

Certificate of Analysis

Product Name:	Sodium Hyaluronate	Origin:	Fermentation
Intrinsic Viscosity:	0.5~1.0 m ³ /kg	Intended Use:	For the manufacture of oral dosage preparations or parenteral (not include intra-ocular or intra-articular) preparations
Batch No.:	SCC15110401	Manufacturing Date:	11/4/2015
Analysis Date:	11/4/2015	Retest Date:	11/4/2017
Standard:	Ph. Eur. 7.0	Grade:	HA-PM-0.5

<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	6.7
Intrinsic viscosity	0.5~1.0m ³ /kg	0.87 m ³ /kg
Molecular Weight		37 K Da
Nucleic acids	$A_{260nm} < 0.5$	0.08
Protein	$\leq 0.1\%$	0.00%
Heavy metal	$\leq 20ppm$	<20ppm
Chlorides	$\leq 0.5\%$	<0.5%
Iron	$\leq 30ppm$	<30ppm
Loss on drying	$\leq 20.0\%$	7.0 %
Residual solvents(Ethanol)	$\leq 5000 ppm$	748 ppm
Microbial contamination	$\leq 100cfu/g$	<20cfu/g
Bacterial endotoxins	$\leq 0.5 IU/mg$	<0.5 IU/mg
Assay(on dried substance)	95%~105%(dried substance)	95.9%

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

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By

