



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR POLYSORBATE 80 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 606-607

Description : Clear or almost clear, oily, yellowish or brownish yellow liquid; odour, faint and characteristic.

Complies/Does Not Comply

Solubility : Miscible with water, with *ethanol*, with *ethyl acetate*, and with *methanol*; practically insoluble in *fixed oils* and in *liquid paraffin* (1 in More than 10000).

Complies/Does Not Comply

S.No.	Test	Reference	Result	Specification	Remark
1.	Identification A. B.	IP		A. The cloudiness disappears during cooling at about 50°C. B. A blue colour is produced.	
2.	pH	IP		Between 6.0 and 8.0	
3.	Acid value	IP		Not More Than 2.0	
4.	Hydroxyl value	IP		Between 65 and 80	
5.	Iodine value	IP		Between 18 and 24	
6.	Saponification value	IP		Between 45 and 55	
7.	Reducing impurities	IP		Not more than 5.0 ml of 0.01M ceric ammonium sulphate is required.	
8.	Heavy metals	IP		Not more than 10 ppm	
9.	Sulphated ash	IP		Not more than 0.2%	
10.	water	IP		Not more than 3.0% w/w	



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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 : _____