



CERTIFICATE OF ANALYSIS

Sodium Hyaluronate MW 1%

Batch n.	20G067
Production date	JUNE 2020
Period of best use	JUNE 2022

Parameter	Unit	Requirement	Method	Result
PHYSICAL-CHEMICAL				
Appearance	-	Clear to slightly opalescent, viscous solution	Internal method (comparison with the standard)	Clear to slightly opalescent, viscous solution
Color	-	Colorless to pale yellow	Internal method (comparison with the standard)	Pale yellow
Odor	-	Characteristic	Internal method (comparison with the standard)	Characteristic
pH	i.u.	4,0 – 6,0	Ph.Eur. 2.2.3	4,8
Viscosity (Brookfield DV-E S03 5 rpm, 25°C)	mPas	5.000 – 15.000	Ph. Eur. 2.2.10	14.500
MICROBIOLOGICAL				
Total bacterial count	CFU/g	≤ 100	Ph.Eur. 2.6.12 / USP (current edition)	<10
Total yeast and mould count	CFU/g	≤ 100	Ph.Eur. 2.6.12 / USP (current edition)	<10
Staphylococcus aureus	g	Absence	Ph.Eur. 2.6.13 / USP (current edition)	Absence
Pseudomonas aeruginosa	g	Absence	Ph.Eur. 2.6.13 / USP (current edition)	Absence
Candida albicans	g	Absence	Ph.Eur. 2.6.13 / USP (current edition)	Absence
Escherichia coli	g	Absence	Ph.Eur. 2.6.13 / USP (current edition)	Absence

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Date: 10th July 2020

Roelmi HPC Technical Department

The analyses are performed on a representative sample and are referred to the product at the time of release. The information included in this Certificate of Analysis does not discharge the user from the control of the product before the use. Roelmi HPC SRL does not take liability for any damage due to improper use. This document refers to the latest version of the specification data sheet and it has been prepared by electronic processing not requiring signature and the traceability to the original signature is managed by internal quality assurance system.

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