



Specifications

Trehalose SG

Description	Non-reducing disaccharide
Appearance	Odorless and white crystalline powder
Storage	Keep in a cool, dark and dry place
Expiry life	3 years after production

Variables	Specifications	Methods
Identification		
(a)	The solution turns to violet.	Notes 1
(b)	The solution does not turns to brown.	Notes 2
Optical rotation [α] ₂₀	+197-+201 °	JP
pH	4.5-6.5	JP
Purity test		
Chloride	Not more than 0.018%	JP
Sulfate	Not more than 0.024%	JP
Heavy metals (as Pb)	Not more than 5ppm	JP
Soluble starch Dextrin & sulfites	The solution does turn to blue by Iodine TS.	Notes 3
Nitrogen	Not more than 0.005%	JP
Water	Not more than 11.0%	JP
Residue on ignition	Not more than 0.1%	JP
Purity (d.s.b.)	Not less than 99.0%	Notes 4
Microbial limits		
- Salmonella sp.	Not detected	JP
- E.coli	Not detected	JP
Bacterial endotoxin	Not more than 0.6 EU/g	JP

JP... THE JAPANESE PHARMACOPOEIA (JP)

[Notes]

1. After adding 5-6 drops of a solution containing 1-naphthol in 95% ethanol (1 in 20) to 1mL of a solution of Trehalose (2 in 5) , mix thoroughly and gently add 2 mL of sulfuric acid: a violet color develops at the interface between the solutions.

2. After adding 1 mL of diluted hydrochloric acid to 2 mL of a solution of Trehalose (1 in 25), mix thoroughly and allow to stand for 20 minutes at room temperature. Add 4 mL of sodium hydroxide TS and 2 mL of Glycine solution (1 in 25), and heat for 10 minutes in boiling water: a brown color does not develop.



3. When add 1 drop of Iodine test solution to 10 mL of a solution of Trehalose (1 in 10), a yellow color develops. Then add 1 drop of starch test solution to this portion, a blue color develops.

4. Standard preparation •• Weigh accurately about 500mg of Trehalose RS (not less than 99.8%), calculated on the anhydrous basis, in a 50 mL volumetric flask, and add 5 mL of *glycerin solution* (1 in 10) and dissolve in water to make volume.

Assay preparation •• Weigh accurately about 500 mg of Trehalose, calculated on the anhydrous basis, in a 50 mL volumetric flask, and add 5 mL of *glycerin solution* (1 in 10) and dissolve in water to make volume.

Procedure •• Separately inject equal volumes (about 20 μ L) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks, Calculate the percentage of C₁₂H₂₂O₁₁ in the portion of Trehalose taken by the formula:

$$100 \times W_s / W_t \times Q_t / Q_s$$

in which W_s and W_t are the weight (mg) of Trehalose RS in the *Standard preparation* and Trehalose in the *Assay preparation*: and Q_t and Q_s are the ratio of the peaks responses of Trehalose and glycerin obtained from the *Assay preparation* and the *Standard preparation*, respectively.