

SPECIFICATION DATA SHEET

ExceptionHYAL[®] HW

Description	CAS n.	EC n.
Sodium Hyaluronate	9067-32-7	Polymer

ANALYTICAL SPECIFICATION			
Parameter	Unit	Requirement	Method
PHYSICAL-CHEMICAL			
Appearance	-	Powder	Internal method (comparison with the standard)
Colour	-	White	Internal method (comparison with the standard)
Odour	-	Characteristic	Internal method (comparison with the standard)
Molecular weight	kDa	1,800 – 2,200	Internal method (calculated)
Limiting viscosity	dl/g	27.0 – 32.0	S.H. Ph.Eur.Monograph
pH (0.1% solution)	-	6.0 – 8.0	Ph.Eur. 2.2.3
Transparency (0.1% solution,550 nm)	%	≥99	Ph.Eur. 2.2.25
Loss on drying	%	≤15	Ph.Eur. 2.2.32
Ashes	%	≤13	Ph.Eur. 2.4.16
Bulk density	g/cm ³	0.3 – 0.6	Ph.Eur. 2.9.34
Glucuronic acid assay	%	≥45	S.H. Ph.Eur.Monograph
Sodium Hyaluronate assay	%	≥95	S.H. Ph.Eur.Monograph
MICROBIOLOGICAL			
Total bacteria count	CFU/g	≤100	Ph.Eur. 2.6.12
Yeasts & Moulds	CFU/g	≤100	Ph.Eur. 2.6.12

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<i>Enterobacteriaceae</i>	CFU/g	≤100	UNI ISO 21528-2
<i>Escherichia coli</i>	g	Absence	Ph.Eur. 2.6.13
<i>Staphylococcus aureus</i>	g	Absence	Ph.Eur. 2.6.13
<i>Salmonella</i>	10g	Absence	Ph.Eur. 2.6.13
<i>Listeria monocytogenes</i>	25g	Absence	UNI ISO 11290-1

OTHER DATA NOT SUBJECTED TO ANALYTICAL CERTIFICATION			
Parameter	Unit	Typical result	Method
Heavy metals (Pb)	ppm	≤20	Ph.Eur. 2.4.8
Arsenic	ppm	≤2	Ph.Eur. 2.4.27
Lead	ppm	≤3	Ph.Eur. 2.4.27
Mercury	ppm	≤0.1	Ph.Eur. 2.4.27
Cadmium	ppm	≤1	Ph.Eur. 2.4.27

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.

Roelmi HPC Technical Department

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