

RAW MATERIAL AND PACKAGING MATERIAL EVALUATION FORM

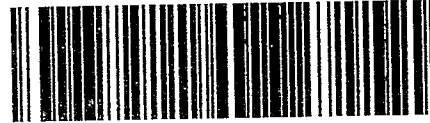
Material Identification

**Item 300524**

**SODIUM CROSCARMELOSE PDR (1)**

Old Part Number 2000001075  
 PO Number 2021-00-40597  
 NutraStar Lot 21012892  
 Received 06/08/2021  
 Vendor Em Sergeant  
 Vendor Lot 71121010083  
 Expires 01/01/2025

NET WT: 25.000 KG



**QUALITY:**

SPECIFICATION VERSION: B

Review test results generated by a QC Technician, External Laboratory or stated on the supplier's CoA with the listed specification. Record the review by using the respective specification form.

REVIEW COMPLETED BY: Andree Coman DATE: 06/08/2021

**DISPOSITION:**

<input checked="" type="checkbox"/> <b>RELEASED</b> – This lot (batch) is approved for use in production, further processing, or distribution.	Quality Signature/Date: <i>manuvelly 06/08/2021</i>
<input type="checkbox"/> <b>RELEASED WITH RESTRICTIONS</b> – This lot (batch) is released for use in production, further processing, or distribution, subject to the following conditions.	Management Signature/Date:
<input type="checkbox"/> <b>REJECTED</b> – This lot (batch) is prohibited from use in production, further processing, or distribution due to the following reasons.	Quality Signature/Date:



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

MATERIAL DESCRIPTION

SPECIFICATION VERSION: B

Storage Conditions: Ambient

Material Name: Sodium Croscarmellose

Item Number: 300524

Lot Number: 21012892

Primary Vendor: Em Sergeant ✓

Category: Chemical Entity

**REQUIRED TESTS AND EXAMINATION**

1. APPEARANCE:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Color	VISUAL	Almost White	Complies
Texture	MACROSCOPIC	Hygroscopic Powder	Complies

2. IDENTIFICATION:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Identity	USP Croscarmellose Sodium Test B	Conforms	Complies

3. STRENGTH (POTENCY):

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Assay	N/A	N/A	N/A

4. PHYSICAL CHARACTERISTIC:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Bulk Density	COA	>0.4 g/mL	N/A
Particle Size	COA/In-house	N/A	N/A

5. COMPOSITION (EXCIPIENT/CARRIER):

SPECIFICATION	Verified
N/A	N/A



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

6. CONTAMINANTS:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Microbiology	COA	TAMC <1,000 cfu/g TYMC <100 cfu/g E. Coli Absent/10g Salmonella Absent/10g	Comply
Heavy Metals	COA	Arsenic < 15µg/g Cadmium < 5µg/g Lead < 5µg/g Mercury < 2µg/g	CA 1

7. QC NOTES:

Bulk Density	N/A
Particle Size	N/A or Mandatory for R&D
Strength	N/A
Micro	N/A
Metals	N/A

8. REVISION HISTORY:

Version	Effective Date	Reason for Change
A	06/21/2018	New Document
B	11/19/2020	New Template

9. DOCUMENT FORM HISTORY (See form history in SOP 03.011-F03.004)

Prepared by:	ORIGINAL SIGNATURES ON FILE
Approved by:	ORIGINAL SIGNATURES ON FILE

INFORMATION	
Title:	Identity of Croscarmellose Sodium
Method:	USP 00
Analyst:	Arlene C
Date:	06/08/2021

Samples:

Item#	Sample Name	Lot#	Notes
300524	Na Croscarmellose	21012892	EM Sergeant
AC 06/08/2021			

Materials & Reagents:

Name	Manufacture	Lot#	Exp. date	Notes
Sulfuric Acid	Sigma Aldrich	MIC CL1572	08/24/2021	—
Naphthal	Sigma	DC844386	05/2022	—
M20H	Sigma	SHB4468	02/15/2024	—
AC 06/08/2021				

Equipment:

Name	ID	Notes
Balance	796	
Vortex		
Centrifuge		
Timer		
Oven		
Other:		
Other:		

Procedure:

Sample ID	Weight	Diluent	Diluent volume	Notes
Cross. Na spl.	1.014 g	H <sub>2</sub> O	50 ml	

Testing solutions:

Name	Weight/Volume	Diluent	Final Volume	Notes
Nap <sup>td</sup> B	0.084 g	MeOH	2.08 ml	

Data Collection:

1 ml of sample solution into test tube - 1ml water  
is added - few drops naphthol B is added +  
2 ml sulfuric acid added on incline a violet-  
reddish to purple violet like color develops w/in  
sample solution -

~~WA~~  
AE 06/08/2021

Conclusion:

Conforms     Non-conforms     Further Testing

Notes:

~~WA~~  
AE 06/08/2021

Quality Review:	maurice 06/08/2021
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## CERTIFICATE OF ANALYSIS

**PRODUCT** CROSCARMELOSE SODIUM NF, JP, Ph. Eur.  
**LOT No.** 71121010083  
**MFG DATE:** JANUARY 2021  
**RE-EVAL DATE:** JANUARY 2025 (4 YEARS)  
**COUNTRY OF ORIGIN** INDIA  
**DESCRIPTION** Almost white, very hygroscopic powder; practically insoluble in acetone, ethanol, ether, and toluene. Produced from wood cellulose.

<u>TEST ITEMS</u>	<u>SPECIFICATIONS</u>	<u>RESULTS</u>
Identification (A,B,C), (1,2,3)	Corresponds to standard	Complies
Degree of Substitution	0.60 – 0.85	0.72
Loss on drying	10.0% max	6.07%
pH	5.0 – 7.0	6.80
Content of water-soluble material	1.0 – 10.0%	8.00%
Sulphated ash	14.0 – 28.0%	20.95%
Settling volume	10.0 – 30.0 mL	15.5 mL
<u>Sodium chloride &amp;</u> Sodium glycolate	0.5% max	< 0.5%
Heavy metals	10 ppm max	< 10 ppm
Arsenic (As)	2 ppm max	< 2 ppm*
Cadmium	2 ppm max	< 2 ppm*
Lead	0.5 ppm max	< 0.5 ppm*
Residue of Ethanol	3.0% max	< 3.0%
Total Aerobic Plate Count	< 100 cfu/g	38 cfu/g
Total Yeast and Mold Count	< 20 cfu/g	< 15 cfu/g
E. coli	Absent in 1g	Not present
Pseudomonas aeruginosa	Absent in 1g	Not present
Staphylococcus aureus	Absent in 1g	Not present
Salmonella species	Absent in 10g	Not present
Particle Size (Retained)		
On 200 Mesh	2% max	< 2%
On 325 Mesh	10% max	< 10%

\* Results reported are expected results based on periodic testing.

The raw materials, manufacturing process and product do not contain any of the solvents listed in Residual Solvents (Ph. Eur. <5.4>, USP <467>) except for ethanol limited to < 0.5%. Elements listed in ICH Q3D Guideline for elemental impurities are not used in manufacturing and not analyzed per batch; detailed information is available upon request.

Storage: Keep away from excessive heat and moisture. Keep containers tightly closed.

This is a copy of the original Manufacturer's/Supplier's Certificate of Analysis

*Ivaylo Balabanov*  
Quality Assurance