |

Quality: Excipient

Performed by: Ekocentrum

Responsible: Mgr. Zdeňka Šinclová, QC

MVDr. Zdenka Borská, QP

**Date:** 17.07.2023

Conclusion: APPROVED

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