CONTIPRO

PRODUCT SPECIFICATION: 00-51-61

Product Name: Sodium Hyaluronate
Quality Class: Pharmaceutical
Manufacturer: Contipro a.s.
Retest Date: 3 years

METHOD	UNIT	SPECIFICATION LIMITS	METHOD REF.
Appearance	---	white or almost white powder, granules or fibrous aggregate	206.1.1-012
Identification - test A (Infrared spectrum)	---	complies with the Ph. Eur. reference spectrum	206.1.1-232
Identification - test B (Sodium)	---	pass	206.1.1-224
Appearance of solution - Appearance	---	clear	206.1.1-223
Appearance of solution - Absorbance	---	≤ 0.010	206.1.1-221
pH	---	5.0 - 8.5	206.1.1-220
Intrinsic viscosity	m3/kg	≥ 0.65	206.1.1-226
Nucleic acids	---	≤ 0.030	206.1.1-222
Chlorides	%	< 0.3	206.1.1-225
Iron	ppm	< 4.0	206.1.1-231
Loss on drying	%	≤ 10.0	206.1.1-208
Microbial contamination	CFU/g	< 5	206.1.1-819
Bacterial endotoxins	IU/mg	< 0.005	206.1.1-279
Sodium hyaluronate	%	95.0 - 105.0	206.1.1-228
Residual isopropanol	%	≤ 0.50	206.1.1-219
Protein	%	≤ 0.035	206.1.1-373

Above Ph. Eur. specification complies with Ph. Eur. last edition.

Criteria on customer's request (not within the scope of Ph. Eur.)

Molecular weight (SEC-MALS)	MDa	actual value	206.1.1-254
Calcium	ppm	≤ 80.0	206.1.1-284
Magnesium	ppm	≤ 80.0	206.1.1-284

No animal origin material was used during the manufacture of this product.

Dolní Dobrouč 2019-11-29

Manufacturer

CONTIPRO
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Customer

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