Certificado de Análisis
Sorbitol

LOTE: 2122P700
FECHA DE PRODUCCIÓN: 18/ MARZO/ 2022
FECHA DE VENCIMIENTO: 17/ MARZO/ 2027
CÓDIGO: 1-000-260

S. NO	TEST	SPECIFICATION	RESULT
1	Description	Clear, Colourless, Syrupy liquid Miscible with water	Clear, Colourless, Syrupy liquid, Miscible with water
2	Identification		
	A. Presence of Sorbitol	A deep pink or wine-red color appears	Passes the test
	B. Examine the Chromatogram Obtained in the Assay	The principal peak in the Chromatogram Obtained with test solution is similar in retention time to the principal peak in the Chromatogram obtained with reference solution.	Complies
	C. Limit of Diethylene Glycol and Ethylene Glycol		
	(1) Diethylene Glycol	Max. 0.10 %	Not detected
	(2) Ethylene Glycol	Max. 0.10 %	Not detected
3	Appearance of solution	Clear & colourless	Clear & colourless
4	Conductivity	Max. 10 µScm⁻¹	0.6 µScm⁻¹
5	pH (14 % Sol.)	5.0 to 7.5	6.1
6	Specific Gravity at 25°C	Min. 1.280 g /mL	1.296 g /mL
7	Reducing Sugars	Not less than 12.8 mL 0.05 N sodium thio sulphate required	18.8 mL of 0.05 N sodium thio sulphate is consumed
8	Reducing Sugar after Hydrolysis	Not less than 8.0 mL of 0.05 M Sodium thiosulphate is required	12.1 mL of 0.05 M sodium thio sulphate is consumed
9	Lead (Pb)	Max.0.5 ppm	Not detected
10	Nickel	Not more than 1.0 ppm	Not detected
11	Additional test Arsenic	Less than 2.0 ppm	Less than 2.0 ppm
12	Water Content	28.5 % to 31.5%	29.6%
13	Content		
	Anhydrous Substance	68.0 % to 72.0%	70.4%
	D-Sorbitol (100% DS)	72.0 % to 92.0%	86.9%
	D-Sorbitol (as is)	Not less than 45.0%	61.2%
14	Residue on Ignition	Max 0.1%	0.02%
15	Microbiology		
	Total aerobic microbial count	Max. 1000 cfu / mL	10 cfu / mL
	Total Yeasts & Molds	Max. 100 cfu / mL	< 10 cfu / mL
16	Specified Pathogens		
	- Staphylococcus aureus	Should be absent	Absent
	- Pseudomonas aeruginosa	Should be absent	Absent
	- Salmonella	Should be absent	Absent
	- Escherichia coli	Should be absent	Absent
	- Candida albicans	Should be absent	Absent
	- Bile tolerant gram negative bacteria	Should be absent	Absent