Syntex is an Argentine company that elaborates active ingredients from biological and semi-synthetic origins for Human and Veterinary Pharmaceutical Industry since 1935. We work with the implementation of technological development that allows the obtaining of derivatives and more efficient evolutions for new uses and applications in Diagnose, Human and Veterinary Medicine. Syntex products are registered and marketed in Argentina and worldwide in highly demanding markets such as Japan, USA, Russia, Jordan, Malaysia and the European Union.

SYNTEX PRODUCTS

HEPARIN

Nowadays, Syntex elaborates and trades Injectable Grade Heparin, Low Molecular Weight Heparin and Heparin for Diagnosis purposes and has its own patent for Low Molecular Weight Heparin Triethanolamine Salt.

HORMONES (eCG - PMSG)

Syntex is one of the biggest eCG manufacturers worldwide. It holds its own closed and controlled rodeo, from which plasma is obtained as raw material for the product elaboration. This process is certified by INTA ("Instituto Nacional de Tecnología Agropecuaria" Rural Technology National Institute). This way, traceability control, compliance of biological safety and highest quality standards in the whole production chain are amply assured.

CHONDROITIN SULPHATE

Syntex produces a well known anti-arthrosic Chondroitin Sulphate, in its native form, for oral and injectable formulations, Low Molecular Weight Chondroitin Sulphate and Ultra Low Molecular Weight Chondroitin Sulphate Triethanolamine Salt for topical use. The latter holds a certificate of suitability issued by the European Union

FERRIC COMPOUNDS

Ferric compounds are developed for anti-anemic use. Syntex currently produces Ferrimannitol Ovalbumin (FMOA), an oral-use ferric derivative that offers good absorption and does not irritate the digestive tract.
Syntex has also developed Soy Ferric Protein (SFP), Chondroitin Sulphate Ferric Complexes, Sodium Iron-Gluconate Complexes and Iron Sucrose.

Syntex BIOLOGICAL SAFETY ACTIVE INGREDIENTS

The World Health Organization has declared Argentina among the few countries in the world that are **free from Bovine Spongiform Encephalopathy or Mad Cow Disease**, strengthening this way the biological safety guarantee of Syntex products.

Syntex API

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SYNTEX
YOUR PARTNER WORLDWIDE.

edqm European Directorate for the Quality of Medicines & HealthCare

cGMP MANUFACTURING PRACTICES

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HEPARINS

HEPARINOIDS

CHONDROITIN SULFATE, BOVINE ORIGIN

HORMONES

FERRIC COMPOUNDS

HEPARINS

HEPARIN FAMILY:

BOVINE ORIGIN
- Sodium (USP, EP, parenteral, non parenteral grade)
- Calcium
- NEW: Low Molecular weight Heparin bovine origin now under development.
- Heparinoids

PORCINE ORIGIN
- Low molecular weight heparin (Parnaparin type) porcine origin
- Lithium and Ammonium salts, diagnose uses.
- Heparinoids
- Sulodexide

CHONDROITIN SULFATE FAMILY, BOVINE ORIGIN

- Oral grade, sodium salt
- Pyrogen free, sodium salt (injectable grade – oftalmic grade)
- Modified Molecular weight sodium salt (injectable grade)
- Low Molecular weight triethanolamine salt (topical grade)

HORMONES

- Equine Chorionic Gonadotrophin (eCG or PMSG)

FERRIC COMPOUNDS

- Ferrimannitol Ovoalbumin

NEW **BOVINE ORIGIN LMWH**
(UNDER DEVELOPMENT, LABORATORY SCALE)

SODIUM HEPARIN AND CALCIUM HEPARIN, INJECTABLE GRADE

Type: Injectable grade
Origin: Bovine and Porcine origin
Description: Very complex glycosaminoglycan thoroughly described in EP, USP and JP.
API Presentation: Bulk powder in double polyethylene bags contained in lined drums.
Indication: Anticoagulant. Its main uses are related to treatment and prophylaxis of thrombogenic states.
Uses: It is used for parenteral final dosage forms in solutions for intravenous or subcutaneous injection in vials or pre-filled syringes.
Other uses: Topical preparations.
Launch: early '80s.
Market: Marketed around the world including several Muslim countries.

