

**NITIKA**

PHARMACEUTICAL SPECIALITIES PVT. LTD.

WHO - GMP & ISO CERTIFIED

NITIKA PHARMACEUTICAL SPECIALITIES PVT. LTD., NAGPUR

Block No. 03 of Plot No. 1296, 1297/08, Ward No. 03, Mouza- Waddhmna, Tah - Hingna,

Amravati Road, Nagpur - 440023, India

CERTIFICATE OF ANALYSIS

PRODUCT NAME: PHARMAPEG MACROGOL (4000)		GRADE: EP	
Received Date : 16/10/2023		Page : 1 of 2	
Release Date : 19/10/2023		Ref Specification No. : QAD/FP/SPEC/MAGL4/02	
Drug License No. : MH/102111		Analysis Report No. : MM234904	
Batch No : MAGL4M1300 L		Qty. Drawn for Analysis : 40 g	
Mfg. Date : SEP.- 2023		Use Before : AUG.- 2028	
SN	TESTS	SPECIFICATIONS	RESULTS
1. *	Characters		
	Appearance	White or almost white solid with a waxy or paraffin like appearance	White Powder
	Solubility	Very soluble in water and in methylene chloride, practically insoluble in in alcohol, in fatty oils and in mineral oils.	Complies
2.	Identification		
	Test A :	It complies with the test for viscosity	Complies
	Test B :	An abundant white, crystalline precipitate is formed.	Complies
	Test C :	The liquid phase becomes blue.	Complies
3. *	Appearance of solution	Solution is clear and not more intensely coloured than reference solution BY6.	Complies
4.	Acidity or Alkalinity	NMT 0.1 mL of 0.1 M NaOH is required to change the colour of indicator to blue.	0.05 ml of 0.1 M NaOH is required
5. *	Viscosity	110 mPas - 170 mPas	125 mPas
6.	Freezing Point	53 °C – 59 °C	55 °C
7.	Hydroxyl value	25 - 32	28
8.	Reducing Substances	As per EP	complies
9.	Formaldehyde	Max 30 ppm.	< 30 ppm
10.	Ethylene oxide and dioxan	Max 1 ppm of ethylene oxide and 10 ppm of dioxan.	< 1 ppm < 10 ppm
11. *	Water	Max.1.0 %	0.49 %
12. *	Sulfated Ash	Max 0.2 %	0.08 %

	Name	Designation	Signature/Date
Prepared By:	Ms. Sweety Mohalkar	Executive – QA	<i>[Signature]</i> 20/10/2023
Checked By:	Mrs. Ranjana Samrutwar	Manager – QC	<i>[Signature]</i> 20/10/2023
Approved By:	Mr. Rahul Malkar	Head - QA	<i>[Signature]</i> 20/10/2023



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Remarks (If Any): In the opinion of the undersigned, the above sample is upto the standard quality as per specifications for above tests only

Note: Asterisk mark (*) test shall be Retest Analysis

Storage & packing Condition: Store in tight containers

NMT	Not More Than	NLT	Not Less Than
Max.	Maximum	Min.	Minimum

	Name	Designation	Signature/Date
Prepared By:	Ms. Sweety Mohalkar	Executive - QA	<i>[Signature]</i> 20/10/2023
Checked By:	Mrs. Ranjana Samrutwar	Manager - QC	<i>[Signature]</i> 20/10/2023
Approved By:	Mr. Rahul Malkar	Head - QA	<i>[Signature]</i> 20/10/2023

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Ref. SOP No. QAD-031