Glentham LIFE SCIENCES

Glentham Life Sciences Ltd Unit 5 Leafield Way Corsham SN13 9SW United Kingdom

- t: +44 (0) 1225 667 798
- f: +44 (0) 2033 978 909
- e: info@glentham.com

w: www.glentham.com

Certificate of Analysis

Product Name	Sucralose, USP grade		
Glentham Code	GC1410	HO、	
CAS Number	56038-13-2		
EINECS	259-952-2		
MDL Number	MFCD03648615	CI	\sim
Batch Number	312AMV	1	
Molecular Weight	397.63		\checkmark
Molecular Formula	C ₁₂ H ₁₉ Cl ₃ O ₈	HO♥	
Storage Temp.	+20°C		Бн

Physical DescriptionWhite crystalline powderConformsIdentificationA, B, C according to USPConformsSolubility (10% in water)Clear, colourless solutionConformspH (10% in water)5.0 - 7.0ConformsSpecific Optical Rotation+84.0 - +87.5 °+86.4Water< 2.0%0.11%Residue on Ignition< 0.7%0.03%Hydrolysis Products< 0.1%ConformsRelated Substances< 0.5%ConformsMethanol< 0.1%Not detectedHeavy Metals< 10pm< 5ppmLead (Pb)< 3ppmNot detectedArsenic (As)98.0 - 102.0 % (anhydrous basis)99.7%	Property	Specification	Batch 312AMV
Solubility (10% in water)Clear, colourless solutionConformspH (10% in water)5.0 - 7.06.3Specific Optical Rotation+84.0 - +87.5 °+86.4Water<2.0%	Physical Description	White crystalline powder	Conforms
pH (10% in water)5.0 - 7.06.3Specific Optical Rotation+84.0 - +87.5 °+86.4Water≤ 2.0%0.11%Residue on Ignition≤ 0.7%0.03%Hydrolysis Products≤ 0.1%ConformsRelated Substances≤ 0.5%ConformsMethanol≤ 0.1%Not detectedHeavy Metals≤ 10pm≤ 5ppmLead (Pb)≤ 1ppmNot detectedArsenic (As)≤ 3ppmNot detected	Identification	A, B, C according to USP	Conforms
Specific Optical Rotation+84.0 - +87.5°+86.4Water≤ 2.0%0.11%Residue on Ignition≤ 0.7%0.03%Hydrolysis Products≤ 0.1%ConformsRelated Substances≤ 0.5%ConformsMethanol≤ 0.1%Not detectedHeavy Metals≤ 10ppm≤ 5ppmLead (Pb)≤ 1ppmNot detectedArsenic (As)≤ 3ppmNot detected	Solubility (10% in water)	Clear, colourless solution	Conforms
Water≤ 2.0%0.11%Residue on Ignition≤ 0.7%0.03%Hydrolysis Products≤ 0.1%ConformsRelated Substances≤ 0.5%ConformsMethanol≤ 0.1%Not detectedHeavy Metals≤ 10ppm≤ 5ppmLead (Pb)≤ 1ppmNot detectedArsenic (As)≤ 3ppmNot detected	pH (10% in water)	5.0 - 7.0	6.3
Residue on Ignition< 0.7%0.03%Hydrolysis Products< 0.1%	Specific Optical Rotation	+84.0 - +87.5 °	+86.4
Hydrolysis Products≤ 0.1%ConformsRelated Substances≤ 0.5%ConformsMethanol≤ 0.1%Not detectedHeavy Metals≤ 10ppm≤ 5ppmLead (Pb)≤ 1ppmNot detectedArsenic (As)≤ 3ppmNot detected	Water	≤ 2.0%	0.11%
Related Substances< 0.5%ConformsMethanol< 0.1%	Residue on Ignition	≤ 0.7%	0.03%
Methanol≤ 0.1%Not detectedHeavy Metals≤ 10ppm≤ 5ppmLead (Pb)≤ 1ppmNot detectedArsenic (As)≤ 3ppmNot detected	Hydrolysis Products	≤ 0.1%	Conforms
Heavy Metals≤ 10ppm≤ 5ppmLead (Pb)≤ 1ppmNot detectedArsenic (As)≤ 3ppmNot detected	Related Substances	≤ 0.5%	Conforms
Lead (Pb) ≤ 1ppm Not detected Arsenic (As) ≤ 3ppm Not detected	Methanol	≤ 0.1%	Not detected
Arsenic (As) ≤ 3ppm Not detected	Heavy Metals	≤ 10ppm	≤ 5ppm
	Lead (Pb)	≤ 1ppm	Not detected
Assay 98.0 - 102.0 % (anhydrous basis) 99.7%	Arsenic (As)	≤ 3ppm	Not detected
	Assay	98.0 - 102.0 % (anhydrous basis)	99.7%
Pharmacopoeia Specification(s) USP Conforms to USP	Pharmacopoeia Specification(s)	USP	Conforms to USP

Specification Version	v1.0
Manufacture Date	2018-10-03
Re-Test Date	2028-10-03

Glentham Life Sciences confirm that the above referenced product conformed to the information displayed in this document on the quality release date. Please check www.glentham.com or contact us using the details above for the current version of this document.

This document was generated electronically and is therefore valid without signature. © Glentham Life Sciences Ltd, 2024