



HYAL[®]

OUR HYALURONIC ACID: EXPERTISE, KNOW-HOW AND CAPABILITIES

- HIGHLY PURIFIED, **PHARMACEUTICAL GRADE**, HYALURONIC ACID (HA)
- FULL COMPLIANCE WITH THE REQUIREMENTS OF THE **PH. EUR. MONOGRAPH**
- COMMERCIALY **AVAILABLE IN BULK**
- **READY-TO-USE** HA FRACTIONS (**HYALASTINE[®]**, **HYALECTIN[®]**, **HYALOFTIL[®]**, **HYAL[®] SH**) AND **TAILOR-MADE** VISCOSITIES
- USED IN PHARMACEUTICALS AND MEDICAL DEVICES CURRENTLY MARKETED IN **OVER 100 COUNTRIES WORLDWIDE**



KNOW-HOW

- **+55** years of research into Hyaluronic Acid
- **+700** patents
- First to file a variety of chemical modifications of the native molecule (partial esterifications, auto-crosslinking, association of crosslinked derivatives, linear HA amide derivatives and others)
- Know-how in the formulation of HA finished dosage forms, in different therapeutic areas
- **Ready-to-use HA fractions** (Hyalastine[®], Hyalectin[®], Hyalofitil[®], Hyal[®] SH) to save R&D costs and shorten supply timing
- Capability to produce **tailor-made viscosities**, according to client's final use and requirements (NLT 3 dl/g)



SOURCES

- Proprietary sources and manufacturing processes:
 - **Biofermentation** of a non-pathogenic *Streptococcus equi* strain, certified as safe for industrial use
 - **Biological** extraction from rooster combs



SITE CERTIFICATES AND REGULATORY

- **GMP-approved** by AIFA, the Italian Medicines Agency, and **US FDA-inspected** production facilities
- Authorized by the Italian Ministry of Health for medicinal products and **APIs**, for **veterinary use**
- Inspected every year by national and international health authorities
- Quality Systems EN ISO 13485:2016 and EN ISO 9001:2015 certified
- Validated process in compliance with Eudralex vol. 4 part I and II
- **Certificate of Suitability** (R0-CEP 2017-220-Rev 00) to the European Pharmacopeia granted by EDQM (sodium hyaluronate from fermentation)
- **Drug Master File** submitted to AIFA



WHO WE ARE

- **Italian company** based in Abano Terme (Padua), established in 1946
- 214,000 m² of industrial site, with 50,000 m² of manufacturing facilities, of which 4,000 m² dedicated to APIs
- 21,000 m² research unit and GMP Site in Noto (Sicily, Italy)
- Part of the P&R Group, one of the leading Italian groups in the chemical sector: +3,500 employees globally, 800 million € turnover (2018), over 75% generated in foreign markets



CONTACT DETAILS

- Please contact our International Sales Department for more information on our Hyaluronic Acid at ha@fidiapharma.it