2024/07/01
Distributed by FUJIFILM Wako Pure Chemical Corporation
Manufactured by FUJIFILM Wako Pure Chemical Corporation

Code No.20-2103

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℃
	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℃
(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%

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

revised on 2024/05/17