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

2000 LAUNCH OF AN OPERATIVE COMPANY IN ITALY: ALTERGON ITALIA

2005 AUTHORIZATION BY AIFA FOR THE FIRST DEDICATED MANUFACTURING PLANT FOR FLECTOR®

2008 AUTHORIZATION BY FDA

2010 SAP MANAGEMENT IMPLEMENTATION AND START-UP OF HYALURONIC ACID (PHARMA)

2011 HYALURONIC ACID PRODUCTION PROCESS APPROVED BY AIFA

2012 FDA FULL APPROVAL FOR MEDICATED PATCHES PRODUCTION

2014 AUTOMATED WAREHOUSE APPROVAL BY AUTHORITIES

2015 EXPANSION OF HYALURONIC ACID PHARMA PLANT (SHYALT® ULTRAPURE)

2016 CERTIFICATE OF SUITABILITY (CEP) BY EDQM AND SUBMISSION TO FDA OF THE HYALURONATE DMF (MAF)

2017 AUTHORIZATION BY AIFA AND FDA FOR A NEW PRODUCTION LINE FOR PATCHES & ORODISPERSIBLE FILMS

2018 AUTHORIZATION BY MINISTRY OF INDUSTRY & TRADE - RUSSIAN FEDERATION FOR SODIUM HYALURONATE BULK, MEDICATED PATCHES & ORODISPERSIBLE FILMS

2021 RENEWAL OF CERTIFICATE OF SUITABILITY BY EDQM AND UPDATE OF MAF n° 2718
AIFA AUTHORIZATION FOR THE PRODUCTION LINE OF IMPREGNATED STERILE GAUZES

2022 EXPANSION OF THE HYALURONIC ACID PHARMA PRODUCTION CAPACITY & PRE-FILLED SYRINGES (PFS) FOR CROSSLINKING HYALURONATE

2024/25 APPROVAL BY KOREAN AUTHORITY (KFDA) OF THE HYALURONATE KDMF

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.

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.

ORODISPERSIBLE FILMS (ODF)

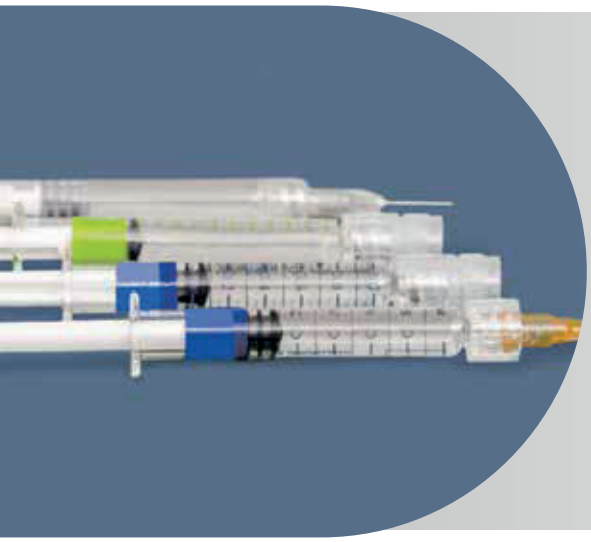
Orodispersible films (ODF) constitute an innovative oral drug delivery system. This dosage form is placed on patient's tongue or oral mucosal tissue and it rapidly dissolves to release the API for mucosal and sublingual absorption. As the film dissolves, the drug enters the blood stream buccally or sublingually. 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.

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.



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.

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 HANa PRODUCTION FACILITIES

An innovative manufacturing 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

Ultrapure Hyaluronic Acid - SHYALT® with customized Molecular Weights (from 40 KDa to 4000 KDa) is obtained starting from the cell strain Streptococcus equi zooepidemicus, through a multi-step process that includes fermentation, filtration, ultra-purification, finishing up to the final packaging. The strain has been deposited at the Institut Pasteur in Paris.

Certificate of Suitability by EDQM
CEP 2014-263 – Rev 01

A CONTINUALLY EVOLVING COMPANY

2010 HANa
Dedicated Plant
First plant, 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
A State of the Art multipurpose Pilot Plant equipped for the study and development of new biotech processes.

2016 HANa
Expansion of the production capacity - fully GMP.

2022/25 HANa
Huge expansion of the PHARMA PLANT and the production capacity.
Fully GMP and EDQM certified, with a low content of endotoxins and elemental impurities.

API BIOTECH = HANa

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 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 0.2 - 3.2 m^3/kg.

Especially suitable for intra-articular/ intra-ocular use or 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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