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SPECIFICATION

Product Name: SUCRALOSE

Chemical Name: 1',6'-Dichloro-1', 6'-dideoxy-β-D-fructofuranosyl-4-chloro-4-deoxy-α-D-galactopyranoside

Chemical formula: C₁₂H₁₉ Cl₃O₈

Molecular Weight: 397.64 **CAS :** [56038-13-2]

Identification

A: The infrared absorption spectrum of a potassium bromide dispersion of the Product exhibits relative maxima at the same wavelengths as those of a similar preparation of Sucralose Standard for analytical use.

B: The retention time of the major peak in the liquid chromatogram of the Product Preparation is the same as that of the Standard Preparation obtained in the Assay.

C: 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.

Character: A white to off-white powder; odorless and without unpleasant aftertaste, stable to heat, light and acids; freely soluble in water, ethanol and methanol; slightly soluble in ethyl acetate.

<u>ITEM</u>	<u>STANDARD</u>
Appearance	White crystalline micronized powder
Assay(on dry basis) (%)	98.0-102.0
PH (10% aqueous solution)	5.0-7.0
Specific rotation, [α] _D ²⁰	+84.0°~+87.5°
Moisture (%)	≤2.0
Methanol (%)	≤0.1
Arsenic(as As) (mg/kg)	≤3
Lead (as Pb),(mg/kg)	≤1
Heavy metals(as Pb) (mg/kg)	≤10
Ignited Residue(%)	≤0.7
Chlorinated monosaccharides /Hydrolysis Products (%)	≤0.1
Other chlorinated disaccharides /Related Substances (%)	≤0.5
Triphenylphosphine Oxide(mg/kg)	≤150
Particle Size	1200 mesh
<u>MICROBIOLOGICAL REQUIREMENTS</u>	
Total Aerobic Count (cfu/g)	≤250
Yeasts/Molds (cfu/g)	≤50
E.Coli (cfu/g)	≤ 10
S. Aureus(cfug)	≤ 10
Salmonella	Absent in 25g
Conclusion: The quality in conformity with FCC(VIII)/USP/NF/EC(E955)/ EP(7.2). The product is manufactured in accordance with GMP standard.	
Shelf life: 2 years when properly stored in cool& dry place and well-closed containers.	