

1. Identification of Substance

Product	: Sorbitol Solution - 70% Crystallizing
Packing	: 300 kgs. food grade HDPE drums, Bulk SS tankers.
Shelf Life	: 5 years from the date of manufacture.
Storage &	: To be stored in a clean dry and dust free godown. Maintain ambient temperature.
Preservation	Keep away from water, moisture and direct sunlight.
Intended Use	: For food and pharmaceutical applications and cosmetic applications such as oral care, etc.
Sampling Plan	: As per guideline HL/QC/FG-SMP/01
Retest Programme	: Schedule 6 Months
Tests	: Water % Assay Appearance

2. Physical & Chemical Parameters

Parameter	Specification	Method of Analysis
Description	Clear Colorless Syrupy Liquid. Miscible with Water.	Indian Pharmacopoeia
Identification A- Examine the chromatograms obtained in the assay	In the assay, the corresponding peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).	Indian Pharmacopoeia
Identification B Diethylene Glycol and Ethylene Glycol	Diethylene Glycol : $\leq 0.10\%$ Ethylene Glycol : $\leq 0.10\%$	Indian Pharmacopoeia
Identification C Presence of Sorbitol	Deep pink or wine -red colour produced.	Indian Pharmacopoeia
Appearance of solution	14% w/v solution in water in clear and colorless.	Indian Pharmacopoeia
Conductivity	$\leq 10 \mu\text{S/cm}$.	Indian Pharmacopoeia
Diethylene Glycol	$\leq 0.10\%$	Indian Pharmacopoeia
Ethylene Glycol	$\leq 0.10\%$	Indian Pharmacopoeia



Reducing Sugars	≤ 12.8 mL of 0.05 M solution thiosulphate in required and not more than 0.2% calculated as glucose equivalent.	Indian Pharmacopoeia
Lead by	≤ 0.5 ppm	Indian Pharmacopoeia
Nickel	≤ 1.0 ppm	Indian Pharmacopoeia
Water %	28.0% to 32.0%	Indian Pharmacopoeia
Assay Anhydrous substance D-Sorbitol (by HPLC) On anhydrous basis	68.0% to 72.0% 92.0% to 101.0%	Indian Pharmacopoeia

3. Microbiological Specifications:

Parameter	Specifications
Total Aerobic microbial count	≤ 1000 CFU/gm.
Total Yeast and Moulds	≤ 100 CFU/gm.
Specified Pathogens	Absent /gm.