

CIFICATE OF ANALYSIS

PRODUCT NAME : DRUGCOAT L 100-55D

CIN NO. L24296GJ1994PLC021524

GENERIC NAME : Partially - Neutralized Methacrylic Acid And Ethyl
Acrylate Copolymer USP/NF

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Batch No.	: L100-55D/001/04/2025	A.R. No.	: FP1004/001/04/25/1
Mfg. Date	: 23-04-2025	Date of Receipt	: 27-04-2025
Re-Test Date	: 22-04-2028	Date of Completion	: 03-05-2025
Analysed as per	: USP-NF	Sample Size	: 0.120 kg
Product Code	: 1004		
Mfg. Site	: Survey No. 131/1 & 131/2, At:Dhanot, Nr. Chhatral, Chhatral-Kadi Road, TALUKA : KALOL - 382729, GANDHINAGAR, GUJARAT, INDIA		
Lic. No.	: G/25/2145		
Sr.	Test	Specification	Result
1	Description	White or almost white, free flowing powder	White free flowing powder.
2	Solubility	Freely soluble in alcohol, in methanol, and in a 40 g/L solution of sodium hydroxide. Soluble in solutions at pH values above pH 5.5 under salt formation; practically insoluble in ethyl acetate and in acidic aqueous solutions.	Freely soluble in alcohol, in methanol, and in a 40 g/L solution of sodium hydroxide. Soluble in solutions at pH values above pH 5.5 under salt formation; practically insoluble in ethyl acetate and in acidic aqueous solutions.
3	Identification		
	1 (A) By IR	The IR absorption spectrum of Partially-Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer exhibits maxima corresponding to the same wavelengths as that of a similar preparation of USP Partially-Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer (1:1) WS, treated in the same manner.	The IR absorption spectrum of Partially-Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer exhibits maxima corresponding to the same wavelengths as that of a similar preparation of USP Partially-Neutralized Methacrylic Acid and Ethyl Acrylate Copolymer (1:1) WS, treated in the same manner.
	2 (B) Assay	Should meet requirement under assay	Meets requirement under assay
4	Assay (% Unit of Methacrylic acid)	43.2 % - NMT 47.6 %	45.68 %
5	Residue on Ignition	2.0 - 3.5 %	2.194 %
6	Limit of Methacrylic acid and ethyl acrylate	NMT 0.01 % for the total amount of monomers.	0.0021 %
7	Loss on Drying	NMT 5 %	2.32 %
8	Viscosity	20 - 100 mPa.s, at 23 ± 0.1°C, 50 RPM	30.10 mPa.s
9	Microbial Enumeration Tests		
	1 Total aerobic microbial count	NMT 10 ³ cfu/g	10 cfu/g
	2 Total Combined Yeasts and Moulds Count	NMT 10 ² cfu/g	00 cfu/g
	3 Staphylococcus aureus	Should be absent in 1 g sample	Absent
	4 Pseudomonas aeruginosa	Should be absent in 1 g sample	Absent
	5 Salmonella	Should be absent in 10 g sample	Absent
	6 Escherichia coli	Should be absent in 1 g sample	Absent

Conclusion : The above sample complies as per USP-NF specification .

Prepared By <i>Hitali</i> 03/05/2025	Checked By <i>MS</i> 03/05/2025	Approved By <i>[Signature]</i> 03/05/2025
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