ND Pharma & Biotech

SUCRASOL™

SPECIFICATION SHEET

1. PRODUCT DESCRIPTION

Sucralose is a sweet, white to off-white, odorless, crystalline powder. It is freely soluble in water, in alcohol and slightly soluble in ethyl acetate. It is suitable for human consumption as a high-intense, non-nutritive sweetener and flavor enhancer.

2. PROPERTIES

2.1	Synonym	1,6 -Dichloro-1,6-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside
2.2	Molecular Formula	$C_{12}H_{19}Cl_3O_8$
2.3	Molar Mass	397.64 g/mol
2.4	Solubility in Water	24.7% w/v at 25°C

3. TEST AND SPECIFICATION (Tests according to current FCC and USP/NF for Sucralose)

TEST ITEMS	STANDARD LIMITS	TEST METHODS
Identification		
(A) Identify (IR)	The spectrum of the sample exhibits the same as that of the reference standard.	Current FCC/USP/NF
(B) Identify (HPLC)	The retention time of the sample is the same as that of the standard.	Current FCC/ USP/NF
(C) Identity (TLC)	The R_f value of the sample is the same as that of the standard.	Current FCC/USP/NF
Assay	98.0% - 102.0% of $C_{12}H_{19}Cl_3O_8$ on the anhydrous basis	Current FCC/USP/NF
Lead	NMT 1mg/kg	Current FCC
Methanol	NMT 0.1%	Current FCC/USP/NF
Hydrolysis Products	Passes test	Current FCC/USP/NF
Optical (Specific) Rotation $[\alpha]_D^{20}$	Between +84.0° to 87.5°	Current FCC/ USP/NF
Related Substances	Passes test	Current FCC/USP/NF
Residue on Ignition	NMT 0.7%	Current FCC/USP/NF
Water	NMT 2.0%	Current FCC/USP/NF
Heavy Metals (as Pb)	NMT 0.001%	Current USP/NF

4. ADDITIONAL TEST AND SPECIFICATIONS

TEST ITEMS	STANDARD LIMITS	TEST METHODS
Arsenic	NMT 3mg/kg	GB/T 5009.76-2003 Method II
Mercury	< 0.1mg/kg	CVAAS (GB/T 5009.17-2003 Method II)
Cadmium	< 0.1mg/kg	GFAAS (GB/T 5009.15-2003 First Method)
pH (10% aqueous solution)	6.0～7.5	Q/KH 00055-2009
Organoleptic	Passes test	Q/KH 00055-2009
Particle Size	Actual particle size may be customized by using different screening sieves. It may pass through 40-, 60-, 100- or 200-mesh screen, etc.	KH-CX(17)/i(04-10)-A/0

5. MICROBIOLOGICAL TEST AND SPECIFICATIONS

TEST ITEMS	STANDARD LIMITS	TEST METHODS
Total Aerobic Count	NMT250cfu/g	GB/T 4789.2-2008
Molds and Yeasts	NMT50cfu/g	GB/T 4789.15-2008
Total Coliforms	Negative to test (<10cfu/g)	GB/T4789.3-2008
Escherichia Coli	Negative to test (<10cfu/g)	GB/T 4789.38-2008
Staphylococcus Aurreus	Negative to test (Absent in 25g)	GB/T 4789.10－2008
Salmonella Species	Negative to test (Absent in 25g)	GB/T 4789.4－2008
Pseudomonas Aeruginosa	Negative to test (Absent in 25g)	SNT 2099-2008

6. CERTIFICATIONS

6.1 SUCRASOL ™ complies with FCC, USP/NF, JECFA, E955 (EC), EP, BP

6.2 Kosher

is certified as Kosher by the Orthodox Union.

6.3 Halal

is certified as Halal.

6.4 Allergens

does not contain any commonly known allergens. No special labeling is required under the current regulations issued by the FDA or the EU.

6.5 Genetically Modified Organisms (GMOs)

powder is not generated from ingredients or processing aids derived from GMOs.

It is a GMO free material.

6.6 Bovine spongiform encephalopathy (BSE)
No animal derived ingredients are employed

6.7 FDA Facility Registration. ND Pharma & Biotech is registered within FDA in the U.S.

7. PACKAGING, HANDLING, STORAGE AND MARKING

7.1 Supplier Packaging
This product is packed in materials that provide adequate, securely sealed protection, and is free from foreign substances, which is then packaged on clean, undamaged GMA 1 pallets.

7.2 Store at room temperature and protected form other materials/odors/humidity etc.

7.3 Package Label
The package label includes manufacturer's information, product name, container's number, use function, storage requirement, lot number, net weight, date of manufacture, expiration date, drum number, manufacturer's contact information, and specific transportation requirement.

7.4 Lot Description/ Identification

DIGITAL INTERNATIONAL NOMENCLATOR AND/OR ALTERNATIVELY ALPHANUMERIC NOMENCLATURE

8. TESTING REQUIREMENTS

8.1 A Certificate of Analysis (COA) according to FCC and USP/NF (section 3) is provided with each shipment.
Additional items (section 4) and a microbiological test (section 5) will be available upon the customers' request.

8.2 If customer testing is necessary, we suggest that Sucralose assay and organoleptics should be used. Both tests will provide the most information about the product without performing the entire set of tests listed in Section 3.

9. SHELF LIFE

24 Months if properly stored and packaging preservation conditions.

For use in foodstuffs as additive.

10. SAFETY MEASUREMENTS

Please read the Material Safety Data Sheet.

*Notes: “PS” in Product Code “KH-S (PS)” stands for Particle Size; it can be 40, 60, 100 or 200, etc