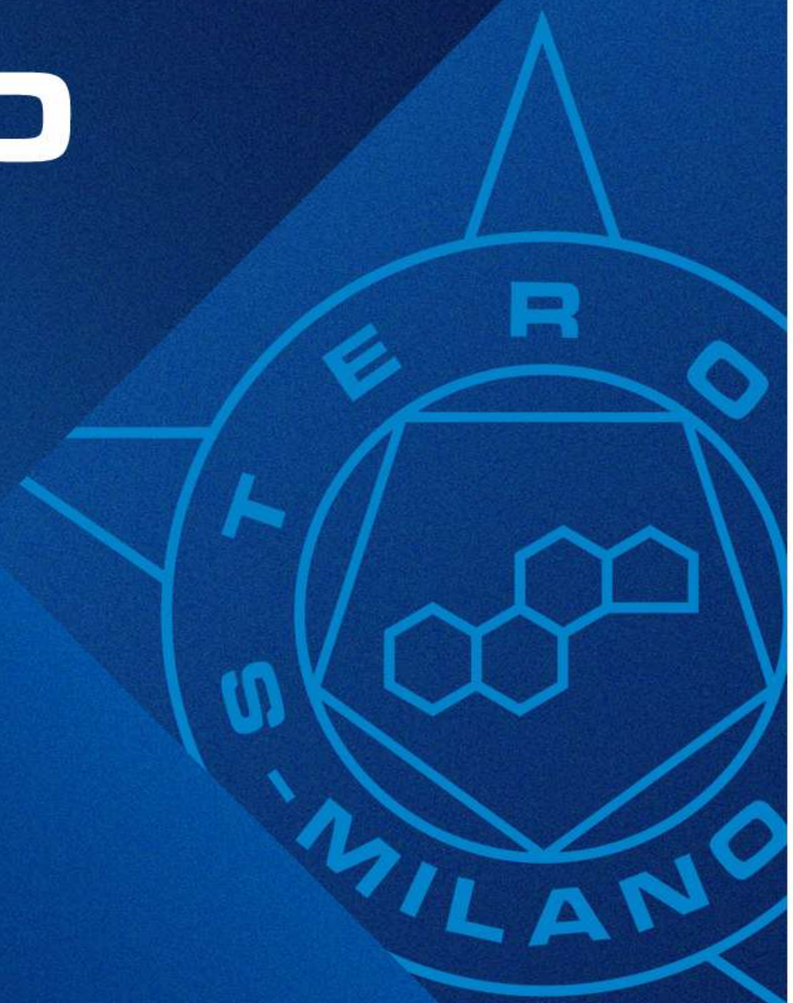
STEROID

Since 1953



MANUFACTURING APIs

EXECUTIVE SUMMARY

— Almost 70 Years Success Story in Steroidal API production

— Long Lasting Partnership with Multinationals

— Diverse International Experienced Management Team

— Private Owned Company led by the Third Entrepreneurial Generation

— Worldwide Sales, Global Presence

— Highly Diversified Revenues and Solid Cash Flow

— Solid Regulatory Track Record; FDA Approved

— State of the Art New R&D Facility

— Recent Investments in Capacity Expansions

THE COMPANY

Steroid S.p.A. is a private company founded in 1953 and It provides custom synthesis and contract manufacturing services (CMO) for both development and commercial scale manufacturing of Intermediates and API's. Steroid S.p.A. has a strong history in Corticosteroids, Estrogens, Progestinics and Anabolics, closely linked to Neurosteroids.
Production Facility located in Milan, Italy committed to continuous improvements and fully compliant with current Good Manufacturing Practices (cGMPs), European and US Standards. Periodically inspected by leading pharmaceutical companies and global and local health authorities.

