

TREHALOSE SG JP, USP-NF, Ph.Eur., CP

Injectable grade

Heat-stability of TREHALOSE SG

Material

TREHALOSE SG Lot No. 4D04

Preparation of test solutions

TREHALOSE SG (dihydrate crystal) aqueous solutions were prepared at concentrations of 33, 40 and 50 g/L.

Heating conditions of solutions and evaluation of Trehalose content

Forty (40) mL each of the Trehalose solutions were poured into glass containers and heated at 122°C for 0, 20, 40, 60 or 120 min.

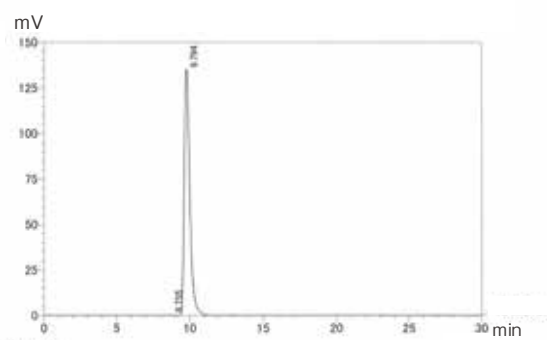
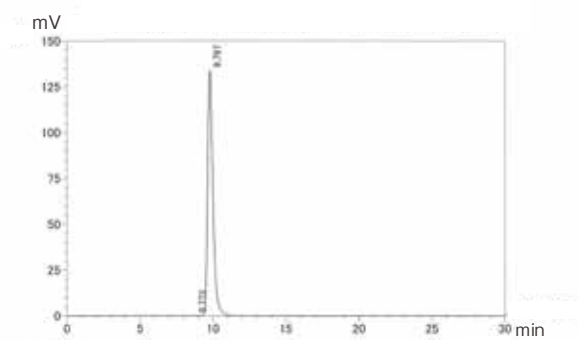
The solutions were analyzed by HPLC and the Trehalose content (%) was calculated by the Area normalization method.

Results

No changes in Trehalose content were observed even when the solutions were heated at 122°C for 120 min.

Trehalose content (%) before and after heating

Heating condition	0 min	122°C 20 min	122°C 40 min	122°C 60 min	122°C 120 min
Trehalose 33 g/L	99.96	99.95	99.96	99.95	99.96
Trehalose 40 g/L	99.96	99.96	99.96	99.95	99.96
Trehalose 50 g/L	99.96	99.96	99.96	99.96	99.95



Chromatograms of TREHALOSE SG solution (50 g/L) heated at 122°C for 0 min left, and 120 min right.

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