

# FICHA TÉCNICA

## Ácido Hialurónico

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			
Aspect	-	Powder	Internal method (comparison with the standard)
Color	-	White	Internal method (comparison with the standard)
Odor	-	Characteristic	Internal method (comparison with the standard)
Molecular weight KDa > 1,800			Internal method (calculated)
	Limiting viscosity dl/g	27.0 – 32.0	S.H.
pH (0.1% solution) i.u.		6.0 – 7.5	Ph.Eur.Monograph Ph.Eur. 2.2.3
Transparency (0.1% solution, 550 nm) %		>99	Ph.Eur. 2.2.25
Loss on drying %		10	Ph.Eur. 2.2.32
Proteins %		0.10	≤ S.H.
Heavy metals (Pb) ppm		20	≤ Ph.Eur.Monograph Ph.Eur. 2.4.8
Sodium Hyaluronate assay %		95	≥ S.H.
Glucuronic acid assay %		45	≥ Ph.Eur.Monograph S.H.
MICROBIOLOGICAL			
Total bacteria count CFU/g		100	≤
Yeasts & Moulds CFU/g		100	≤ Ph.Eur. 2.6.12
			Ph.Eur. 2.6.12

<i>Staphylococcus aureus</i>	g	Absent	Ph.Eur. 2.6.13
<i>Pseudomonas aeruginosa</i>	g	Absent	Ph.Eur. 2.6.13
<i>Candida albicans</i>	g	Absent	Ph.Eur. 2.6.13

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: 24 months from production date, in sealed original container, if stored as described above.