Leading Pharmaceutical Innovation

A CDMO for
YOUR
Hyaluronic Acid products
& Medicated Patches

altergon

Hyaluronic
Acid
Experts

Leading Pharmaceutical Innovation

Born in 2000 in Morra De Sanctis (Avellino), Altergon represents a Centre of Excellence and Innovation for the production of medicated patches and active pharmaceutical biotech ingredients (Hyaluronic Acid and GAG's).

With a total area of about 55.000 sqm, Altergon production site consists today of 4 manufacturing buildings and 10 production lines, 4 modern R&D laboratories, with pilot plants for the several platforms of Drug Delivery – medicated patches, microneedles, oral films, sterile impregnated gauzes – a Process & Product Design (PPD) laboratory, a modern Quality Control laboratory and an automated warehouse. A side building for general services (including a conference room) is available. Moreover, Altergon takes advantage of SAP Management System.

The research and development activities, the manufacturing processes as well as the packaging operations are performed by means of high quality modern technology in strict compliance with the rules and ethical principles, managed by high qualified and experienced technical staff.

Thanks to the uniqueness of the patented processes, Altergon is today among the leading worldwide producers of medicated Hydrogel patches (Flector®), Drug in Adhesive matrix patches (Nitroglycerin, Piroxicam, Diclofenac and others) and ultra pure pharmaceutical grade Sodium Hyaluronate (SHYALT® ULTRAPURE).

A CONTINUALLY EVOLVING COMPANY

1985 ALTERGON SA founded in Lugano

Launch of an Operative Company in Italy: Altergon Italia **2000**

2005 Authorization by AIFA for the first dedicated manufacturing plant for Flector®

Authorization by FDA **2008**

2010 SAP management implementation and start-up of Hyaluronic Acid (Pharma)

Hyaluronic Acid production process approved by AIFA **2011**

2012 FDA full approval for medicated patches production

Automated warehouse approval by Authorities **2014**

2015 Expansion of Hyaluronic Acid Pharma Plant (SHYALT® ULTRAPURE)

Certificate of Suitability (CEP) by EDQM and submission to FDA of the Hyaluronate DMF (MAF) **2016**

2017 Authorization by AIFA and FDA of a new production line for patches & orodispersible films

Renewal of Certificate of Suitability (CEP) by EDQM and update of MAF n. 2718
AIFA Authorization for the production line of impregnated sterile gauzes **2021**

2022 Expansion of the hyaluronic acid pharma production capacity & Pre-filled syringes (PFS) for crosslinking hyaluronate

Approval by Korean Authority (KFDA) of the hyaluronate KDMF **2024**
2025

Pharmaceutical Products

HYDROGEL PATCHES

Patch with a soft hydrogel compound, gently adheres to the skin.

Due to the drug delivery system, it grants a controlled release of the active ingredients – 12/24 hours according to the formulation.

Comfortable, easy to apply and remove, it does not stain clothes or use volatile organic solvents. It is therefore normally very well tolerated.

ORODISPERSIBLE FILMS (ODF)

Orodispersible films (ODF) constitute an innovative oral drug delivery system. This dosage form is placed on patient's tongue or oral mucosal tissue and it rapidly dissolves to release the API for mucosal and sublingual absorption. As the film dissolves, the drug enters the blood stream buccally or sublingually. This leads to reduce drug exposure and to a rapid onset of action, avoiding the hepatic "first-pass".

Orodispersible films have emerged as an advanced alternative to the traditional tablets, capsules, suppositories and liquids in a wide range of pharma (and nutraceuticals) applications. They offer a fast and accurate dosing in a safe and efficacious format, convenient and handheld.

PRE-FILLED SYRINGES (PFS)

Dedicated site production of innovative CROSS-LINKED HYALURONIC ACID pre-filled syringes (PFS) terminally sterilized and suitable for medical and orthopaedic applications, patented and innovative for the higher purification.

