

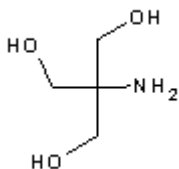


**PRODUCT CODE: Z41940**

**Tris (USP, BP, Ph. Eur.) low endotoxin pure, pharma grade**

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$C_4H_{11}NO_3$



M.= 121,14

CAS [77-86-1]

EINECS 201-064-4

TARIC 2922 19 00 90

**SYNONYMS:** 2-Amino-2-Hydroxymethyl-1,3-Propanediol, THAM, Tris, Trizma, Trometamol, Tromethamine, Tromethylol Aminomethane

**PHYSICAL DATA:** crystalline powder, White, Soluble in water 550 g/l at 25 °C M.P.: 171 - 172 °C • B.P.: 219 - 220 °C • pH(0.1 M)10,4 • pKa20 °C8,3 •

**BIBLIOGRAPHY:** Merck Index **13**, 9.842 Sax **TEM500** • Safety **2**, **3532 A** • Beilstein **4**, **303 IV**, **1903** • BRN 741883 • ACS **XI** • BP.**2025** • USP **43** • Ph. Eur. **10.0** (2019) **11.0** (2023) • Royal Decree **I1725** •

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**HAZARDOUS:** RTECS: TY 2900000 • LD L0 oral rbt 1.000 mg/kg • LD50 oral rat 5.900 mg/kg •

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#### SPECIFICATIONS:

|                                       |               |
|---------------------------------------|---------------|
| Assay (Acidim) calc. a.d.s.           | 99,0 -100,5 % |
| Identity :                            |               |
| Identity according to Pharmacopoeias: | passes test   |
| pH sol. 10 %                          | 10,0 - 11,5   |
| pH sol. 5 %                           | 10,0 - 11,5   |
| Melting range                         | 168 - 172 °C  |

**Maximum limit of impurities**

|                                                          |             |
|----------------------------------------------------------|-------------|
| ABS                                                      |             |
| at $\lambda$ a 290 nm, 1 cm 40% sol. in H <sub>2</sub> O | 0,1         |
| Appearance of solution                                   | passes test |
| Insoluble matter in H <sub>2</sub> O                     | 0,025 %     |
| Loss on drying at 105°C                                  | 0,5 %       |
| Residue on ignition (as SO <sub>4</sub> )                | 0,1 %       |
| Chloride (Cl)                                            | 0,003 %     |
| Microbial Limits                                         |             |
| Bacterial endotoxins                                     | 2,5 UI/g    |
| Total Aerobic Microbial Count (TAMC)                     | 1000 cfu/g  |
| Total combined yeast and moulds (TYMC)                   | 100 cfu/g   |
| Residual solvents (Ph.Eur/USP)                           | passes test |
| Related substances (T.L.C.)                              | 1,0 %       |
| Heavy metals (as Pb)                                     | 0,001 %     |
| Fe                                                       | 0,001 %     |
| Elemental impurities (ICH Q3D):                          |             |
| Class 1                                                  |             |
| Cd                                                       | 0,5 ppm     |
| Pb                                                       | 0,5 ppm     |
| As                                                       | 1 ppm       |
| Hg                                                       | 1,5 ppm     |
| Class 2A                                                 |             |
| Co                                                       | 5 ppm       |
| V                                                        | 10 ppm      |
| Ni                                                       | 20 ppm      |
| Class 2B                                                 |             |
| Tl                                                       | 2 ppm       |
| Au                                                       | 10 ppm      |
| Pd                                                       | 10 ppm      |
| Ir                                                       | 10 ppm      |
| Os                                                       | 10 ppm      |
| Rh                                                       | 10 ppm      |
| Ru                                                       | 10 ppm      |
| Se                                                       | 15 ppm      |
| Ag                                                       | 15 ppm      |
| Pt                                                       | 10 ppm      |
| Class 3                                                  |             |
| Li                                                       | 55 ppm      |
| Sb                                                       | 120 ppm     |
| Ba                                                       | 140 ppm     |
| Mo                                                       | 25 ppm      |
| Cu                                                       | 250 ppm     |
| Sn                                                       | 600 ppm     |
| Cr                                                       | 25 ppm      |