



Specification for Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED(TM) (T9700)

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|-------------------|--|
| Item Number | T9700 |
| Item | Tris(hydroxymethyl)aminomethane, USP, EP, BP, bioCERTIFIED(TM) |
| CAS Number | 77-86-1 |
| Molecular Formula | C ₄ H ₁₁ NO ₃ |
| Molecular Weight | 121.14 |
| MDL Number | |
| Synonyms | Tromethamine ; Trismat® ; Trometamol ; TRIS ; TRIS Base |

| Test | Specification | |
|--|---|------------|
| | Min | Max |
| APPEARANCE | WHITE OR ALMOST WHITE, CRYSTALLINE POWDER OR COLORLESS CRYSTALS | |
| ASSAY BY TITRATION (DRI ED BAS IS) (USP) | 99.0 | 101.0% |
| ASSAY BY TITRATION (DRIED BASIS) (EP/BP) | 99.0 | 100.5% |
| MELTING RANGE (USP) | 168° | 172°C |
| pH OF A 5% SOLUTION @ 25°C (USP/EP/BP) | 10 .0 | 11.5 |
| APPEARANCE OF SOLUTION (EP/BP) | CLEAR AND COLORLESS | |
| APHA COLOR, 20% AQUEOUS SOLUTION | | 20 |
| LOSS ON DRYING (USP) | | 1.0% |
| LOSS ON DRYING (EP/BP) | | 0.5% |
| RESIDUE ON IGNITION (USP) | | 0.1% |
| SULFATED ASH (EP/BP) | | 0.1% |
| CHLORIDES (EP/BP) | | 100 ppm |
| IRON (EP/BP) | | 10 ppm |
| RELATED SUBSTANCES (EP/BP) | | 1.0% |
| ELEMENTAL IMPURITIES | AS REPORTED | |
| MICROBIAL LIMITS: | | |
| TAMC | | 1000 CFU/g |
| TYMC | | 100 CFU/g |
| ENDOTOXIN | | 0.03 EU/mg |
| IDENTIFICATION (A) USP | SPECTRUM MATCHES REFERENCE | |
| IDENTIFICATION (B) USP | YELLOW COLOR IS PRODUCED | |

| Test | Specification | |
|----------------------------|---|-------|
| | Min | Max |
| IDENTIFICATION (C) USP | THE COLOR CHANGES FROM LIGHT YELLOW TO ORANGE | |
| IDENTIFICATION : A (EP/BP) | STRONGLY ALKALINE | |
| IDENTIFICATION : B (EP/BP) | 168°C | 174°C |
| IDENTIFICATION : C (EP/BP) | SPECTRUM MATCHES REFERENCE | |
| IDENTIFICATION D (EP/BP) | SAMPLE CORRESPONDS TO STANDARD | |
| EXPIRATION DATE | | |
| MANUFACTURE DATE | | |
| MONOGRAPH EDITION | | |
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| RESIDUAL SOLVENTS | AS REPORTED | |

Spectrum Chemical Mfg Corp

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|--------------------------------|-----------------------------|
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