

CERTIFICATE OF ANALYSIS

PrincipHYAL (800 - 1000)

Batch n.	22G164
Production date	APRIL 2021
Period of best use	APRIL 2024

Parameter	Unit	Requirement	Method	Result
PHYSICAL-CHEMICAL				
Appearance	-	Powder	IO 07-06A	Powder
Color	-	White	IO 07-06A	White
Odor	-	Characteristic	IO 07-06A	Characteristic
Molecular weight	kDa	800 - 1000	IO 07-06AA	985
Limiting viscosity	dl/g	14,4 - 17,3	S.H. Ph.Eur.Monograph	17,0
pH (0.1% solution)	i.u.	6,0 - 8,0	Ph.Eur. 2.2.3	6,7
Transparency (0.1% solution, 550 nm)	%	≥ 99	Ph.Eur. 2.2.25	Complies
Loss on drying (105°C)	%	≤ 10	Ph.Eur. 2.2.32	6
Proteins	%	≤ 0,10	S.H. Ph.Eur.Monograph	<0,10
Sodium Hyaluronate assay	%	≥ 95	S.H. Ph.Eur.Monograph	98
Glucuronic acid assay	%	≥ 46	S.H. Ph.Eur.Monograph	47
MICROBIOLOGICAL				
Total bacterial count	CFU/g	≤ 100	Ph.Eur. 2.6.12 / USP (current edition)	Complies
Total yeast and mould count	CFU/g	≤ 100	Ph.Eur. 2.6.12 / USP (current edition)	Complies

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<i>Staphylococcus aureus</i>	g	Absent	Ph.Eur. 2.6.13 / USP (current edition)	Complies
<i>Pseudomonas aeruginosa</i>	g	Absent	Ph.Eur. 2.6.13 / USP (current edition)	Complies
<i>Candida albicans</i>	g	Absent	Ph.Eur. 2.6.13 / USP (current edition)	Complies
<i>Escherichia coli</i>	g	Absent	Ph.Eur. 2.6.13 / USP (current edition)	Complies

Date: 24th June 2022

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.

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