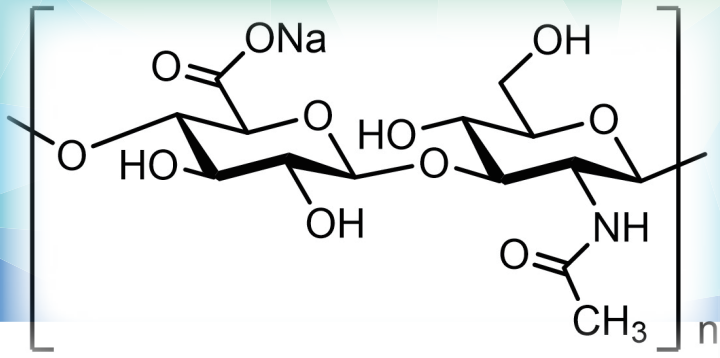
Sodium Hyaluronate

by IWAKI SEIYAKU



IWAKI & CO., LTD.
IWAKI SEIYAKU CO., LTD.

Sodium Hyaluronate by IWAKI SEIYAKU

Features of Hyaluronate IW

Quality you can expect from a pharmaceutical manufacturer

Since our founding on January 28, 1931, IWAKI SEIYAKU CO., LTD. has steadfast grown as a manufacturer of pharmaceutical formulations and ingredients with the strong support of our stakeholders.

With the completion of our new GMP plant, we have increased the GMP capacity of our existing automated bulk lines and high-performance multipurpose lines, and secured the means to flexibly meet the full gamut of needs from small lots to large lots.

And, with a quality control system that is cGMP- and ICH-compliant, DMF- and CEP-registered and FDA-approved, we are confident that customers will be more than pleased with our products.

- c-GMP : current Good Manufacturing Practice
- ICH : International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
- DMF : Drug Master File
- CEP : Certificate of Suitability to the Monographs of the European Pharmacopoeia

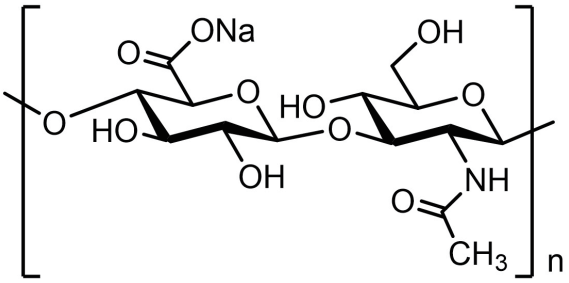
Guaranteed Animal Origin Free

Hyaluronate IW Series products are made by a process of fermentation and culturing using a type of lactic acid bacteria known as *Streptococcus zooepidemicus*. No products or culture mediums of animal origin are used anywhere in the manufacturing process.

Beauty Effect of Sodium Hyaluronate

Sodium hyaluronate is an acidic mucopolysaccharide that exists in the dermis, stratum corneum and between epidermal cells of the skin. It is an important component for keeping skin elastic and moist.

Because sodium hyaluronate decreases with age and external factors like UV rays, supplementing sodium hyaluronate loss is an effective anti-aging approach.



Products information

Hyaluronate IW cosmetic grade

Product name	Type	INCI Name	Composition(%)	Molecular weight
Hyaluronate IW 90	Powder	Sodium Hyaluronate	100	0.8~1.17×10⁶Da
Hyaluronate IW 120		Sodium Hyaluronate	100	1.1~1.6×10⁶Da
Hyaluronate IW 200		Sodium Hyaluronate	100	1.9~2.7×10⁶Da
Hyaluronate IW 1% Aqueous Solution (P)	Liquid	Sodium Hyaluronate	1.00	1.37~1.53×10⁶Da
		Phenoxyethanol	0.80	
		Water	98.20	
Hyaluronate IW 1% Aqueous Solution (M-P)		Sodium Hyaluronate	1.00	1.37~1.53×10⁶Da
		Phenoxyethanol	0.12	
		Methylparaben	0.10	
		Water	98.78	

Hyaluronate IW food grade

Product name	origin	Composition(%)	Molecular weight
Hyaluronate IW Food Additive	Fermentation culture method	100	0.8~1.6×10⁶Da

* This product is food additive.

