

RAW MATERIAL AND PACKAGING MATERIAL EVALUATION FORM

Item 300542

SILICON DIOXIDE - VEGAN

Old Part Number 2000001116
 PO Number 2021-00-39418
 NutraStar Lot 21009842
 Received 05/05/2021
 Vendor Green Wave Ingredients
 Vendor Lot 210117
 Expires 01/21/2023

NET WT: 10.000 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: Elizabeth Rayst DATE: 05/05/21

DISPOSITION:

<input checked="" type="checkbox"/> RELEASED - This lot (batch) is approved for use in production, further processing, or distribution.	Quality Signature/Date: <i>maia viles</i> 05/05/2021
<input type="checkbox"/> RELEASED WITH RESTRICTIONS - This lot (batch) is released for use in production, further processing, or distribution, subject to the following conditions.	Management Signature/Date:
<input type="checkbox"/> REJECTED - This lot (batch) is prohibited from use in production, further processing, or distribution due to the following reasons.	Quality Signature/Date:

安徽山河药用辅料股份有限公司检验报告单

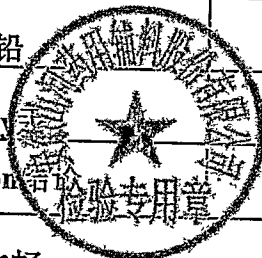


ANHUI SUNHERE PHARMACEUTICAL EXCIPIENTS CO., LTD.

CERTIFICATE OF ANALYSIS

Product: Silicon Dioxide (SH-CD1)

Batch No.	210117	REP DATE 报告日期	JAN.27,2021	
Packing包装	10kg/bag	MFG DATE 生产日期	JAN.22,2021	
Quantity数量	6000kg	EXP DATE 有效日期	JAN.21,2023	
Tests项目	USP40NF35	Testing Result 检测结果	Testing Method 检测方法	
Identification鉴别	Complies	Conforms	USP40NF35	
PH酸碱度	4.0~8.0	7.3	USP40NF35	
Loss on drying干燥失重	≤5.0%	3.34%	USP40NF35	
Loss on ignition灼烧失重	≤8.5%	2.75%	USP40NF35	
Chloride氯化物	≤0.1%	<0.1%	USP40NF35	
Sulfate硫酸盐	≤0.5%	<0.5%	USP40NF35	
Arsenic砷盐	≤3ppm	<3ppm	USP40NF35	
Assay含量	≥99.0%	99.40%	USP40NF35	
Lead铅	≤5ppm	<5ppm	USP40NF35	
Mercury汞	≤1ppm	<1ppm	USP40NF35	
Conclusion结论	It conforms the above test of USP40NF35.			



Analyst: 茆文畅

Checker: 曹岩

QA Manager: 刘大勇



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

MATERIAL DESCRIPTION

SPECIFICATION VERSION: B

Storage Conditions: Ambient

Material Name: Silicon Dioxide

Item Number: 300542

Lot Number: 21009842

Primary Vendor: Green Wave
Ingredients

Category: Chemical Entity

REQUIRED TESTS AND EXAMINATION

1. APPEARANCE:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Color	VISUAL	White	Conforms
Texture	MACROSCOPIC	Powder	conforms

2. IDENTIFICATION:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Identity	IR SOP 03.013	Conforms	98%

3. STRENGTH (POTENCY):

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

4. PHYSICAL CHARECTERISTIC:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Bulk Density	COA	>0.4 g/mL	N/A
Particle Size	COA	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	Cat 1
Heavy Metals	COA	Arsenic < 15µg/g Cadmium < 5µg/g Lead < 5µg/g Mercury < 2µg/g	Cat 1

7. QC NOTES:

Bulk Density	N/A
Particle Size	N/A
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	02/09/2021	Updated 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