Leading Pharmaceutical Innovation







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 57.000 sqm, Altergon production site consists today of 4 manufacturing buildings and 8 production lines, 4 modern R&D laboratories, with pilot plants for the several platforms of Drug Delivery: medicated patches - microneedles - Process Product Design (PPD) fermentation - oral films, a modern Quality Control laboratory and an automated warehouse. A side building for general services (including a conference lecture hall) 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 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 patches (Flector®), Drug in Adhesive matrix patches (Nitroglycerin, Piroxicam, Diclofenac and others) and ultra pure pharmaceutical grade Hyaluronic Acid (SHYALT®).





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 (ULTRAPURE SHYALT®)	
	CERTIFICATE OF SUITABILITY (CEP) BY EDQM AND SUBMISSION TO FDA OF THE HYALURONATE DMF (MAF)	2016
2017	AUTHORIZATION BY AIFA & FDA FOR A NEW PRODUCTION LINE FOR PATCHES & ODF	
	ATION BY MINISTRY OF INDUSTRY ™ - RUSSIAN FEDERATION FOR ALURONATE BULK, MEDICATED PATCHES AND ORODISPERSIBLE FILMS	2018
2021	RENEWAL OF CERTIFICATE OF SUITABILITY BY EDQM AND UPDATE OF MAF 2718 AIFA AUTHORIZATION FOR THE PRODUCTION LINE OF IMPREGNATED STERILE G	
EXPANS	SION OF THE HYALURONIC ACID PHARMA PRODUCTION CAPACITY & PFS (PRE-FILLED SYRINGES) FOR CROSSLINKING HYALURONATE	2022

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, does not stain clothes, does not use volatile organic solvents and it is therefore normally very well tolerated.



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, 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.





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.



PRE-FILLED SYRINGES (PFS)

Dedicated line to the production of cross-linked Hyaluronic Acid pre-filled syringes (PFS) terminally sterilized and suitable for medical and orthopaedic applications, patented and innovative for the higher purification.

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 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.



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 and patented manufacturing biotech process for the production of Sodium Hyaluronate (HANa) has been established.

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

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 Pasteur Institute in Paris.

Certificate of Suitability by EDQM n° R1-CEP 2014-263-Rev 00



First plant, validated and approved under ICHQ7 EUGMP part II engineered under ISPE vol. 6 HANa guideline for Biopharmaceutical 1st line Manufacturing Facilities. AIFA authorized, CEP and GMP certified.

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

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

Huge expansion of the PHARMA PLANT under GMP and EDQM certified.









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