

## Certificate of Analysis

**Productname:** Aqua purificata Bag In Box

**Inspection No:** I03665/0421/536

**Sample Unit:** 1 x 2 l

**Batchnumber:** 21C23-T06-087185

**Batch Size:** 1 344 x 2 l

**Expiration date:** 30.04.2024

**Analysed according to:** ČL 2017-Dopl.2018, Ph.Eur.10.0

**Identification of producer:** V01454

|                        | Requirement                  | Result  | Unit    | Standard remark | Insp. Site |
|------------------------|------------------------------|---------|---------|-----------------|------------|
| CHARACTERS             |                              |         |         |                 |            |
| Appearance             | Clear and colourless liquid. | Conform |         |                 |            |
| TESTS                  |                              |         |         |                 |            |
| Conductivity           | ≤5,1                         | 1,0     | μS.cm-1 |                 |            |
| Nitrates               | ≤0,2                         | <0,2    | μg/g    |                 |            |
| Acidity or alkalinity  | Conform                      | Conform |         |                 |            |
| Oxidisable substances  | Conform                      | Conform |         |                 |            |
| Chlorides              | Conform                      | Conform |         |                 |            |
| Sulphates              | Conform                      | Conform |         |                 |            |
| Ammonium               | ≤0,2                         | <0,2    | μg/g    |                 |            |
| Calcium and magnesium  | Conform                      | Conform |         |                 |            |
| Residue on evaporation | ≤0,001                       | 0,0008  | %       |                 |            |
| Microbiology           | Conform                      | Conform |         |                 |            |
| TAMC                   | ≤102                         | <102    | CFU/g   |                 |            |
| Metallic residues      | CHMP/ICH/353369/2013         | Conform |         |                 |            |

**Performed by:** SVU

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



**Date:** 05.05.2021

**Conclusion:** APPROVED

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