

SPECIFICATION

Trometamol

Japanese Pharmaceutical Codex

REQUIREMENT	SPECIFICATION
* Description (JPC) Identification (JPC) pH (JPC) Melting point (JPC) Purity (JPC) (1) Clarity and color of solution (JPC) (2) Heavy metals (JPC) (3) Arsenic (JPC) Loss on drying (JPC) Residue on ignition (JPC) Assay (after drying) (JPC) Identification (USP-NF) Assay (dried basis) (USP-NF) Impurities (USP-NF) (1) Residue on ignition (USP-NF) Specific tests (USP-NF) (1) Melting range or temperature (USP-NF) (2) pH (USP-NF) (3) Loss on drying (USP-NF)	White crystalline powder to pass test 10.3~10.7 168~172°C - to pass test not more than 8ppm not more than 1.6ppm not more than 0.5% not more than 0.10% not less than 99.0% to pass test 99.0~101.0% - NMT 0.1% - 168~172°C 10.0~11.5 NMT 1.0%
* Appearance (Ph.Eur.) Identification (Ph.Eur.) Appearance of solution (Ph.Eur.) pH (Ph.Eur.) Related substances (Ph.Eur.) Chlorides (Ph.Eur.) Iron (Ph.Eur.) Loss on drying (Ph.Eur.) Sulfated ash (Ph.Eur.) Bacterial endotoxins (Ph.Eur.)	White or almost white, crystalline powder, or colourless crystals to pass test to pass test 10.0 to 11.5 to pass test not more than 100ppm not more than 10ppm not more than 0.5% not more than 0.1% less than 0.03IU/mg

Japanese Pharmaceutical Codex(Trometamol)(* : Additional test performed by Wako)United States Pharmacopeia - National Formulary(Trometamine)European Pharmacopoeia(Tromethamol)(* : Additional test performed by Wako)