

**ANALYSIS CERTIFICATE**

**CODE:** 141750

**BATCH:** 0002259910

**PRODUCT:** Triethanolamine (USP-NF) pure, pharma grade

**ISSUE DATE:** 14/03/2023

**RETEST DATE:** 03/2029

| SPECIFICATIONS                            | GUARANTEE VALUE | ACTUAL VALUE |
|-------------------------------------------|-----------------|--------------|
| Assay (Acidim.)                           | 99,0-107,4%     | 99,3%        |
| Identity according to Pharmacopoeias:     | passes test     | passes test  |
| Density 25/25                             | 1,120-1,128     | 1,123        |
| Refractive index n 20/D                   | 1,482-1,485     | 1,484        |
| Maximum limit of impurities               |                 |              |
| Residue on ignition (as SO <sub>4</sub> ) | 0,05 %          | 0,001 %      |
| Total bases                               | passes test     | passes test  |
| Related substances                        | passes test     | passes test  |
| Residual solvents (Ph.Eur/USP)            | passes test     | passes test  |
| Water (H <sub>2</sub> O)                  | 0,15 %          | 0,09 %       |
| Heavy metals (as Pb)                      | 0,0005%         | <0,0005%     |
| Elemental impurities (ICH Q3D):           |                 |              |
| Class 1                                   |                 |              |
| Cd                                        | 0,5 ppm         | <0,5 ppm     |
| Pb                                        | 0,5 ppm         | <0,5 ppm     |
| As                                        | 1,5 ppm         | <1,5 ppm     |
| Hg                                        | 1,5 ppm         | <1,5 ppm     |
| Class 2A                                  |                 |              |
| Co                                        | 5 ppm           | <5 ppm       |
| V                                         | 10 ppm          | <10 ppm      |
| Ni                                        | 20 ppm          | <20 ppm      |
| Class 2B                                  |                 |              |
| Tl                                        | 0,8 ppm         | <0,8 ppm     |
| Au                                        | 10 ppm          | <10 ppm      |
| Pd                                        | 10 ppm          | <10 ppm      |
| Ir                                        | 10 ppm          | <10 ppm      |
| Os                                        | 10 ppm          | <10 ppm      |
| Rh                                        | 10 ppm          | <10 ppm      |
| Ru                                        | 10 ppm          | <10 ppm      |
| Se                                        | 15 ppm          | <15 ppm      |
| Ag                                        | 15 ppm          | <15 ppm      |
| Pt                                        | 10 ppm          | <10 ppm      |
| Class 3                                   |                 |              |
| Li                                        | 55 ppm          | <55 ppm      |
| Sb                                        | 120 ppm         | <120 ppm     |
| Ba                                        | 140 ppm         | <140 ppm     |
| Mo                                        | 25 ppm          | <25 ppm      |
| Cu                                        | 250 ppm         | <250 ppm     |
| Sn                                        | 600 ppm         | <600 ppm     |
| Cr                                        | 25 ppm          | <25 ppm      |

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