2022/01/19
Distributed by FUJIFILM Wako Pure Chemical Corporation
Manufactured by FUJIFILM Wako Pure Chemical Corporation

Code No.20-2058

SPECIFICATION

Trometamol

Japanese Pharmaceutical Codex

REQUIREMENT		SPECIFICATION
*	Description	White crystalline powder
	Identification	to pass test
	pH	10.3～10.7
	Melting point	168～172℃
	Purity	-
(1)	Clarity and color of solution	to pass test
(2)	Heavy metals	not more than 8ppm
(3)	Arsenic	not more than 1.6ppm
	Loss on drying	not more than 0.5%
	Residue on ignition	not more than 0.10%
	Assay (after drying)	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℃
(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 colourless crystals
	Identification (Ph.Eur.)	to pass test
	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

Assay (dried substance) (Ph.Eur.)	99.0～100.5%

(1/3)Japanese Pharmaceutical Codex(Tromethamol)(*:Additional test performed by Wako)(2/3)United States Pharmacopeia - National Formulary)(Tromethamine)(3/3)European Pharmacopoeia(Tromethamol)(*:Additional test performed by Wako)

revised on 2018/04/19