Hyaluronate IW powder type

Property	Specification	Test Method
Appearance	White to pale yellow, fine powder, having a slight, characteristic odor	JSQI, Sodium hyaluronate (2)
Identification (1) Polyanion	Qualitative-reaction	JSQI, Sodium hyaluronate (2)
(2) Na^+	Qualitative-reaction	JSQI, Sodium hyaluronate (2)
(3) Uronic acid	Qualitative-reaction	JSQI, Sodium hyaluronate (2)
(4) IR	Spectrum identified exhibiting similar intensities of absorption to the reference standard at the same wave numbers	JP, Official monographs, Purified Sodium Hyaluronate
Molecular weight	0.8～1.17×10^6Da (IW90) 1.1～1.6 ×10^6Da (IW120) 1.9～2.7 ×10^6Da (IW200)	JP, General tests 2.53 viscosity determination calculated by limiting viscosity
pH	6.0～7.0	JSQI, Sodium hyaluronate (2)
Appearance of solution	Colorless, clear and viscous liquid	0.5%, aq. Soln.
Purity (1) Heavy metals	Not more than 20ppm	JSQI, Sodium hyaluronate (2)
(2) Arsenic	Not more than 2ppm	JSQI, Sodium hyaluronate (2)
(3) Protein	Not more than 0.1%	JSQI, Sodium hyaluronate (2)
(4) Other acid mucopolysaccharides	Not detected	JSQI, Sodium hyaluronate (2)
(5) Streptococcus haemolyticus	Not detected	JSQI, Sodium hyaluronate (2)
(6) Hemolysis	Not detected	JSQI, Sodium hyaluronate (2)
Loss on drying	Not more than 10.0%	JSQI, Sodium hyaluronate (2)
Residue on ignition	16.0～19.0%	JSQI, Sodium hyaluronate (2)
Assay (1) Nitrogen	3.0～3.6%	JSQI, Sodium hyaluronate (2)
(2) Glucuronic acid	44.0～48.0%	JSQI, Sodium hyaluronate (2)
Microbial limit test	Not more than 100cfu/g	JP, General test 4.05 microbial limit tests

Hyaluronate IW liquid type

Property	Specification	Test Method
Appearance	A colorless, transparent, viscous liquid, having a slight, characteristic odor	Sensory test
Identification IR	The absorption around 3400, 1610, 1405,1040cm^{-1} was recognized	Japanese Pharmacopoeia, FT-IR, KBr method
Viscosity	13,400～18,400mPa・s	Japanese Pharmacopoeia, rotational visco-meter, No.4, 6rpm, 60sec
Molecular weight	1.37～1.53×10^6Da	Calculated by viscosity
pH	5.5～7.5	Japanese Pharmacopoeia, 10% aqueous solution
Heavy metals	Not more than 20ppm	Japanese Pharmacopoeia
Arsenic	Not more than 2ppm	Japanese Pharmacopoeia

Property	Specification	Test Method
Assay	0.9～1.1%	Carbazole-sulfuric acid method
Microbial limit test	Not more than 100cfu/g	Japanese Pharmacopoeia
Specified microorganisms	Not detected	Japanese Pharmacopoeia
Turbidity Spectrophotometry	Guaranteed based on HA, Not more than 0.004 Abs/10mm	Japanese Pharmacopoeia, 100mm, 430nm, 0.5%HA solution
Turbidity Light scattering	Guaranteed based on HA, Not more than 17	Turbidimeter 0.5%HA solution

Hyaluronate IW food additive type

Property	Specification	Test Method
Appearance	White to pale yellow, fine powder, having a slight, characteristic odor	JFSA, General Rules
Identification IR	The absorption around 3400, 1610, 1400, 1040cm^{-1} was recognized	JFSA, General tests IR(1), KBr method
Limiting viscosity	15～25dL/g	JFSA, General tests Viscosity measuring method (Capillary viscometer method)
pH	6.0～7.0	JFSA, General tests pH measurement method (0.1g, boiled and cooled water 100mL)
Appearance of solution	Colorless, clear and viscous liquid	JFSA, General Rules (0.5%, aq. Soln.)
Heavy metals	Not more than 20ppm	JFSA, General tests Heavy metals test method (1.0g, Method 2, control solution Standard lead solution)
Arsenic	Not more than 2ppm	JFSA, General tests Arsenic test method (Sample 1g, Apparatus B, Method 3)
Streptococcus haemolyticus	Not detected	JSQI, Sodium Hyaluronate (2)
Hemolysis	Not detected	JSQI, Sodium Hyaluronate (2)
Loss on drying	Not more than10.0%	JFSA, General tests Loss on drying test method (0.1g, in vacuum, phosphorus pentoxide, 60℃, 4hr)
Assay Glucuronic acid	44～48%	JSQI, Sodium Hyaluronate (2)
Microbial limit test	Not more than 300cfu/g	JFSA, General tests microbial limit tests 1. viable count test ((1) membrane filtration method)
Fungi・Yeast	Not more than 100cfu/g	JFSA, General tests microbial limit tests 1. viable count test ((1) membrane filtration method)
Specified microorganisms Coliform bacteria, Salmonella, Staphylococcus aureus	Not detected	Japanese Pharmacopoeia, General tests microbial limit tests Specified microorganisms

Other products information

Grade	Cosmetic grade		Food grade
Type	Powder type	Liquid type	Food additive type
Packaging	＜Aluminum pouch＞ 100g packing 1kg packing	＜Plastic container＞ P：20kg packing M-P：1kg packing, 20kg packing	＜Aluminum pouch＞ 1kg packing 4kg(1kg×4) packing
Storage	Store in closed container in cool (below 5℃) and well ventilated place until use.		
Expiry date	Please see COA (unopened)	1 year after delivery (unopened)	Please see COA (unopened)

Distributor IWAKI & CO., LTD.

8-2, Nihonbashi Honcho 4-Chome, Chuo-ku, Tokyo 103-8403 Japan (Head Office)
TEL：+81-3-3279-0481

Manufacturer IWAKI SEIYAKU CO., LTD.

IW Nihonbashi Building, 19-8 Nihonbashi-koamicho, Chuo-ku, Tokyo 103-8434, Japan(Head Office Branch)
TEL：+81-3-3668-1570