

Certificate of Analysis

888 Woodstock Street Georgetown, SC 29440 Phone: 843-546-8556 Fax: 843-520-0203

Manufacturing Location

3V SIGMA USA INC. 888 Woodstock St. Georgetown, SC 29440

Product: SYNTHALEN ® K

3V Order Number: 34001/S6 **Customer Name:**

Customer Order Number: E11351 10

Lot Number: 1524B031

Date of Manufacture: 02/08/2024 Expiration Date: 02/07/2026 Quantity Shipped: 2040.0000 KG

TEST RESULTS

Test	Specification	Results
Appearance (White Powder)	PASS - PASS	PASS
Residual Solvent (Conforms to the pharmacopeia)		
Identification test (IR)	PASS - PASS	***
Heavy metals	0 - 15	***
Weight Loss	0.0 - 2.0	0.5 %
pH 0.5 % in H2O	2.70 - 3.50	2.73
Carboxyl. group	56.00 - 68.00	***
Brookfield Viscosity 25C (spindle 7 20 rpm) 0.5% in H2O (at pH 7.3 - 7.8 with NaOH)	40000 - 60000	47400 cps
Brookfield viscosity 25C (spindle 6 20 rpm) 0.2% in H2O (at pH 7.3 - 7.8 with NaOH)	20000 - 30000	25750 cps

Certification and Compliance Statements

Other Certification Statements:

The Quality Management System at the manufacturing site for this product is in compliance with the ISO 9001:2015 and EFfCI requirements.

Product: SYNTHALEN ® K **Lot Number:** 1524B031

Authorized Signature:

Rosa DiBitondo, Director Of Quality And Compliance

Date of Approval: 02/09/2024

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