

COMPOSITION

Medium

INGREDIENTS	CAS number	FUNCTION	% (g/100ml)
Water for injections	7732-18-5	Solvent	96.66
Sodium Hyaluronate	9067-32-7	Active ingredient: filling and moisturizing agent	2.10
BDDE	2425-79-8	Cross-linker	0.19
Sodium Hydroxide	1310-73-2	Buffering agent	0.31
Hydrochloric acid (37%)	7647-01-0	Buffering agent	0.67
Phosphoric acid (85%)	7664-38-2	Buffering agent	0.07

FINISHED PRODUCT SPECIFICATION

Medium		
PARAMETERS	STANDARD VALUES	METHOD
Physical Aspect	Gel	Visual
Colour	Colorless	Visual
pH	6,5 ± 1	CH01 (pH meter)
BDDE residue	< 2 ppm	GC - MS
Hyaluronate title	≥2,0%	UV-VISIBLE
Sterility test	Sterile	ISO 11737-2
Bacterial Endotoxin Detection	≤ 0,50 EU/ml	EP 2.6.14, USP 85
Volume Control	1g± 5%	CH03 (analytical balance)