

## SPECIFICATION

## Sucrose

## Japanese Pharmacopoeia

| REQUIREMENT   | SPECIFICATION  |
|---|--|
| * Description (JP)<br>Identification (JP)<br>Optical rotation (JP)<br>Purity (JP)<br>(1) Color value (JP)<br>(2) Clarity of solution (JP)<br>(3) Sulfite (as SO <sub>2</sub> ) (JP)<br>(4) Reducing sugars (JP)<br>Conductivity (JP)<br>Loss on drying (JP)<br>Dextrins (JP)<br>Bacterial endotoxins (JP)<br>Identification (USP-NF)<br>Impurities (USP-NF)<br>(1) Sulfite (USP-NF)<br>Specific tests (USP-NF)<br>(1) Appearance of solution (USP-NF)<br>(2) Conductivity (USP-NF)<br>(3) Optical rotation (USP-NF)<br>(4) Color value (USP-NF)<br>(5) Dextrins (USP-NF)<br>(6) Reducing sugars (USP-NF)<br>(7) Loss on drying (USP-NF)<br>(8) Bacterial endotoxins test (USP-NF) | White crystalline powder, or lustrous colorless or white crystals to pass test<br>+66.3~+67.0°<br>-<br>not more than 45<br>to pass test<br>not more than 10ppm<br>to pass test<br>not more than 35 μS·cm <sup>-1</sup><br>not more than 0.1%<br>to pass test<br>less than 2EU/g **<br>to pass test<br>-<br>to pass test<br>-<br>to pass test<br>NMT 35 μS·cm <sup>-1</sup><br>+66.3~+67.0°<br>NMT 45<br>to pass test<br>to pass test<br>NMT 0.1%<br>less than 2IU/g ** |
| * Appearance (Ph.Eur.)<br>Identification (Ph.Eur.)<br>Appearance of solution (Ph.Eur.)<br>Conductivity (Ph.Eur.)<br>Specific optical rotation (Ph.Eur.)   | White or almost white, crystalline powder, or lustrous, colourless or white or almost white crystals to pass test<br>to pass test<br>maximum 35 μS·cm <sup>-1</sup><br>+66.3~+67.0°  |

|   |                    |
|---|--------------------|
| Colour value (Ph.Eur.)                  | maximum 45         |
| Dextrins (Ph.Eur.)                      | to pass test       |
| Reducing sugars (Ph.Eur.)               | to pass test       |
| Sulfites(as SO <sub>2</sub> ) (Ph.Eur.) | maximum 10ppm      |
| Loss on drying (Ph.Eur.)                | maximum 0.1%       |
| Bacterial endotoxins (Ph.Eur.)          | less than 2IU/g ** |

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