COMPANY HISTORY

- **1953** Steroid was founded in Milan, Italy
- **'70s** Expansion to Global Market
- **'80s** Acquisition of shares by a single family
- **'90s** Facility Expansion
- **2000's** Accreditation in major markets
- **2013** Ownership consolidation by the third generation
- **2014** Expansion of manufacturing equipment & labs
- **2017** Inspection and approval
- **2019** Internationally experienced Management
- **2021+** Manufacturing capacity up to 50 MT

MANAGEMENT TEAM

The team with a diverse chemical and pharma background brings a wide spectrum of chemical and technical expertise to develop flexible, scalable solutions and cost-effective processes, tailored to customer's needs.

Previous working background of the current **Steroid Management Team** include companies like:

MARKET and SALES

Steroid provides API's to over 100 customers (Innovative Pharma and Generic Companies) in over 32 Countries worldwide. Trademark of e.g. Fresenius-Kabi, Mylan, Pfizer, Recordati, Sandoz, Sanofi, Teva, Zambon, Zoetis.

COMMERCIAL PRODUCTS

ESTROGENS

ESTRADIOL CYPIONATE USP (M, S)
ESTRADIOL ENANTHATE IN-HOUSE
ESTRADIOL HEXAHYDROBENZOATE IN-HOUSE
ESTRADIOL VALERATE EP, USP (M)

PROGESTINICS

ALGESTONE ACETOPHENIDE IN-HOUSE
HYDROXYPROGESTERONE CAPROATE USP
NORETHISTERONE ENANTHATE IN-HOUSE

CORTICOIDS

BECLOMETHASONE DIPROPIONATE (M, S) EP
DEXAMETHASONE ACETATE EP, JPC
DEXAMETHASONE ISONICOTINATE EP
DEXAMETHASONE 21-PALMITATE IN-HOUSE
DEXAMETHASONE 21-TERTBUTYLACETATE IN-HOUSE
DEXAMETHASONE 21-TRIMETHYLACETATE IN-HOUSE (M)
DEXAMETHASONE 21-VALERATE IN-HOUSE
DIFLUPREDNATE JP (M)
HYDROCORTISONE 21-CAPROATE IN-HOUSE
HYDROCORTISONE BUTYRATE USP (M)
HYDROCORTISONE VALERATE USP
PREDNISOLONE PIVALATE EP (M)
PREDNISOLONE SODIUM METASULPHOBENZOATE IN-HOUSE
PREDNISOLONE VALERATE ACETATE JP (M)

ANABOLICS

BOLDENONE UNDECYLENATE IN-HOUSE
CLOSTEBOL ACETATE IN-HOUSE (M, S)
OXYMETHOLONE BP
STANOZOLOL EP, USP (M)
TESTOSTERONE CYPIONATE USP
TESTOSTERONE DECANOATE EP
TESTOSTERONE ENANTHATE CEP, EP, USP
TESTOSTERONE ISOBUTYRATE IN-HOUSE
TESTOSTERONE ISOCAPROATE EP
TESTOSTERONE PHENYLPROPIONATE BP
TESTOSTERONE PROPIONATE EP (M)
TESTOSTERONE UNDECANOATE IN-HOUSE

KEY TO ABBREVIATIONS

M: Available also Micronized
S: Available also Sterilized
BP: British Pharmacopoeia
CEP: European Pharmacopoeia Certificate of Suitability
EP: European Pharmacopoeia
IN-HOUSE: Internal specifications
JP: Japanese Pharmacopoeia
JPC: Japan Pharmaceutical Codex
USP: United States Pharmacopoeia

Periodically inspected by leading pharmaceutical companies and global and local health authorities.

PRODUCTION

Four independent plant buildings host reactors ranging from 400–3000 liter batch size in Glass Lined, Stainless Steel, and Hastelloy C. All operations are under strict cGMP conditions.

Steroid is increasing total output to potential 50 Mt in 2-3 years. Multipurpose workshops, with a wide variety of reactions flexible to accommodate demand.

