PHIL-INTERNATIONAL CO., LTD.

Format ID: C 30470, C 30471, C 30472 (06)

PRESIDENT G. S. CHANG (CEP)

Certificate of Analysis

*Product Name : Shiseido Sodium Hyaluronate SZE Grade -EP
*Lot No. : S117DA
*Date of Manufacture : 25 June, 2019
*Expiry Date : Jun. 2022
*Storage Condition : in a refrigerator (2 - 8°C), in an airtight container, protected from light and humidity.

Property	Specification	Test Method	Result
01) Characters - Appearance	White or almost white, very hygroscopic powder or fibrous aggregate.	Ph.Eur. (01/2017:1472)	Conforms
02) Characters - Solubility	Sparingly soluble or soluble in water, practically insoluble in acetone and in anhydrous ethanol.	Ph.Eur. (01/2017:1472)	Conforms
03) Identification A (IR)	Examine by infrared absorption spectrophotometry , comparing with the *Ph. Eur. Reference spectrum of sodium hyaluronate.*	Ph.Eur. (01/2017:1472)	Conforms
04) Identification B (Na^+)	It gives reaction (a) of sodium.	Ph.Eur. (01/2017:1472)	Conforms
05) Appearance of solution	Solution S is clear, and its absorbance at 600 nm is maximum 0.01.	Ph.Eur. (01/2017:1472)	Conforms ≤ 0.01
06) pH	5.5 - 7.0	Ph.Eur. (01/2017:1472)	6.0
07) Intrinsic viscosity	1.4 - 1.9 m^3/kg	Ph.Eur. (01/2017:1472)	1.8 m^3/kg
08) Nucleic acids	Absorbance of solution S at 260 nm is maximum 0.1.	Ph.Eur. (01/2017:1472)	≤ 0.1
09) Protein	Maximum 0.1 %	Ph.Eur. (01/2017:1472)	0.05%
10) Chlorides	Maximum 0.1 %	Ph.Eur. (01/2017:1472)	≤ 0.1 %
11) Iron	Maximum 20 ppm	Ph.Eur. (01/2017:1472)	≤ 20 ppm
12) Heavy metals	Maximum 10 ppm	Ph.Eur. (01/2011:1472)	≤ 10 ppm
13) Loss on drying	Maximum 10.0 %	Ph.Eur. (01/2017:1472)	4.7%
14) Assay	95.0 - 105.0 %	Ph.Eur. (01/2017:1472)	101.4%
15) Microbial limit test	TAMC: Not more than 100 CFU/g	Ph.Eur. (01/2017:1472)	≤ 100 CFU/g
	TYMC: Not more than 100 CFU/g		≤ 100 CFU/g
16) Bacterial endotoxins	Less than 0.041U/mg	Ph.Eur. (01/2017:1472)	< 0.0015 IU/mg
17) Residual solvents	Ethanol: Maximum 10,000 ppm	Ph.Eur. (01/2008:50400)	3,800 ppm
	Methanol: Maximum 3,000 ppm	Ph.Eur. (01/2008:50400)	< 1,000 ppm
18) Sulphated glycosaminoglycans *1)	N/A	-	-

*1) Shiseido sodium hyaluronate products are obtained by bacterial fermentation.

Operator Taeko Enoki

QC Manager Nakahara Kazuyoshi

QA Manager Kazuyuki Shigaya

Approved Date Oct 24, 2019

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Reference Information

Please find the molecular weight result from the following product for your reference, which is calculated by Laurent's formula.

Product name	:	Shiseido Sodium Hyaluronate SZE Grade -EP
Lot No.	:	S117DA
Intrinsic viscosity	:	1.8 m^3/kg
Molecular weight	:	1.02 Mda

Date: Nov. 20, 2019

QA manager Kazuyuki Ikegami
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