

## SPECIFICATION

## Acetylcysteine

## Japanese Pharmacopoeia

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

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

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