REGULATORY HISTORY

- 1991
Italian MoH Inspection and Approval for the manufacture of human&veterinary APIs

- 2003
First AIFA GMP approval for APIs for human use

- 2004
AIFA GMP approval for APIs for human use

- 2007
AIFA GMP approval for APIs for human use

- 2008
Japanese PMDA accreditation

- 2010
AIFA GMP approval for APIs for human use

- 2014
AIFA GMP approval for APIs for human use

- 2015
Italian MoH inspection and approval for APIs for veterinary use

- 2017
First US FDA inspection and approval

- 2018
AIFA GMP approval for APIs for human use Italian MoH inspection and approval for APIs for veterinary use

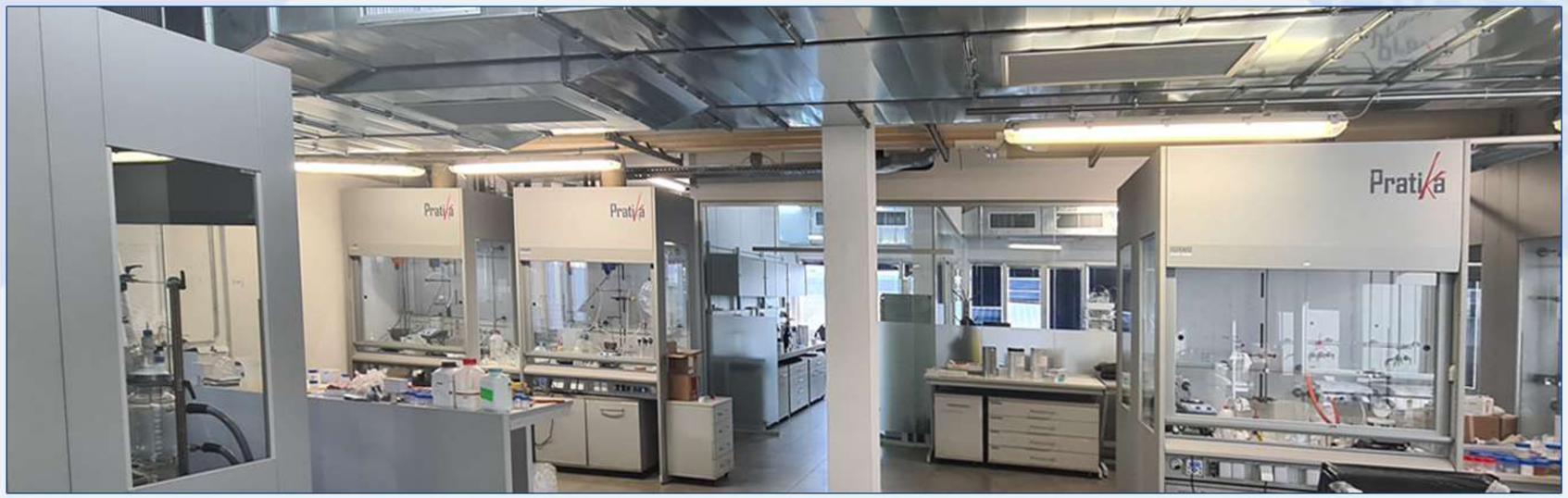
- 2019
Korean KFDA accreditation
AIFA GMP approval for APIs for human use

AIFA AGENZIA ITALIANA DEL FARMACO
FDA
Pmda JAPAN
KFDA Korea Food & Drug Administration 식품의약품안전청
Ministero della Salute

R&D

The new labs are fully equipped with all necessary analytical instrumentation and reactor sizes to support the chosen route of synthesis and facilitate scaling up processes.

- Volume ranges from lab scale in glass up to 20 lt.
- Pilot-plant capabilities range from 100 to 600 lt.
- Glass Lined, Stainless Steel and Hastelloy C.
- Process Optimization and Development.
- Analytical Method development.
- Tech Transfer Project Management.



