

SPECIFICATION DATA SHEET

FaraHyal H (1600-2000) KDa

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	Comparison with the standard
Color	-	White	Comparison with the standard
Odor	-	Characteristic	Comparison with the standard
Molecular weight	kDa	1600-2000	Calculated
Intrinsic Viscosity	dL/g	25-30	S.H. Ph.Eur.Monograph
pH (0.1%sol)	i.u.	6,0 – 8,0	Ph.Eur.2.2.3
Transparency	T _{550nm}	≥ 99%	Ph.Eur.2.2.25
Loss on drying	%	≤ 10.0	Ph.Eur.2.2.32
Protein	%	≤ 0.1	S.H. Ph.Eur.Monograph
Ashes	%	≤ 13	S.H. Ph.Eur.Monograph
Bulk density	g/cm ³	0,3-0,5	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

Total yeast and mould count	CFU/g	≤ 100	Ph.Eur.2.6.12
<i>Staphylococcus aureus</i>	/g	Negative	Ph.Eur.2.6.13
<i>Pseudomonas Aeruginosa</i>	/g	Negative	Ph.Eur.2.6.13
<i>Escherichia coli</i>	/g	Negative	Ph.Eur.2.6.13
<i>Candida Albicans</i>	/g	Negative	Ph.Eur.2.6.13
OTHER DATA NOT SUBJECTED TO ANALYTICAL CERTIFICATION			
Parameter	Unit	Typical result	
Heavy Metal	ppm	≤ 10	
Arsenic	ppm	≤ 0.5	
Lead	ppm	≤ 1.0	
Mercury	ppm	≤ 0.1	
Cadmium	ppm	≤ 0.3	
Iron	ppm	≤ 80	
Chlorides	%	≤ 0,5	

Storage: keep the product in the original container well closed in fresh and dry place, repaired from humidity, light or heat sources. Temperature at 2-10°C cool and dry place.

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

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