Hyaluronic Acid Analysis

according to GMP and cGMP (FDA)
Hyaluronic Acid Analysis

Many health products like pharmaceuticals, medical devices and cosmetics are composed of hyaluronic acid. Confarma has more than 10 years of experience on analyzing products based on this compound. We offer a complete range of dedicated analytical services for the control of raw materials and finished products.

FINISHED PRODUCTS:
- Filler agent (cross linked, non-cross linked)
- Ophtalmic use
- Cream
- Intra-articular injection (Osteoarthritis)

RAW MATERIALS:
- NaHA (sodium hyaluronate)
- Lidocaine
- Vitamin (sorbitol)
- Glycerol
- Buffer

For all products based on hyaluronic acid for medical or cosmetic use, we offer a full range of analysis:
- Physico-chemistry
- Biology/Microbiology
- Molecular Biology

RESEARCH & DEVELOPMENT
- Method development and validation
- Stability studies
- Extractables and leachables
- In vitro Pyrogen Test (MAT)

QUALITY CONTROL
- Bioburden (Ph. Eur., USP, ISO)
- Sterility Test (Rapid sterility Test in 5 days)
- Osmolarity
- Endotoxines (LAL)
- pH measurement
- Analysis and determination of Hyaluronic Acid (NaHA) according to European Pharmacopoeia
- Analysis and determination of BDDE cross-linker (1,4-butanediol diglycidyl ether)
- Particulate contamination
- Proteins

STUDIES
- Biocompatibility – ISO 10993
- Cell based assays
- Cleaning validation
- Site qualification mapping
- Disinfectant validation
- Container Closure Integrity Testing