

D-(+)-Trehalose dihydrate

Meets USP-NF, EP, BP and JP testing specifications

Product Code: TC177M

Product Description :

Molecular weight: 378.33

Molecular formula: $C_{12}H_{22}O_{11} \cdot 2H_2O$

CAS No.: 6138-23-4

Quality Control:

Appearance (USP)

White odourless, nonhygroscopic crystalline powder.

Appearance (EP, BP)

White or almost white, crystalline powder.

Appearance (JP)

White crystals or crystalline powder

Solubility (USP)

Soluble in water, solubility increase with temp.; practically insoluble in dehydrated alcohol

Solubility (EP, BP)

Freely soluble in water, slightly soluble in methanol, practically insoluble in ethanol(96%)

Solubility (JP)

It is freely soluble in water, and slightly soluble in methanol & in ethanol (99.5%).

Identification 1 (JP)

A purple color appears at the zone of contact

Identification A : FTIR (USP, EP, BP)

Matches with the standard pattern

Identification 2 (JP)

No brown colour appears

Identification B (USP)

A violet colour develops at the interface between the two solutions

Identification B (EP, BP)

A violet colour develops at the interface

Identification 3 (JP)

Both spectra exhibits similar intensities of absorption at the same wave numbers

Identification C (USP, EP, BP)

No brown colour developed

Appearance of solution (EP, BP)

10% solution in water is clear and colourless

Colour & clarity of solution (USP)

The absorbance difference is NMT 0.100

pH (10% w/v sol at 25°C (USP, EP, BP, JP)

4.50 - 6.50

Chlorides (USP, EP, BP)

$\leq 0.0125\%$

Chlorides (JP)

$\leq 0.018\%$

Heavy metals (JP)

$\leq 0.0005\%$

Nitrogen (USP, JP)

$\leq 0.005\%$

Soluble starch (USP, EP, BP)

No blue colour develops

Residue on ignition (USP, JP)

$\leq 0.1\%$

Sulphates (USP, EP, BP)

$\leq 0.02\%$

Sulphate (JP)

$\leq 0.024\%$

Sulphated ash (EP, BP)

$\leq 0.1\%$

Specific rotation (USP)

+197.0° to +201.0° (c = 10% in water at 20°C)

Specific rotation (EP, BP, JP)

+197.0° to +201.0° (c = 10% in water at $20 \pm 0.5^\circ\text{C}$, anhydrous substance)

Water (K.F.) (USP, EP, BP, JP)

9.00 - 11.00%

Related substance : HPLC (JP)

The total area of the peaks which are eluted before the peak of trehalose and the total area of the peaks which are eluted after the peak of trehalose obtained from the sample solution are both not larger than 1/2 times the peak area of trehalose obtained from the standard solution.

Related substance : System suitability : RSD : HPLC (JP)

$\leq 1.0\%$

Related substance, HPLC 1 : System suitability : Resolution (USP, EP, BP)

≥ 1.5 between trehalose and maltotriose

Related substance, HPLC 2 : System suitability : RSD : (USP)

$\leq 2.0\%$ for trehalose peak

Related substance : HPLC (USP)

$\leq 0.5\%$

Related substances 1 : impurities A, B for each impurity : HPLC (EP, BP)

$\leq 0.50\%$

Related substances 2 : unspecified impurities : HPLC (EP, BP)

$\leq 0.20\%$

Related substances 3 : total impurities : HPLC (EP, BP)

$\leq 1.0\%$

Dextrin soluble starch & sulphite (JP)

A yellow colour appears, which is change to blue on addition of 1 drop of starch TS

Assay : System suitability 1 : Resolution 1 : HPLC (JP)

≥ 1.5 between the peak of trehalose and maltotriose

Assay : System suitability 2 : Resolution 2 : HPLC (JP)

≥ 4.0 between the peak of trehalose and glucose

Assay : System suitability 3 : Resolution 3 : HPLC (JP)

≥ 3.0 between the peak of glucose and the internal standard

Assay : System suitability : RSD : HPLC (JP)

The ratio of the peak area of trehalose to that of the internal standard is not more than 1.0%

Assay HPLC, anhydrous basis (JP)

98.0 - 101.0%

Assay HPLC, anhydrous basis (USP, EP, BP)

97.0 - 102.0%

Bacterial endotoxin 1 (EP, BP)

≤ 4.0 IU/g for solutions with conc. 100g/L or less of trehalose dihydrate

Bacterial endotoxin 2 (EP, BP)

≤ 2.5 IU/g for solutions with conc. more than 100g/L of trehalose dihydrate

Bacterial endotoxin (USP)

Complies

TAMC (USP, EP, BP)

100cfu/g

TYMC (USP, EP, BP)

100cfu/g

Salmonella species (USP, EP, BP)

Absent

Escherichia coli (USP, EP, BP)

Absent

Storage and Shelf Life:

Store below 30°C away from bright light.

Shelf life is 48 months.

Use before expiry date given on the product label.

Revision : 04/2023

Disclaimer :

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