

## Certificate of Analysis

**Productname:** Aqua purificata Bag In Box

**Inspection No:** H08525/0920/536

**Batchnumber:** 20D06-T15-078567

**Expiration date:** 31.08.2023

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

**Sample Unit:** 1 x 5 l

**Batch Size:** 1 532 x 5 l

**Identification of producer:** V01454

|                        | Requirement                  | Result  | Unit                  | Standard remark | Insp. Site |
|------------------------|------------------------------|---------|-----------------------|-----------------|------------|
| CHARACTERS             |                              |         |                       |                 |            |
| Appearance             | Clear and colourless liquid. | Conform |                       |                 |            |
| TESTS                  |                              |         |                       |                 |            |
| Conductivity           | $\leq 5,1$                   | 0,90    | $\mu\text{S.cm}^{-1}$ |                 |            |
| Nitrates               | $\leq 0,2$                   | <0,2    | $\mu\text{g/g}$       |                 |            |
| Acidity or alkalinity  | Conform                      | Conform |                       |                 |            |
| Oxidisable substances  | Conform                      | Conform |                       |                 |            |
| Chlorides              | Conform                      | Conform |                       |                 |            |
| Sulphates              | Conform                      | Conform |                       |                 |            |
| Ammonium               | $\leq 0,2$                   | <0,2    | $\mu\text{g/g}$       |                 |            |
| Calcium and magnesium  | Conform                      | Conform |                       |                 |            |
| Residue on evaporation | $\leq 0,001$                 | 0,0007  | %                     |                 |            |
| Microbiology           | Conform                      | Conform |                       |                 |            |
| TAMC                   | $\leq 102$                   | <102    | CFU/g                 |                 |            |
| Metallic residues      | CHMP/ICH/353369/2013         | Conform |                       |                 |            |

**Performed by:** SVU

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



**Date:** 24.09.2020

**Conclusion:** APPROVED

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