Leading Pharmaceutical Innovation

altergon

Hyaluronic Acid Experts

Leading Pharmaceutical Innovation

Altergon, born in 2000 in Morra de Sanctis (Avellino) 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 45,000 sqm, the production site of Altergon consists today of 4 manufacturing plants, 2 R&D laboratories, 2 pilot plants, a modern Quality Control and an intensive automated warehouse.

The research and development activities, the manufacturing processes, the packaging operations are performed using high quality modern technology in strict accordance with the rules and ethical principles and managed by high-qualified, experienced technical staff.

Thanks to the uniqueness of the patented processes, the company is today among the leading European producers of medicated hydrogel plasters (Flector®), Drug in Adhesive Matrix Patch (Nitroglycerin, Piroxicam Diclofenac and others) and Ultrapure, Pharmaceutical-Grade hyaluronic acid (Shyalt®).

A CONTINUALLY EVOLVING COMPANY

1985 ALTERGON SA FOUNDED IN LUGANO

2000 LAUNCH OF AN OPERATIVE COMPANY IN ITALY: ALTERGON ITALIA

2002 ESTABLISHMENT OF RESEARCH AND DEVELOPMENT ACTIVITIES IN COLLABORATION WITH KEY UNIVERSITIES

2003 START OF SCALE UP AND CONSTRUCTION OF MANUFACTURING PLANTS

2005 AUTHORISATION BY AIFA, THE ITALIAN DRUG AGENCY, FOR THE FIRST DEDICATED MANUFACTURING PLANT

2008 AUTHORISATION BY THE FDA

2009 EXTENSION OF THE MANUFACTURING FACILITIES FOR MEDICATED PLASTERS

2010 SAP MANAGEMENT IMPLEMENTATION

2011 HYALURONIC ACID PRODUCTION PROCESS APPROVED BY AIFA

2012 FDA FULL APPROVAL FOR MEDICATED PATCHES PRODUCTION

2014 AUTOMATED WAREHOUSE

2015 HYALURONIC ACID SECOND LINE EXTENSION AND PILOT PLANT

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

2017 AUTHORISATION BY AIFA & FDA FOR A NEW PRODUCTION LINE FOR PATCHES

Pharmaceutical Products

HYDROGEL PLASTER

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

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

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

DRUG IN ADHESIVE MATRIX / TRANSDERMAL PATCHES

The adhesive layer is particularly thin and dry, 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 for example in the field of cardiac therapy as well as for antiinflammatories, hormones, in the therapy of pain.

ORODISPERSIBLE FILMS

Orodispersible films (ODF) constitute an innovative oral drug delivery system. This dosage form is placed on patient's tongue or oral mucosal tissue, and 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 reduced 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 fast, accurate dosing in a safe, efficacious format that is convenient and portable and facilitates the compliance.

MASKS AND SPECIAL PATCHES

Hydrogel Mask patches are formulated to sooth, refresh and hydrate the skin of face, neck and decolletè. The particular molecular structure of the Hydrogel Mask patch allows a significant quantity of water to be contained, which evaporates during the application, refreshing and hydrating the treated area and 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.

Hyaluronic Acid
(Active Pharmaceutical Ingredient)

THE HANa PRODUCTION FACILITIES

An innovative and patented manufacturing biotech process for the production of sodium hyaluronate (HANa) has been validated.

Italian Patent n° 0001413257
European Patent n°EP2870255B1
USA Patent n° 9347079

A Ultrapure Hyaluronic Acid - SHYALT® with "customized" molecular weights (from 40 kDa to 3 millions Daltons) is obtained starting from the cell strain Streptococcus equi, through a multi-step process that includes fermentation, filtration and ultra-purification up to the final packaging. The strain is deposited at the Pasteur Institute in Paris.

Certificate of Suitability by EDQM n° R0-CEP 2014-263-Rev 00

A CONTINUALLY EVOLVING COMPANY

2010
HANa – 1st line (850 sqm)
Main line built, validated and approved under ICHQ7 EUGMP part II - engineered *under ISPE* vol. 6 guideline for Biopharmaceutical Manufacturing Facilities. AIFA authorised, CEP and GMP certificate.

2015
Pilot Plant 300 sqm
A State of the Art multipurpose Pilot Plant equipped for the study and development of new biotech processes.

2016
HANa – 2st line (300 sqm)
Expansion of the Production capacity - dedicated to HANa specific for Medical Device (production under ISO 9001) Fully GMP, with a low content of endotoxins.

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 - Ultrapure 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 3,000 Kda and Intrinsic Viscosity 0.2 - 3.2 m^3/kg.

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

SHYALT ULTRAPURE® is covered by CEP n° R0-CEP 2014-263-Rev 00

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