

SPECIFICATION DATA SHEET

PrincipHYAL (800 - 1000)

EU INCI name	US INCI name	CAS n.	EC n.
Sodium Hyaluronate	Sodium Hyaluronate	9067-32-7	---- (polymer)

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

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

OTHER DATA NOT SUBJECTED TO ANALYTICAL CERTIFICATION

Parameter	Unit	Typical result	Method
Total heavy metals (Nichel, cadmium, lead, arsenic, cobalt, chromium, mercury, antimony)	ppm	≤10	AAS/ ICP-MS
Residual solvents (ethanol)	%	≤ 0,5	GC

Storage: keep the product in the original container well closed in fresh and dry place, repaired from humidity, light or heat sources.

Period of best use: 36 months from production date, in sealed original container, if stored as described above.

Roelmi HPC Technical Department

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