DRUG IN ADHESIVE MATRIX / TRANSDERMAL PATCHES

The adhesive layer is particularly thin and dry and it adheres to the skin providing a gradual release of the drug. The active ingredient may act locally (topical patch) or in the general body circulation (transdermal systemic action).

The transdermal drug delivery technology may find wide application, as for instance in the field of cardiac therapy as well as in anti-inflammatories, hormones and in the pain therapy.

MASKS AND SPECIAL PATCHES

Hydrogel Mask patches are formulated to sooth, refresh and hydrate the skin of face, neck and decollete.The particular molecular structure of the Hydrogel Mask patch allows a significant quantity of water to be contained, which evaporates during the application. It refreshes and hydrates the treated area by releasing the functional ingredients in the skin through osmosis.

Special patches are designed to provide more comfortable format and higher adhesiveness for specific applications (i.e. knees, elbows, shoulders). Many flexible and customised formats are available, with hydrogel and drug in adhesive technologies: rounded corners, easy peeling, not standard shapes. Special patches can be developed also with natural functional components.

STERILE IMPREGNATED GAUZES

An innovative dedicated plant for the production of sterile impregnated dressing specifically designed for wound healing purpose, thanks to the Hyaluronic Acid hygroscopic features that guarantee the right level of hydration in the dermis and contribute to the tissue regeneration process.

Hyaluronic Acid
(Active Pharmaceutical Ingredient)

THE HYALURONATE PRODUCTION FACILITY

Altergon Sodium Hyaluronate is obtained starting from the selectioned high productivity cell strain Streptococcus equi zooepidemicus that has been deposited at the Institut Pasteur in Paris.

A dedicated and fully GMP manufacturing plant with an innovative biotech process for the production of Sodium Hyaluronate (HANa) has been patented.

Italian Patent n. 0001413257
European Patent n. 2870255
USA Patent n. 9,347,079
China n. ZL201380035588.8
Hong Kong n. HK1206788
Canada n. 2879538

Thanks to its core capabilities, Altergon is able to customize the Intrinsic Viscosity for the whole range from 0.2 m^3/Kg to 3.2 m^3/Kg by working in the liquid phase, ensuring the utmost batch to batch Consistency and Uniformity.

This expertise has allowed Altergon to be the only worldwide company to be certified by EDQM with a unique CEP:

CEP 2014-263 - Rev 01

Our Milestones

2009 2010 **Industrial Production and Purification Plant:**
a plant dedicated to the hyaluronate, validated and approved under ICHQ7 EUGMP part II – engineered under ISPE vol. 6 guideline for Biopharmaceutical Manufacturing Facilities. AIFA authorized, CEP and GMP certified.

2015 **Pilot Plant "GMP – LIKE":**
a State of the Art multipurpose Pilot Plant equipped for the study and development of new biotech processes or customization.

2016 2024 **HANa:** : a continuous and huge expansion of the plant and the production capacity, fully GMP and EDQM certified, with a low content of endotoxins and elemental impurities. Empowerment of a new Hub for Business Development and Innovation: the Hyaluronate Key Customer Care.

THE HYALURONATE BIOTECH

SHYALT®
ULTRAPURE
SODIUM HYALURONATE ALTERGON

ULTRA **PURE**
ULTRA **SAFE**
ULTRA **MODERN**

Altergon Italia R&D labs patented a brand new process for the production of SHYALT ® ULTRAPURE – Ultra pure Hyaluronic Bulk. The patent recognises the originality of the process for the production and purification of Hyaluronic Acid for pharmaceutical and medical injectable applications and formulations.

SHYALT ® ULTRAPURE comes in customizable batches with Molecular Weight between 40 and 4000 KDa and Intrinsic Viscosity in the whole range from 0.2 m^3/Kg to 3.2 m^3/Kg.

Especially suitable for intra-articular/ intra-ocular use and for the modern concept of Cross-link with high and improved resistance to thermal production treatments.

SHYALT ® ULTRAPURE is covered by CEP 2014-263 - Rev 01

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