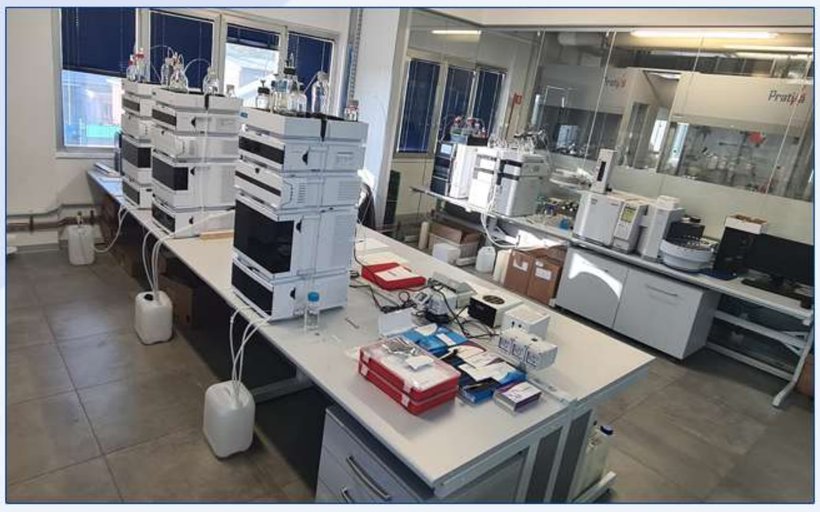
ANALYTICS

A dedicated quality/analytical lab provides instantaneous production support, and Stability testing/Forced Degradation Studies.

Standard Equipment includes for example:

- LC, LCMS, HPLC, HS-GC, GCMS
- Polarimeter, FT/IR, UV/Vis, Densimeter, Refractive Index
- Stability Chambers (25C-60% RH), (40C-75% RH), (30C-75% RH)

In case of unique technologies, cooperation with Universities and independent organisations is part of Steroid' standard procedures.



STRATEGIES

Development of both NCEs and existing API's linked to those macro trends that follow future needs: air pollution/respiratory diseases, aging, mental diseases are some of the key fields.

In accordance to this vision, a portfolio of potential steroidal APIs has been identified and selected to be fully developed, Neurosteroids is one of the key areas.

Steroid intend to expand its current product portfolio by the manufacture of sterile APIs via aseptic filtration.

ENVIROMENT, HEALTH, SAFETY

Consistently investing in EHS, integrated Environment, Health and Safety considerations into the business strategy and decision making.

CORE CAPABILITIES

Production and R&D capabilities

- >30 MT Steroidal APIs Manufacturing Capacity
- High-Potency Compounds
- Sterilized APIs
- Hazardous Reactions (Fluorination in 2021)
- DEA Controlled Substances
- Regulatory Support and QA/QC
- Process Safety Assessment
- Kilo Lab and Small Scale Manufacturing
- Pilot Plant Manufacturing
- Batch Release and Stability Lot Testing
- Analytical Methods Development and Validation

Analytical and other services capabilities

- Analytical Method Development and Validation
- Analytical Testing Services
- Bulk Characterization
- Chromatography
- Crystallization Process Development
- Diffraction Studies
- Enantiomeric Resolution
- Gas Testing
- Heavy Metals Testing
- Mass Spectrometry
- Microbiology
- Microscopy
- Micronization
- Particle Characterization
- Physical Characterization
- PSD control
- Residual Solvents
- Spectroscopy
- Structural Characterization
- Thermal Analysis and Calorimetry
- Water Analysis

THANK YOU

Disclaimer

The information contained in these documents is confidential, privileged and only for the information of the intended recipient and may not be used, published or redistributed without the prior written consent of Steroid S.p.A.

The opinions expressed are in good faith and while every care has been taken in preparing these documents, Steroid S.p.A makes no representations and gives no warranties of whatever nature in respect of these documents, including but not limited to the accuracy or completeness of any information, facts and/or opinions contained therein.

Steroid S.p.A., its subsidiaries, the directors, employees and agents cannot be held liable for the use and reliance of the opinions, estimates, forecasts and findings in these documents.