



Raya Hyaluron EP 1 pharma grade

INCI name:	Sodium hyaluronate
Chemical description:	D-Glucuronsäure-N-Acetyl-D-Glucosamin Polymer
Trade name:	Raya Hyaluron EP 1 pharma grade
Product category:	Medical grade Sodium Hyaluronate
Applications:	eye drops, eye lotions, contact lens solutions, medical lubricants, topical preparations (gel. film etc.) oral pharmaceutical preparations
Packaging:	in bags
Filling Quantity:	1 kg/bag Special packaging and smaller fillings quantity on request
Shelf life:	up to 18 months, not opened
Storage conditions:	dry and cool avoid direct sunlight and heat

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Product Spezifikation Raya Hyaluron EP 1 pharma grade

Test	Spezifikation	Result Batch 14051201
Identification		
Appearance	white powder or fibrous aggregate	conforms
Infrared absorption	like Ph.Eur. reference	conforms
Transparency solution	$A_{600nm} \leq 0.01$	0.00 (clear)
Reaction of sodium	positive	conforms
Properties		
Assay Sodium hyaluronate	95.0 - 105.0 %	101.3 %
Glucuronic acid	$\geq 44 \%$	47 %
pH	5.0 - 8.5	7.2
Limiting viscosity	1.6 - 2.8 m ³ /kg	2.4 m ³ /kg
Loss on drying	$\leq 15.0 \%$	6.6 %
Molecular weight	1400 - 1600 k Da	1420 k Da
Heavy Metals	≤ 10 ppm	< 10 ppm
Protein	$\leq 0.05 \%$	0.00 %
Microbial contamination	< 100 cfu/g	< 20 cfu/g
Bacterial endotoxins	< 0.5 IU/mg	conforms
Residuals solvents (ethanol)	≤ 5000 ppm	conforms
Nucleic acids	$A_{260nm} \leq 0.5$	0.01