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novo EXCIPIENTS PVT. LTD.	RAW MATERIAL SPECIFICATION Quality Control Department		Page No.	1 of 3
Name of Raw Material	Propylene Glycol			
Specification No.	RM/SPEC/HM/067-01	Supersedes No.	RM/SPEC/067-02	
Reference	IP/USP	Effective Date	25/04/2025	
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	Mar'2030	

GENERAL INFORMATION

Pharmacopeial reference : IP/USP

Special requirement of pack : Material should be packed in HDPE drum.

Approved vendor : Please refer current approved vendor list.

Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled

Analysis Sample	Control sample
160 g	220 g

Retest Period : 12 Months

Storage : Store protected from moisture and preserve in tight containers.

	PREPARED BY	REVIEWED BY	APPROVED BY
Name	Manisha Dhere	Appa S. Shinde	Manish Mahajan
Sign/Date	25/04/25	25/04/25	25/04/2025
Designation	Sr. Executive	Asst. Manager	Manager
Department	Quality Control	Quality Control	Quality Assurance

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	Quality Control Department		
Name of Raw Material	Propylene Glycol		
Specification No.	RM/SPEC/HM/067-01		

SR. NO.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	A clear colorless, viscous liquid; hygroscopic.	IP
		Clear colorless, viscous liquid having slightly characteristic taste, practically odorless. Absorbs moisture when exposed to moist air.	USP
02.	Solubility	Miscible with water, with acetone, with chloroform. Soluble in ether and is immiscible with fixed oils.	IP
		Miscible with water, with acetone and with chloroform. Soluble in ether and will dissolve many essential oils but is immiscible with fixed oils.	USP
03.	Identification Test		
	Test A: (By IR)	The IR-Spectrum of test sample should be concordant with that of standard spectrum	IP/USP
	Test B : Limit of Diethylene Glycol and Ethylene Glycol		IP/USP
	Diethylene Glycol :	NMT 0.10 %	
	Ethylene Glycol:	NMT 0.10 %	
	Test C	The retention time of the propylene glycol peak obtained with the test solution corresponds to the propylene glycol peak in the chromatogram obtained with the reference solution.	IP
	Test D: The chromatograms obtained in identification Test B	The retention time of the propylene glycol peak of the sample solution corresponds to that of the standard solution.	USP
04.	Acidity	NMT 0.2 ml of 0.1 M sodium hydroxide should be consumed.	IP
		NMT 0.20 ml of 0.10 N sodium hydroxide	USP
05.	Relative density/ Specific gravity	1.035 to 1.037	IP/USP
06.	Diethylene Glycol and Ethylene Glycol	Diethylene Glycol : NMT 0.1 % Ethylene Glycol: NMT 0.1 %	IP
07.	Heavy Metals	NMT 5 ppm	IP

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	25/04/25	25/04/25	25/04/2025

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NOVO EXCIPIENTS PVT. LTD.	RAW MATERIAL SPECIFICATION Quality Control Department	Page No.	3 of 3
Name of Raw Material	Propylene Glycol		
Specification No.	RM/SPEC/HM/067-01		

SR. NO.	TEST	SPECIFICATIONS	REFERENCE
08.	Chloride	70 ppm	IP/USP
09.	Sulphates	60 ppm	IP/USP
10.	Sulphated ash	NMT 0.007 % w/w	IP
11.	Residue on Ignition	The weight of residue NMT 3.5 mg	USP
12.	Water#	NMT 0.2 %	IP/USP
13.	Assay #	NLT 99.5 %	IP/USP
# : Re-evaluation tests			

REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	1) New individual pharmacopoeial grade document prepared as per approved Change control No. CC/QC/23/002 2) SPEC and ATR prepared as per approved change control No. CC/QC/25/008	25/04/2025

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	25/04/25	25/04/25	25/04/2025