

## SPECIFICATION

## Acetylcysteine

## Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description (JP)	White crystals or crystalline powder
Identification (JP)	to pass test
Optical rotation [ $\alpha$ ] <sub>D20</sub> (JP)	+21.0~+27.0°
Melting point (JP)	107~111°C
Purity (JP)	-
(1) Chloride (JP)	not more than 0.040%
(2) Sulfates (JP)	not more than 0.030%
(3) Ammonium (JP)	not more than 0.02%
(4) Iron (JP)	not more than 10ppm
(5) Related substances (JP)	to pass test
Loss on drying (JP)	not more than 0.5%
Residue on ignition (JP)	not more than 0.3%
Assay (calculated on the dried basis) (JP)	99.0~101.0%
* Bacterial endotoxins	less than 10EU/g
Identification (USP-NF)	to pass test
Assay (dried basis) (USP-NF)	98.0~102.0%
Impurities (USP-NF)	-
(1) Residue on ignition (USP-NF)	NMT 0.5%
Specific tests (USP-NF)	-
(1) Optical rotation (USP-NF)	+21~+27°
(2) pH (USP-NF)	2.0~2.8
(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
Specific optical rotation (Ph.Eur.)	+21.0~+27.0°
Related substances (Ph.Eur.)	to pass test
Zinc (Ph.Eur.)	maximum 10ppm
Loss on drying (Ph.Eur.)	maximum 1.0%

Sulfated ash (Ph.Eur.)	maximum 0.2%
Assay (dried substance) (Ph.Eur.)	98.5~101.0%

The Japanese Pharmacopoeia (Acetylcysteine)(\*):Additional test performed by Wako)United States Pharmacopeia - National Formulary (Acetylcysteine)European Pharmacopoeia (Acetylcysteine)(\*):Additional test performed by Wako)