



Certificate of Analysis



Material	VWRB3599-12KG
Material description	D-Trehalose dihydrate
Grade	Ph.Eur./NF/ENDOTOXIN TESTED
Lot	19D235202
Expiration Date	2020 Mar 20
CAS Number	6138-23-4
Molecular formula	C ₁₂ H ₂₂ O ₁₁ .2H ₂ O
Molecular mass	378.33
Date of manufacture	2017 May 23
Made in	USA
Storage	Store between 15 °C and 30 °C.
Supplier	51984

Characteristics

Specifications

Measured values

Appearance:	.	.
White or almost white crystalline powder	Passes test	Passes test
NF specifications:	.	.
Assay (calculated on anhydrous) [NF]	97.0 --> 102.0 %	99.4 %
Identification A (IR)	Passes test NF	Passes test NF
Identification B	Passes test NF	Passes test NF
Identification C	Passes test NF	Passes test NF
Residue on ignition [NF]	Max. 0.1 %	Max. 0.1 %
Heavy metals (as Pb) [NF]	Max. 5 ppm	Max. 5 ppm
Related substances [NF]	Max. 0.5 %	Max. 0.5 %
Clarity and colour of solution	Passes test NF	Passes test NF
Spec.opt.rot.(20°C)(on anhydrous) [NF]	197 --> 201 °	198 °
pH (10 % W/V) [NF]	4.5 --> 6.5	5.4
Water [NF]	9.0 --> 11.0 %	9.2 %
Cl (Chloride) [NF]	Max. 0.0125 %	Max. 0.0125 %
SO ₄ (Sulphate) [NF]	Max. 0.0200 %	Max. 0.0200 %
N (Nitrogen) [NF]	Max. 0.005 %	0.001 %
Soluble starch	Passes test NF	Passes test NF
Escherichia coli [NF]	Absent	Absent
Salmonella [NF]	Absent	Absent
Total aerobic microbial count [NF]	Max. 100 CFU/g	Passes test
Total combined yeasts and molds [NF]	Max. 100 CFU/g	Passes test
Ph.Eur. specifications:	.	.
Assay (calculated on anhydrous)[Ph.Eur.]	97.0 --> 102.0 %	99.4 %
Identification A (IR)	Passes test Ph.Eur.	Passes test Ph.Eur.
Identification B	Passes test Ph.Eur.	Passes test Ph.Eur.
Identification C	Passes test Ph.Eur.	Passes test Ph.Eur.
Appearance of solution	Passes test Ph.Eur.	Passes test Ph.Eur.

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For further manufacturing use only. Not for use as an Active Pharmaceutical Ingredient.



Characteristics	Specifications	Measured values
pH [Ph.Eur.]	4.5 --> 6.5	5.4
Spec.opt.rot. (on anhydrous) [Ph.Eur.]	197 --> 201 °	198 °
Related substances [Ph.Eur.]:	.	.
Impurities A,B [Ph.Eur.]	Max. 0.5 %	Max. 0.5 %
Unspecified impurities [Ph.Eur.]	Max. 0.2 %	Max. 0.2 %
Total [Ph.Eur.]	Max. 1.0 %	Max. 1.0 %
Disregard limit [Ph.Eur.]	Max. 0.1 %	Max. 0.1 %
Cl (Chloride) [Ph.Eur.]	Max. 125 ppm	Max. 125 ppm
SO4 (Sulphate) [Ph.Eur.]	Max. 200 ppm	Max. 200 ppm
Soluble starch	Passes test Ph.Eur.	Passes test Ph.Eur.
Water [Ph.Eur.]	9.0 --> 11.0 %	9.2 %
Sulphated ash [Ph.Eur.]	Max. 0.1 %	Max. 0.1 %
Escherichia coli [Ph.Eur.]	Absent	Absent
Salmonella [Ph.Eur.]	Absent	Absent
Microbial contamination (TAMC) [Ph.Eur.]	Max. 1000 CFU/g	Passes test
Microbial contamination (TYMC) [Ph.Eur.]	Max. 100 CFU/g	Passes test
Bacterial endotoxins	Max. 2.5 EU/g	Passes test

Signature

We certify that this batch conforms to the specifications listed above.

This document has been produced electronically and is valid without a signature.

Anand Matta, Head of Laboratory - Aurora
VWR Chemicals, LLC, 220 Lena Dr., Aurora, OH 44202, USA

The following Class 1, 2 or 3 Solvents may be present in this product and are identified and quantified below. All comply with the limits prescribed in the current USP/ENDOTOXIN TESTED GRADE.

Class: Class 2, Solvent: Methanol, Concentration Limit (ppm): 3000

Class: Class 3, Solvent: Ethanol, Concentration Limit (ppm): 5000

Class: Class 3, Solvent: Methyl isobutyl ketone, Concentration Limit (ppm): 5000

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