

## SPECIFICATION

## Sodium Bicarbonate

## Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description (JP)	White crystals or crystalline powder
Identification (JP)	to pass test
pH (JP)	7.9~8.4
Purity (JP)	-
(1) Clarity and color of solution (JP)	to pass test
(2) Chloride (JP)	not more than 0.040%
(3) Carbonate (JP)	to pass test
(4) Ammonium (JP)	to pass test
Assay (NaHCO <sub>3</sub> ) (JP)	not less than 99.0%
* Bacterial endotoxins	less than 10EU/g
Identification (USP-NF)	to pass test
Assay (USP-NF)	99.0~100.5%
Impurities (USP-NF)	-
(1) Insoluble substances (USP-NF)	to pass test
(2) Normal carbonate (USP-NF)	to pass test
(3) Chloride (USP-NF)	NMT 0.015%
(4) Limit of sulfur compounds (USP-NF)	NMT 0.015%
(5) Arsenic (USP-NF)	NMT 2 ppm
(6) Limit of ammonia (USP-NF)	NMT 20 ppm
Specific tests (USP-NF)	-
(1) Loss on drying (USP-NF)	NMT 0.25%
Identification (Ph.Eur.)	to pass test
Appearance of solution (Ph.Eur.)	to pass test
Carbonates (Ph.Eur.)	to pass test
Chlorides (Ph.Eur.)	maximum 150ppm
Sulfates (Ph.Eur.)	maximum 150ppm
Ammonium (Ph.Eur.)	maximum 20ppm
Calcium (Ph.Eur.)	maximum 100ppm
Iron (Ph.Eur.)	maximum 20ppm

Japanese Pharmacopoeia (Sodium Bicarbonate)(\*):Additional test performed by Wako)United States Pharmacopeia - National Formulary (Sodium Bicarbonate)European Pharmacopoeia (Sodium Hydrogen Carbonate)