

## Certificate of Analysis

|                             |                            |                            |                                                          |
|-----------------------------|----------------------------|----------------------------|----------------------------------------------------------|
| <b>Product Name:</b>        | Sodium Hyaluronate         | <b>Origin:</b>             | Fermentation                                             |
| <b>Intrinsic Viscosity:</b> | 1.6~2.2 m <sup>3</sup> /kg | <b>Intended Use:</b>       | Intra-ocular preparations & intra-articular preparations |
| <b>Batch No.:</b>           | 15111301                   | <b>Manufacturing Date:</b> | 11/14/2015                                               |
| <b>Analysis Date:</b>       | 11/15/2015                 | <b>Retest Date:</b>        | 11/14/2017                                               |
| <b>Standard:</b>            | Ph. Eur. 7.0               | <b>Grade:</b>              | HA-EP-1.8                                                |

| <u>Items</u>               | <u>Specifications</u>                                           | <u>Results</u>          |
|----------------------------|-----------------------------------------------------------------|-------------------------|
| Appearance                 | White or almost white powder or fibrous aggregates              | White powder            |
| Identification             |                                                                 |                         |
| A. Infrared absorption     | Complies with Ph. Eur. Reference spectrum of Sodium hyaluronate | Complies                |
| B. Reaction of sodium      | Positive                                                        | Positive                |
| Appearance of solution     | Clear, $A_{600nm} < 0.01$                                       | Clear, 0.00             |
| pH                         | 5.0-8.5                                                         | 6.4                     |
| Intrinsic viscosity        | 1.6~2.2m <sup>3</sup> /kg                                       | 2.01 m <sup>3</sup> /kg |
| Nucleic acids              | $A_{260nm} < 0.5$                                               | 0.01                    |
| Protein                    | ≤0.1%                                                           | 0.00%                   |
| Heavy metal                | ≤10ppm                                                          | <10ppm                  |
| Chlorides                  | ≤0.5%                                                           | <0.5%                   |
| Iron                       | ≤30ppm                                                          | <30ppm                  |
| Loss on drying             | ≤15.0%                                                          | 2.8 %                   |
| Residual solvents(Ethanol) | ≤5000 ppm                                                       | 72 ppm                  |
| Microbial contamination    | ≤100cfu/g                                                       | <20cfu/g                |
| Bacterial endotoxins       | ≤0.05 IU/mg                                                     | <0.05 IU/mg             |
| Assay(on dried substance)  | 95%~105%(dried substance)                                       | 102.0%                  |

Stored: Store in a cool, dry location in a tightly sealed container.

Stanford Advanced Materials

By

