

**BIOTECH OPHTHALMICS PVT LTD
QUALITY CONTROL DEPARTMENT**

CERTIFICATE OF FINISH PRODUCT ANALYSIS

PRODUCT NAME : Sodium Hyaluronate Solution 10 mg/ml for Ophthalmic Use

Batch No	1609253	A.R.No.	40000042996
Batch Size	5.5 Lit	Shelf Life	36 Months
Filled Volume	1 ml	Sample Qty.	65 PFS
Container Type	Prefilled Syringe	Date of Receiving	15/09/16
Mfg. Date	2016/09	Date of Testing	15/09/16
Exp. Date	2019/08	Date of Release	29/09/16

Sr. No.	Test	Results	Specification
1.	Description	Complies	Clear gel free from particles.
2.	Extractable Volume	Complies	The volume measured for each of the containers is not less than the nominal volume.
3.	pH at 25°C $\pm$ 2°C	7.20	Between 6.8 and 7.6
4.	Osmolality	346 mOsm/kg	270 – 400 mOsm/kg
5.	Refractive Index at 25°C $\pm$ 2°C	1.338	Between 1.336 and 1.339
6.	Spectral transmittance	Complies	NLT 95.0% transmittance (From 400 nm to 1100 nm)
7.	Injection Force Test	13.8 N	NMT 20 N
8.	Shear viscosity at 25°C $\pm$ 2°C	3,60,000 mPas	NLT 3,00,000 mPas
9.	Assay	100.51 %	It Contains NLT 90.0% and NMT 115.0% of the labeled claim of Sodium Hyaluronate
10.	Elasticity	55.88 Pas	30.0 – 65.0 Pas
11.	Complex Viscosity	57.42 Pas	25.0 – 65.0 Pas
12.	Sterility	Complies	Should be sterile
13.	Bacterial Endotoxins	Complies	NMT 0.5 EU/mL

The above-mentioned test complies as per OVD: ISO 15798: 2013/Ph.Eur.

SIGN	ANALYZED BY		APPROVED BY
			
DATE	29/09/16	29/09/16	29/09/16
DESIGNATION	QC CHEMIST	MICROBIOLOGIST	QC MANAGER