LITHIUM HEPARIN AND AMMONIUM HEPARIN , DIAGNOSTIC USE

Type: Diagnostic use
Origin: Porcine origin
Description: It is the Lithium or Ammonium salt of sulfated glycosaminoglycans, which is present as a mixture of heterogeneous molecules of natural mucopolysaccharides of varied molecular weights.
API Presentation: Bulk powder in double polyethylene bags contained in lined drums.
Indication: In-vitro anticoagulant agent.
Uses: It is used for the collection of blood samples for sodium and potassium determinations, or to prepare heparinized syringes and tubes. Diagnostic reagents.
Launch: early '80s.
Market: Marketed around the world including several Muslim countries.

LOW MOLECULAR WEIGHT HEPARIN

Type: Injectable grade
Origin: Porcine origin
Description: Obtained by chemical depolymerization of parenteral grade Sodium Heparin (US Pat 4977250, Europ. Pat 268885).
API Presentation: Bulk powder in double polyethylene bags contained in lined drums.
Indication: antithrombotic agent.
Uses: It is used for injectable formulations (Pre-filled syringes and vials).
Launch: 2001
Market: Japan.

HEPARINS

LOW MOLECULAR WEIGHT HEPARIN TRIETANOLAMINE SALT, TOPICAL GRADE

Type: Topical grade
Origin: Porcine origin.
Description: It is a further salification of LMWH with triethanolamine (Argentine Pat. Nº AR043110B1; Europ. Pat. Nº 1561760A2; US Pat. Appl. 2005/0234015A1 Oct. 20, 2005).It´s reduced molecular weight and low ionicity lead to an active skin penetration.
API Presentation: Bulk powder in double polyethylene bags contained in lined drums.
Indication: Treatment of peripheral vascular disorders, varices, haemorroids, hematomas, and topical protection of veins, for instance, after infusion of chemotherapeutical agents (alleviating this way the concomitant phlebitis).
Uses: It can be used in ointments and topical formulations.

HEPARINOIDS

HEPARINOIDS

Type: Oral and Topical Grades
Origin: Porcine and Bovine origin
Description: Mucopolysaccharides with different grades of sulfation. The most important are Dermatan Sulfate, Heparan sulfate and Chondroitin Sulfate.
API Presentation: Bulk powder in double polyethylene bags contained in drums.
Indication: They present a wide range of biological activities but with a limited anticlotting activity. Anti-edematous and anti-congestive agent.
Uses: It is used for injectable formulations (Pre-filled syringes and vials).
Launch: Early `80s.
Market: Marketed around the world including several Muslim countries.

SULODEXIDE

Type: Oral grade
Origin: Porcine origin
Description: According to Martindale 34° Ed., Sulodexide is a heparinoid consisting of a mixture of low molecular weight heparins (Fast Moving Heparin, FM) and Dermatan Sulfate (DS). Review of the 14th Annual Pharmacy Conference on Anticoagulation Therapy (1999) also defines Sulodexide as a mixture of glycosaminoglycan sulfates, 80% low molecular weight heparin and 20% dermatan sulfate, total components of Sulodexide extracted from porcine intestinal mucosa.
API Presentation: Bulk powder in double polyethylene bags contained in lined drums
Indication: Anticloting activity. Sulodexide is an active pharmaceutical ingredient used in medicine for its anticoagulant activity and enhancing activity over antithrombin III
Uses: It is used for the treatment of vascular pathologies with thrombotic risk, such as peripheral occlusive arterial disease, cardiovascular pathologies, etc. Due to its lipid-lowering activity (reducing triglycerides and cholesterol values in plasma), it is used also in the prophylaxis of myocardial re-infarction. Recently, novel application was found for Sulodexide, in the treatment of diabetic nephropathy in patients with both insulin and non-insulin dependent diabetes mellitus. Strong reduction in albumin excretion was obtained by using Sulodexide in such cases.
Launch: 2016
Market: Under development in Europe and Asia.

