

Unitech

Unitech Chemicals (Zibo) Ltd

Add: Yongliu West Road, Linzi, Zibo, Shandong, China

Tel: 0086 533 6292769/7217338 Fax: 0086 533 7217339

Email: sales@unisweet.com.cn; sales@unitechzibo.com

CERTIFICATE OF ANALYSIS

Product	Sucralose	Quantity	495kg	Test date	2023-11-14
Batch NO.	U123111206 ✓	Manufacture date	2023-11-12	Expired date	2025-11-11 ✓

TESTED RESULTS

ITEM	STANDARD	RESULT
Identification A(IR)	Infrared spectra of standard and sample should meet each other	Pass ✓
Identification B (Retention time of HPLC)	The retention time of the principal peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.	Pass ✓
Identification C(By TLC)	The R _f value of the major spot in the thin-layer chromatogram of the Product Preparation is the same as that of the Standard Preparation obtained in the test for Related Substances.	Pass ✓
Appearance	White powder	Pass
Particle Size (100 mesh),%	≥95	Pass
Assay,%	98.0~102.0	99.94 ✓
Specific Rotation,°	+84.0~+87.5	+86.2 ✓
Moisture,%	≤2.0	0.2 ✓
PH (10% aqueous solution)	5.0-7.0	5.61 ✗
Ignited Residue,%	≤0.7	0.1 ✓
Methanol,%	≤0.1	0.01 ✓
Heavy Metals (as lead) ,mg/kg	≤10	<10 ✗
Arsenic(As),mg/kg	≤3	<1 ✗
Lead,mg/kg	≤1	Not Detected ✗
Triphenylphosphine Oxide,mg/kg	≤150	<150 ✗
Hydrolysis Products,%	≤0.1	Pass ✓
Related Substances,%	≤0.5	Pass ✓
Total Aerobic count,cfu/g	≤250	30
Yeasts & moulds,cfu/g	≤50	10
Coliform,MPN/g	<3.0	<0.3
E.coli	Negative	Negative
S.aureus	Negative	Negative
Salmonella	Negative	Negative
Storage condition	Store in well closed container, in dry and cool place, at a temperature not exceeding 21℃.	
Conclusion	The quality in conformity with the E-955/USP 36 / FCC 8	
Inspector: Sun Jinxia	Checked: Tang Xianghui	Approved: Phili Wang

Butuh penyesuaian
terlampir

STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU

No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Sucralose	Unitech Chemicals	USP 36	USP 47/FI VI	pH	Pemerian disesuaikan dengan USP 47	Identifikasi disesuaikan dengan USP 47	RD.02-SBP/089.01	Penyesuaian CoA dari Manufacturer
					Logam berat	-	-		
					Arsen				
					Lead/Timbal				
					Triphenylphosphine Oxide				
					Identifikasi D (Nanoram)	Cemaran Mikroba	-		Update SPBB

Diperiksa Oleh

Disetujui Oleh,

al 25/10 24
Koordinator QC

W 25/10 24
Koordinator TS

W 25/10 24
Koordinator QA

W 25/10 24
Manager QA