

## CERTIFICATE OF ANALYSIS

### SORBITOL Solution 70 % Non Crystallising – BP / EP & USP

#### Description

Sorbitol solution is used in a wide variety of oral care, pharmaceutical, soaps, paints, food, confectionary, industrial applications. Typically sorbitol solution is used as a bulking agent, sweeteners, and humectant.

#### Batch Details

Batch No.....

Manufacturing Date.....

No. of Container with Quantity

Batch Size ----

Expiry Date ----

..... 400 x 300.00 Kg

#### Results of Analysis

S.No.	Test	Specification	Results
1	Description / Appearance	Clear, colourless, syrupy liquid, Miscible with water	Clear, colourless, syrupy liquid, miscible with water
2	Identification		
	A. 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 (a)	Complies (as per BP/EP & USP)
	B. Optical rotation	Between +1.5 and +3.5 °	+2.15° (as per BP) +2.12° (as per EP)
	C. Colour & clarity (as per BP & EP)	It is a clear syrupy liquid at 25 ° C	Passes the test
	D. By Chemical test (as per USP)	A deep pink or wine red color appears	Passes the test
	E. Limit of Diethylene glycol and Ethylene glycol ( as per USP)		
	Diethylene glycol	Not more than 0.10 %	Not Detected
	Ethylene glycol	Not more than 0.10 %	Not Detected
3	Appearance of solution (As per BP&EP)	Solution is clear and colourless	Solution is clear & colourless
4	Conductivity (as per BP&EP)	Max. 10 µS cm <sup>-1</sup>	1.0 µS cm <sup>-1</sup> (as per BP) 1.0 µS cm <sup>-1</sup> (as per EP)
6	Reducing sugars (as per BP&EP)	Max.0.2 % calculated as glucose equivalent .	0.16% ( as per BP) 0.15% (as per EP)
7	Reducing sugars (as per USP)	Max.0.3 % calculated as glucose equivalent .	0.16% (as per USP)
8	Reducing Sugar after hydrolysis (as per BP &EP)	Max.9.3 % calculated as glucose equivalent .	5.08 % (as per BP) 4.95 % (as per EP)
9	Lead (as per BP&EP)	Max. 0.5 ppm	Below 0.1 ppm
10	Nickel (as per BP /EP &USP)	Max. 1 ppm	Below 0.1 ppm
11	Water ( as per BP&EP)	28.0 % to 32.0 %	30.22%(as per BP) 30.25%(as per EP)
12	Water ( USP )	28.5 % to 31.5 %	29.72%(as per USP)
13	Assay - anhydrous substance	68.0 to 72.0 %	69.78% (as per BP) 69.75% (as per EP)
	D- glucitol (D-Sorbitol C <sub>6</sub> H <sub>14</sub> O <sub>6</sub> ) (as on anhydrous basis)	72.0 to 92.0 %	83.76% (as per BP) 83.83% (as per EP)
14	Assay (as per USP)	NLT 45.0% w/w	57.45% (as per USP)
15	Residue on ignition (as per USP)	NMT 0.1 %	0.016 % w/w
16	pH (as per USP)	5.0 to 7.5	6.63
17	Microbial limits		
	- Total aerobic microbial count	Not more than 1000 cfu/ml	< 10 cfu/ml
	- Total Yeast and Mold count	Not more than 100 cfu/ml	< 10 cfu/ml
	- Pathogens		
	i) Escherichia coli	Should be absent	Absent
	ii) Salmonella Abony	Should be absent	Absent
	iii) Pseudomonas aeruginosa	Should be absent	Absent
	iv) Staphylococcus aureus	Should be absent	Absent
	v) Candida albicans	Should be absent	Absent
	vi) Bile tolerant gram negative bacteria	Should be absent	Absent

Remarks : The product complies as per BP/EP/USP and In-house specification.

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Analysed by

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