

Certificate of Analysis

Product Name:	Sodium Hyaluronate	Origin:	Fermentation
Intrinsic Viscosity:	2.7~3.6 m ³ /kg	Intended Use:	Intra-ocular preparations & intra-articular preparations
Batch No.:	15061801	Manufacturing Date:	6/19/2015
Analysis Date:	6/22/2015	Retest Date:	6/19/2017
Standard:	HA-EP-3.0	Grade:	HA-EP-3.0

<u>Items</u>	<u>Specifications</u>	<u>Results</u>
Appearance	White or almost white powder or fibrous aggregates	White powder
Identification		
A. Infrared absorption	Complies with Ph. Eur. Reference spectrum of Sodium hyaluronate	Complies
B. Reaction of sodium	Positive	Positive
Appearance of solution	Clear, $A_{600nm} < 0.01$	Clear, 0.00
pH	5.0-8.5	6.4
Intrinsic viscosity	2.7~3.6m ³ /kg	3.32 m ³ /kg
Nucleic acids	$A_{260nm} < 0.5$	0.01
Protein	$\leq 0.1\%$	0.00%
Heavy metal	$\leq 10ppm$	$< 10ppm$
Chlorides	$\leq 0.5\%$	$< 0.5\%$
Iron	$\leq 30ppm$	$< 30ppm$
Loss on drying	$\leq 15.0\%$	10.1 %
Residual solvents(Ethanol)	$\leq 5000 ppm$	68 ppm
Microbial contamination	$\leq 100cfu/g$	$< 20cfu/g$
Bacterial endotoxins	$\leq 0.05 IU/mg$	$< 0.05 IU/mg$
Assay(on dried substance)	95%~105%(dried substance)	98.8%

Stored: Store in a cool, dry location in a tightly sealed container.

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By

