

Item Number	T9605
Item	alpha, alpha-Trehalose, Dihydrate, Low Endotoxin, NF, EP, JP, ChP bioCERTIFIED (TM)
CAS Number	6138-23-4
Molecular Formula	C ₁₂ H ₂₂ O ₁₁ •2H ₂ O
Molecular Weight	378.33
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (ANHYDROUS BASIS) (NF/EP)	97.0	102.0%
ASSAY (ANHYDROUS BASIS) (JP)	98.0	101.0 %
ASSAY (ANHYDROUS BASIS) (ChP)	98.0	102.0 %
SPECIFIC OPTICAL ROTATION (ANHYDROUS SUBSTANCE) (NF/EP/JP/ChP)	+197° to +201°	
WATER CONTENT (NF/EP/JP/ChP)	9.0	11.0%
pH (NF/EP/JP)	4.5	6.5
ACIDITY (ChP)	4.5	6.5
SOLUBLE STARCH (NF/EP/ChP)	NO BLUE COLOR DEVELOPS	
DEXTRIN, SOLUBLE STARCH, AND SULFITE (JP)	YELLOW COLOR APPEARS WHICH IS CHANGED TO BLUE ON ADDITION OF 1 DROP OF STARCH TS	
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS	
COLOR AND CLARITY OF SOLUTION:		
ABSORBANCE @ 720 nm (NF)		0.050
ABSORBANCE @ 420 nm – ABSORBANCE @ 720 nm (NF)		0.100
ABSORBANCE @ 720 nm (ChP)		0.033
ABSORBANCE @ 420 nm – ABSORBANCE @ 720 nm (ChP)		0.067
RESIDUE ON IGNITION (NF/JP/ChP)		0.1 %
SULFATED ASH (EP)		0.1 %
RELATED SUBSTANCES:		
SUBSTANCES ELUTING BEFORE TREHALOSE (NF)		0.5 %

Test	Specification	
	Min	Max
SUBSTANCES ELUTING AFTER TREHALOSE (NF)		0.5 %
IMPURITY A (EP)		0.5 %
IMPURITY B (EP)		0.5 %
EACH UNSPECIFIED IMPURITY (EP)		0.2 %
TOTAL IMPURITIES (CHP)		0.5 %
TOTAL IMPURITIES (JP)	HALF OF THE PEAK AREA OF THE STANDARD	
CHLORIDES (NF/EP)		125 ppm
CHLORIDES (JP)		180 ppm
SULFATES (NF/EP)		200 ppm
SULFATES (JP)		240 ppm
NITROGEN (NF/JP)		0.005 %
HEAVY METALS (CHP/JP)		5 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
MICROBIAL LIMITS:		
TOTAL AEROBIC MICROBIAL COUNT		50 CFU/g
TOTAL YEASTS AND MOLD COUNT		10 CFU/g
BACTERIAL ENDOTOXINS		0.3 EU/g
SALMONELLA		Absent/10g
ESCHERICHIA COLI		Absent/g
IDENTIFICATION A (NF A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION B (NF B)	VIOLET COLOR DEVELOPS	
IDENTIFICATION C (NF C)	BROWN COLOR DOES NOT DEVELOP	
IDENTIFICATION D (EP A)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION E (EP B)	VIOLET COLOR DEVELOPS	
IDENTIFICATION F (EP C)	NO BROWN COLOR DEVELOPS	
IDENTIFICATION G (JP 1)	PURPLE COLOR DEVELOPS	
IDENTIFICATION H (JP 2)	NO BROWN COLOR DEVELOPS	
IDENTIFICATION I (JP 3)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION J (CHP 1)	VIOLET COLOR DEVELOPS	
IDENTIFICATION K (CHP 2)	NO BROWN COLOR DEVELOPS	

Test	Specification	
	Min	Max
IDENTIFICATION L (CHP 3)	RETENTION TIME CORRESPONDS TO STANDARD	
IDENTIFICATION M (CHP 4)	SPECTRUM MATCHES REFERENCE	
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	

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