

CERTIFICATE OF ANALYSIS

Material: Sorbitol solution 70% (Non-Crystallizing)

Batch No: SBNCEX/024
Manufacturing Date: February 2021
Expiry Date: Two Years from Manufacturing

S.No	Test	Observations	Limits
1	DESCRIPTION	Complies	Clear, Colourless, Syrupy liquid, Miscible with water
2	SOLUBILITY	Complies	Miscible with water, with glycerin and with 1,2-propanediol
3	IDENTIFICATION (A)HPLC chromatogram	Complies	Corresponds to principal peak of reference solution(a)
	(B)Optical Rotation	+2.20°	+1.50° to +3.50°
	(C) Clarity @25° C	Clear	It is clear Syrupy liquid
4	APPEARANCE OF SOLUTION	Clear and colourless	A 14.0% w/v solution in water is clear and colorless
5	CONDUCTIVITY	1.6	NMT 10 µS/cm, measured on undiluted liquid sorbitol while gently stirring with a magnetic stirrer
6	REDUCING SUGARS	0.132%	NMT 0.2%, calculated as glucose equivalent and NLT 12.8 ml of 0.05M Sodium thio-sulphate
7	REDUCING SUGARS AFTER HYDROLYSIS	5.72%	NMT 9.3%, calculated as glucose equivalent and NLT 8.0 ml of 0.05M Sodium thio-sulphate
8	LEAD	Complies	NMT 0.5 ppm
9	NICKEL	Complies	NMT 1 ppm
10	WATER	30.2	28.0% to 32.0%
11	ASSAY:		
	(I) ANHYDROUS SUBSTANCE	69.8	68.0% to 72.0%
	(II) D-GLUCITOL	81.2	72.0% to 92.0% w/w of D-glucitol, calculated on the anhydrous basis by Liquid Chromatography
12	Total Aerobic Viable Count	60	1000 cfu/g maximum
13	Total Fungal Count	Less than 10	100 cfu/g maximum

Remarks: Material complies with required specification