

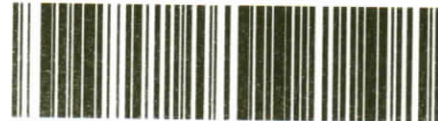
RAW MATERIAL AND PACKAGING MATERIAL EVALUATION FORM

Item 300189

DHEA POWDER BULK

Old Part Number 2000000379
 PO Number 2021-00-44162
 NutraStar Lot 21021233
 Received 10/11/2021
 Vendor Jiaherb
 Vendor Lot JTQBXZT-T-200804
 Expires 08/23/2022

NET WT: 25.000 KG



Quality Approval of Receipt: A.C Warehouse Approval of Receipt: DM

QUALITY:

SPECIFICATION VERSION: C

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: [Signature] DATE: 10/11/21

DISPOSITION:

<input checked="" type="checkbox"/> RELEASED – This lot (batch) is approved for use in production, further processing, or distribution.	Quality Signature/Date: <u>Christian Isoto</u> 10/11/21
<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:



CERTIFICATE OF ANALYSIS

DHEA Dehydroepiandrosterone 99%

GENERAL INFORMATION

Lot Number	JTQBXT-T-200804	Report Date	08/31/2020
Manufacture Date	08/24/2020	Expiration Date	08/23/2022
Country of Origin	China		

ITEM	SPECIFICATION	TEST RESULTS	METHOD
------	---------------	--------------	--------

PHYSICAL & CHEMICAL

Identification	Corresponds to Reference Standard	Complies	FTIR USP<854>
Appearance	White to off-white crystalline powder	Complies	Organoleptic
Assay	Between (%) 98.5-102.0	99.53	HPLC USP<621>
Melting Range	Between (°C) 149-151	148.3-149.6	USP<741>
Specification Rotation	Between (°) +12.0 - +15.0	Complies	USP<781S>
Sulfated Ash	NMT (%) 0.1	Complies	USP<221>
Any Impurity	NMT (%) 0.1	Complies	HPLC USP<621>
Total Impurities	NMT (%) 0.5	Complies	HPLC USP<621>
Particle Size	NLT 95% through 80 mesh	Complies	USP<786>
Loss on Drying	NMT (%) 0.5	0.20	USP<731>

CONTAMINANTS

Lead (Pb)	NMT (ppm) 1.0	Complies	ICP-MS USP<730>
Arsenic (As)	NMT (ppm) 1.0	Complies	ICP-MS USP<730>
Cadmium (Cd)	NMT (ppm) 1.0	Complies	ICP-MS USP<730>
Mercury (Hg)	NMT (ppm) 1.0	Complies	ICP-MS USP<730>

MICROBIOLOGICAL

Total Plate Count	NMT (cfu/g) 1,000	Complies	USP<2021>
Yeast & Mold	NMT (cfu/g) 100	Complies	USP<2021>
E.Coli.	Absent (cfu/10g)	Complies	USP<2022>
Salmonella	Absent (cfu/10g)	Complies	USP<2022>
Staphylococcus aureus	Absent (cfu/10g)	Complies	USP<2022>

PACKING & STORAGE

Packed in a polyethylene lined corrugated package.
Store in a well-closed container away from moisture, light, and heat.
Net Weight: 25kg Pack Type: Drum

SHELF LIFE

24 months if under the conditions above and in its original packaging.

Completed by: Qiangang Wang

Signature: *Qiangang Wang*

Title: Quality Control Manager



RAW MATERIAL SPECIFICATION AND ANALYSIS FORM

MATERIAL DESCRIPTION

SPECIFICATION VERSION: C

Storage Conditions: Ambient

Material Name: DHEA Powder Bulk

Item Number: 300189

Lot Number: 21021233

Primary Vendor: Unichem Ent., Inc.

Category: Chemical Entity

REQUIRED TESTS AND EXAMINATION

1. APPEARANCE:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Color	VISUAL	White or Almost White	Conforms
Texture	MACROSCOPIC	Crystalline Powder	Conforms

2. IDENTIFICATION:

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Identity	IR SOP 03.013	Conforms	96%

3. STRENGTH (POTENCY):

SPECIFICATION	TEST METHOD	ACCEPTANCE CRITERIA	Results
Assay	COA	≥99.0%	Conforms

4. PHYSICAL CHARECTERISTIC:

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

7. QC NOTES:

Bulk Density	N/A
Strength	N/A
Micro	N/A
Metals	N/A

8. REVISION HISTORY:

Version	Effective Date	Reason for Change
A	10/10/2018	New Document
B	08/21/2020	Update To New Template
C	11/12/2020	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