



Certificate of Analysis

Productname: Aqua conservata/Konserviertes Wasser DAC

Inspection No: H10718/1120/536
Batchnumber: 20103-T04-082478
Expiration date: 30.11.2022
Analysed according to: DAC 2018

Sample Unit: 1 x 250 ml
Batch Size: 492 x 250 ml

| | 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 | 6,0 | | | |
| 4-hydroxybenzoic acid (2.2.29) | Conform | Conform | | HPLC | |
| Microbiology | Conform | Conform | | | |
| TAMC | $\leq 2 \times 10^2$ | Conform | CFU/g | | |
| TYMC | $\leq 2 \times 10^1$ | 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/ICH/82 260/2006 | Conform | | | |
| ASSAY | | | | | |
| Propyl 4-hydroxybenzoate | 0,024 - 0,026 | 0,025 | % | HPLC | |
| Methyl 4-hydroxybenzoate | 0,071 - 0,079 | 0,074 | % | HPLC | |

Performed by: Jitka Spáčilová

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

Date: 15.12.2020

Conclusion: APPROVED

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