



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR SORBITOL SOLUTION (70%) IP

Manufacturer Name :		Supplier Name :
Manufacturer's Batch No. :		Manufacturer's Batch Size :
Manufacturing Date :		Expiry Date :
Quantity Received :		Test Quantity :
Document No. :	Effective Date :	Change Control No. :
Control No./ A.R. No. :		Retest Date :

Reference : IP 1996 Page No 709

Description : Clear, colourless or faintly yellow, syrupy liquid; odourless, Complies/Does Not Comply

Solubility : Miscible with water; with glycerin, and with 1,2-propanediol.
Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1	Identification A Colour reaction B Melting range C TLC	IP		A. A pink colour is produced which becomes deep brownish red. B. The residue melts at about 100°C. C. The principle spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2).	
2.	Acidity or alkalinity	IP		Not more than 0.2 ml of 0.01 M Sodium hydroxide is required to change the colour of the solution to pink. Not more than 0.3 ml of 0.01 M hydrochloric acid is required to change the colour of the solution to red.	
3.	Optical rotation	IP		Between + 1.5° and + 3.5°	
4.	Refractive Index	IP		Between 1.455 and 1.465	
5.	Relative density	IP		Not less than 1.285	



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S.No.	Test	Reference	Result	Specification	Remark
6.	Clarity and colour of solution	IP		Solution A is clear and colourless.	
7.	Arsenic	IP		Not more than 2 ppm.	
8.	Heavy Metals	IP		Not more than 10 ppm	
9.	Chloride	IP		Not more than 50 ppm	
10.	Nickel	IP		Not more than 1 ppm	
11.	Sulphate	IP		Not more than 125 ppm	
12.	Reducing sugars	IP		Not less than 12.8 ml of 0.05 M sodium thiosulphate is required.	
13.	Sulphated ash	IP		Not more than 0.1 %	
14.	Assay as total solids	IP		Not less than 68.0 % and not more than 72.0 % w/w	
15.	Assay as polyols expressed as D-glucitol (C ₆ H ₁₄ O ₆) (anhydrous basis)	IP		Not Less Than 62.0 % w/w	

Raw Data Reference :

Analyst Name :

Analyst Name :

Analyst Name :

Analyst Hard Book No. : Page No. :

Analyst Hard Book No. : Page No. :

Analyst Hard Book No. : Page No. :

Results : Sample Conforms / Does Not Conform to Specification

Analyzed By : _____ Date : _____

Checked By : _____ Date : _____

Approved By : _____ Date : _____