

SPECIFICATION

Trometamol

Japanese Pharmaceutical Codex

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