

SPECIFICATION

Sodium Chloride

Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description (JP)	Colorless or white, crystals or crystalline powder
Identification (JP)	to pass test
Purity (JP)	-
(1) Clarity and color of solution (JP)	to pass test
(2) Acidity or alkalinity (JP)	to pass test
(3) Sulfates (JP)	to pass test
(4) Phosphates (JP)	to pass test
(5) Bromides (JP)	to pass test
(6) Iodides (JP)	to pass test
(7) Ferrocyanides (JP)	to pass test
(8) Heavy metals (JP)	not more than 3ppm
(9) Iron (JP)	to pass test
(10) Barium (JP)	to pass test
(11) Magnesium and alkaline-earth materials (JP)	to pass test
(12) Arsenic (JP)	not more than 2ppm
Loss on drying (JP)	not more than 0.5%
Assay (NaCl) (calculated on the dried basis) (JP)	99.0~100.5%
Identification (USP-NF)	to pass test
Assay (NaCl) (USP-NF)	99.0~100.5%
Impurities (USP-NF)	-
(1) Arsenic (USP-NF)	NMT 1ppm
(2) Barium (USP-NF)	to pass test
(3) Ferrocyanides (USP-NF)	to pass test
(4) Iodides (USP-NF)	to pass test
(5) Iron (USP-NF)	NMT 2ppm
(6) Limit of bromides (USP-NF)	NMT 100ppm
(7) Limit of phosphates (USP-NF)	NMT 25ppm
(8) Magnesium and alkaline-earth metals (calculated as Ca) (USP-NF)	NMT 100ppm
(9) Nitrites (USP-NF)	NMT 0.01

(10) Sulfate (USP-NF)	NMT 200ppm
Specific tests (USP-NF)	-
(1) Appearance of solution (USP-NF)	to pass test
(2) Acidity or alkalinity (USP-NF)	to pass test
(3) Loss on drying (USP-NF)	NMT 0.5%
(4) Bacterial endotoxins test (USP-NF)	less than 3.1EU/g *
* Appearance (Ph.Eur.)	White or almost white, crystalline powder or colourless crystals or white or almost white pearls
Identification (Ph.Eur.)	to pass test
Appearance of solution (Ph.Eur.)	to pass test
Acidity or alkalinity (Ph.Eur.)	to pass test
Bromides (Ph.Eur.)	maximum 100ppm
Ferrocyanides (Ph.Eur.)	to pass test
Iodides (Ph.Eur.)	to pass test
Nitrites (Ph.Eur.)	to pass test
Phosphates (Ph.Eur.)	maximum 25ppm
Sulfates (Ph.Eur.)	maximum 200ppm
Arsenic (Ph.Eur.)	maximum 1ppm
Barium (Ph.Eur.)	to pass test
Iron (Ph.Eur.)	maximum 2ppm
Magnesium and alkaline-earth metals (calculated as Ca) (Ph.Eur.)	maximum 100ppm
Loss on drying (Ph.Eur.)	maximum 0.5%
Bacterial endotoxins (Ph.Eur.)	less than 3.1IU/g **
Assay (NaCl) (Ph.Eur.)	99.0~100.5%

Japanese Pharmacopoeia(Sodium Chloride)(*:Additional test performed by Wako)United States Pharmacopeia - National Formulary(Sodium Chloride)(*:The specification is originally set by Wako)European Pharmacopoeia(Sodium Chloride)(*:Additional test performed by Wako)(**:The specification is originally set by Wako)