CHONDROITIN

CONDROITIN SULPHATE

Type: Pyrogen free (for injection) grades
Origin: Bovine origin.
Description: Chondroitin Sulfate from mammalians contains CS-A with minor amounts of CS-C. Both of them are macromolecules made by alternate sequences of D- glucuronate and N-acetyl-galactosamine-4-0- (or 6-0-) sulfate. It is thoroughly described in EP and USP.
API Presentation: Bulk powder in double polyethylene bags contained in lined drums containing 5 kg, 10 kg, 25 kg and 50 kg.
Indication: Anti-arthrosic agent.
Uses: The oral grade is used for oral formulations such as capsules, soft capsules, pouches, tablets, and topic formulations, for instance ointments. The pyrogen free grade is used in injectable dosage forms and intra ocular formulations.
Launch: early '80s.
Market: Marketed in several countries around the world including Russian Federation.

CHONDROITIN

MODIFIED MOLECULAR WEIGHT CONDROITIN SULPHATE PYROGEN FREE

Type: Pyrogen Free (for injection) grade
Origin: Bovine origin.
Description: Modified Molecular Weight Condroitin Sulphate (MMWCS) includes the Low molecular weight chondroitin sulfate (LMWCS), the ultralow molecular weight chondroitin sulphate and other ranges of required molecular weight. The modified molecular weight CS is obtained by chemical de-polymerization from natural CS by methods protected by U S Patent 4.977.250, and Eur. Patent 268.885. The low viscosity of MMWCS solutions allows painless injection and fast absorption.
API Presentation: Bulk powder in double polyethylene bags contained in lined drums containing 5 kg, 10 kg, 25 kg and 50 kg.
Indication: Anti-arthrosic agent.
Uses: It is used for parenteral formulations, eye drops and intra-ocular injections.
Launch: 2012
Market: Marketed in several countries around the world.

LOW MOLECULAR WEIGHT CONDROITIN SULPHATE TRIETHANOLAMINE SALT

Type: Topical grades
Origin: Bovine origin.
Description: Obtained by submitting the low molecular weight chondroitin sulfate to sequences of ion exchange in order to remove the Na+ ion, and replace it by the equivalent weight in triethanolamine, thus obtaining the triethanolamine salt of the de-polymerized product.
API Presentation: Bulk powder in double polyethylene bags contained in lined drums containing 5 kg,10 kg, 25 kg and 50 kg.
Indication: Anti-arthrosic agent.
Uses: Topical use cream for veterinary uses. The aim of this product is the preservation of articular health in racing horses and sports animals in general. No adverse effects on treated animals were ever found.
Launch: early '90s.
Market: Marketed and registered in Europe, New Zealand, Australia and Japan.

FERRIC COMPOUNDS

FERRIMANNITOL OVALBUMIN (FMOA)

Type: Oral grade
Origin: Ferrimannitol Ovalbumin represents a technological optimization regarding ferric albuminate described in MEDICAMENTA VI Edition, Vol. IV, page 3525 and reported in German Pharmacopoeia 1910, 1926, and in Helvet. Pharmacopoeia 1907 and 1934.
Ferric Albuminate (egg´s) is also described in:
- "Handbuch der pharm. Praxis" Hagers 1:1248:1949 (Eisen Albuminat).
- Index Merck XI Ed. Pages 3953-3958 (Ferric Albuminate).
- European Core Inventory (ECOIN) Unit 960 column 2 page 480.
Description: Studies carried out at Syntex S.A. proved the product to be an effective anti-anemic agent, and demonstrated that it presents a marked absence of gastric irritation contrasting widely to recognized products, such as ferrous sulfate Another important issue to be considered is that this new therapeutic availability is totally alien to "slow" kind viral contaminations, in that it contains ovalbumin as proteic basis instead of mammal origin proteic derivatives such as ferritine. Apart from that, production method is adequately validated for the elimination of conventional viruses.
API Presentation: Containers of freeze dried powder or Spray-dried powder. Hydro-glyceric solution of 20 mg Fe/g.
Indication: Anti-anemic agent.
Uses: Despite the fact that Syntex has not carried out assays of dose fixation for humans, product ´s clinical experience in pharmaceutical market allows us to conclude that the dose is 80 mg Fe per day.
Launch: mid '90s.
Market: Marketed and registered in Europe.