

CERTIFICATE OF ANALYSIS

PrincipHYAL (800 - 1000)

Batch n.	20H050
Production date	FEBRUARY 2020
Period of best use	FEBRUARY 2023

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	920
Limiting viscosity	dl/g	14,4 - 17,3	S.H. Ph.Eur.Monograph	16.1
pH (0.1% solution)	i.u.	6,0 - 8,0	Ph.Eur. 2.2.3	6.5
Transparency (0.1% solution, 550 nm)	%	≥ 99	Ph.Eur. 2.2.25	100
Loss on drying (105°C)	%	≤ 10	Ph.Eur. 2.2.32	6.8
Proteins	%	≤ 0,10	S.H. Ph.Eur.Monograph	Complies
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)	<100
Total yeast and mould count	CFU/g	≤ 100	Ph.Eur. 2.6.12 / USP (current edition)	<100

ROELMI HPC srl

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

Date: 16 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.

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