



## Certificate of Analysis

**Productname:** Aqua conservata/Konserviertes Wasser DAC

**Inspection No:** H10721/1120/536  
**Batchnumber:** 20I03-T06-082486  
**Expiration date:** 30.11.2022  
**Analysed according to:** DAC 2018

**Sample Unit:** 1 x 250 ml  
**Batch Size:** 419 x 1 l

|                                     | Requirement                                   | Result  | Unit  | Standard remark | Insp. Site |
|-------------------------------------|-----------------------------------------------|---------|-------|-----------------|------------|
| CHARACTERS                          |                                               |         |       |                 |            |
| Appearance                          | Clear and colourless liquid.                  | Conform |       |                 |            |
| Odour (2.3.4)                       | Odour of Alkyl-4-hydroxybenzoates.            | Conform |       |                 |            |
| IDENTIFICATION                      |                                               |         |       |                 |            |
| B.Chrom.of Alkyl-4-hydroxybenzoates | Conform                                       | Conform |       | HPLC            |            |
| TESTS                               |                                               |         |       |                 |            |
| Appearance (2.2.1), (2.2.2)         | Clear, colourless                             | Conform |       |                 |            |
| pH (2.2.3)                          | 5,0 - 6,5                                     | 5,9     |       |                 |            |
| 4-hydroxybenzoic acid (2.2.29)      | Conform                                       | Conform |       | HPLC            |            |
| Microbiology                        | Conform                                       | Conform |       |                 |            |
| TAMC                                | <=2 x 10 <sup>2</sup>                         | Conform | CFU/g |                 |            |
| TYMC                                | <=2 x 10 <sup>1</sup>                         | Conform | CFU/g |                 |            |
| Pseudomonas aeruginosa              | negative/1g                                   | Conform |       |                 |            |
| Staphylococcus aureus               | negative/1g                                   | Conform |       |                 |            |
| TSE/BSE                             | No contamination with TSE/BSE-risk materials. | Conform |       |                 |            |
| Residual solvents                   | CPMP/CH/82 260/2006                           | Conform |       |                 |            |
| ASSAY                               |                                               |         |       |                 |            |
| Propyl 4-hydroxybenzoate            | 0,024 - 0,026                                 | 0,024   | %     | HPLC            |            |
| Methyl 4-hydroxybenzoate            | 0,071 - 0,079                                 | 0,075   | %     | HPLC            |            |

**Performed by:** Jitka Spáčilová

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

**Date:** 18.12.2020

**Conclusion:** APPROVED

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