



Certificate Of Analysis

17-10082

Customer:
XXXXXXXXXX

PO #: 16487
 Customer Part #: ZHYAACID
 Ship Date: 1/20/17
 Shipment #: 0000007716

#36216
 JAN 24 2017 14:12
 SCANNED
 JMS

Description: Sodium Hyaluronate HA	Lot #: 3951612121X
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	<u>Standard</u>	<u>Result</u> *
<u>Physical Properties</u>		
Appearance	White powder	Complies
Bulk Density Loose (gm/cc)	>= 0.15 <= 0.3	0.27
Particle size thru # 80 (%)	>= 90	Complies
<u>Analytical</u>		
Sodium Hyaluronate (Dry basis, %)	>= 93	95
Hyaluronic Acid (Dry basis, %)	>= 88	90
Glucuronic Acid (Dry basis, %)	>= 45	46
Loss on drying (%)	<= 8.0	7.4
pH	>= 6.0 <= 8.0	6.8
Protein (%)	<= 0.1	0.03
Molecular weight (kDA)	>= 1300 <= 1700	1450
Lead (ppm)	<= 0.5	<0.5
Arsenic (ppm)	<= 1.5	<1.5
Cadmium (ppm)	<= 0.5	<0.5
Mercury (ppm)	<= 0.2	<0.2
<u>Microbiological</u>		
APC (CFU/gm)	<= 1000	<100
Yeast/mold (CFU/gm)	<= 100	Complies
E. coli (CFU/gm)	Negative	Negative
Salmonella (25 gm)	Negative	Negative
<u>Storage Conditions</u>		
Manufacture date		Dec 12, 2016
Expiration date		Dec 12, 2019
Storage		Cool dry place sealed in light resistant container
Manufactured by		Plant # 395
Country of origin		China
Revision #		Rev 9 10/26/2016



Certificate Of Analysis

A handwritten signature in black ink, appearing to read 'Warren K. Majerus', is written over a horizontal line.

Approved By:

Warren K. Majerus
VP Quality Assurance

Date: 1/20/2017

* Test results based on information supplied by the manufacturer, unless otherwise noted.

** Based on third party testing lab results.

*** Based on results from Pharmore's sampling protocol.

The information contained in this certificate of analysis is believed to be accurate and is offered in good faith. Pharmore Ingredients, however, cannot assume any guarantee against natural product variations, patent infringement, liabilities or risk involved from the use of this product. Customers' assume all risk and liability with the use of this product.



SPECIFICATION

Sodium Hyaluronate HA

	Specification	Test Method
<u>Physical Properties</u>		
Appearance	White powder	Visual
Bulk Density Loose (gm/cc)	≥ 0.15 ≤ 0.3	Loose fill
Particle size thru # 80 (%)	≥ 90	Rotap 5 minutes
<u>Analytical</u>		
Sodium Hyaluronate (Dry basis, %)	≥ 93	By calculation
Hyaluronic Acid (Dry basis, %)	≥ 88	By calculation
Glucuronic Acid (Dry basis, %)	≥ 45	UV-Vis
Loss on drying (%)	≤ 8.0	USP curr. edit.
pH	≥ 6.0 ≤ 8.0	USP curr. edit.
Protein (%)	≤ 0.1	USP curr. edit.
Molecular weight (kDA)	≥ 1300 ≤ 1700	USP curr. edit.
Lead (ppm)	≤ 0.5	ICP-MS
Arsenic (ppm)	≤ 1.5	ICP-MS
Cadmium (ppm)	≤ 0.5	ICP-MS
Mercury (ppm)	≤ 0.2	ICP-MS
<u>Microbiological</u>		
APC (CFU/gm)	≤ 1000	USP curr. edit.
Yeast/mold (CFU/gm)	≤ 100	USP curr. edit.
E. coli (CFU/gm)	Negative	USP curr. edit.
Salmonella (25 gm)	Negative	USP curr. edit.
<u>Storage Conditions</u>		
Storage conditions	Cool dry place sealed in light resistant container	
Shelf life	3 years unopened	
Revision #	Rev 9 10/26/2016	

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