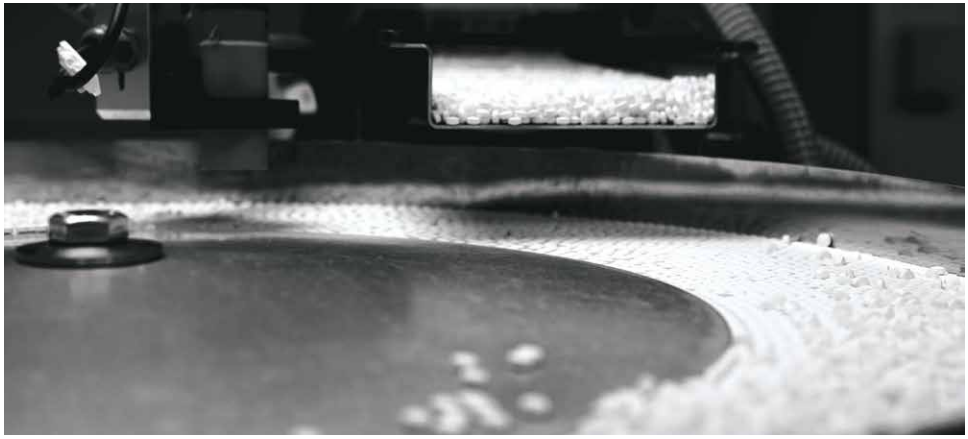
We

Aim

On Innovation




Plan

Our Progress

The Company

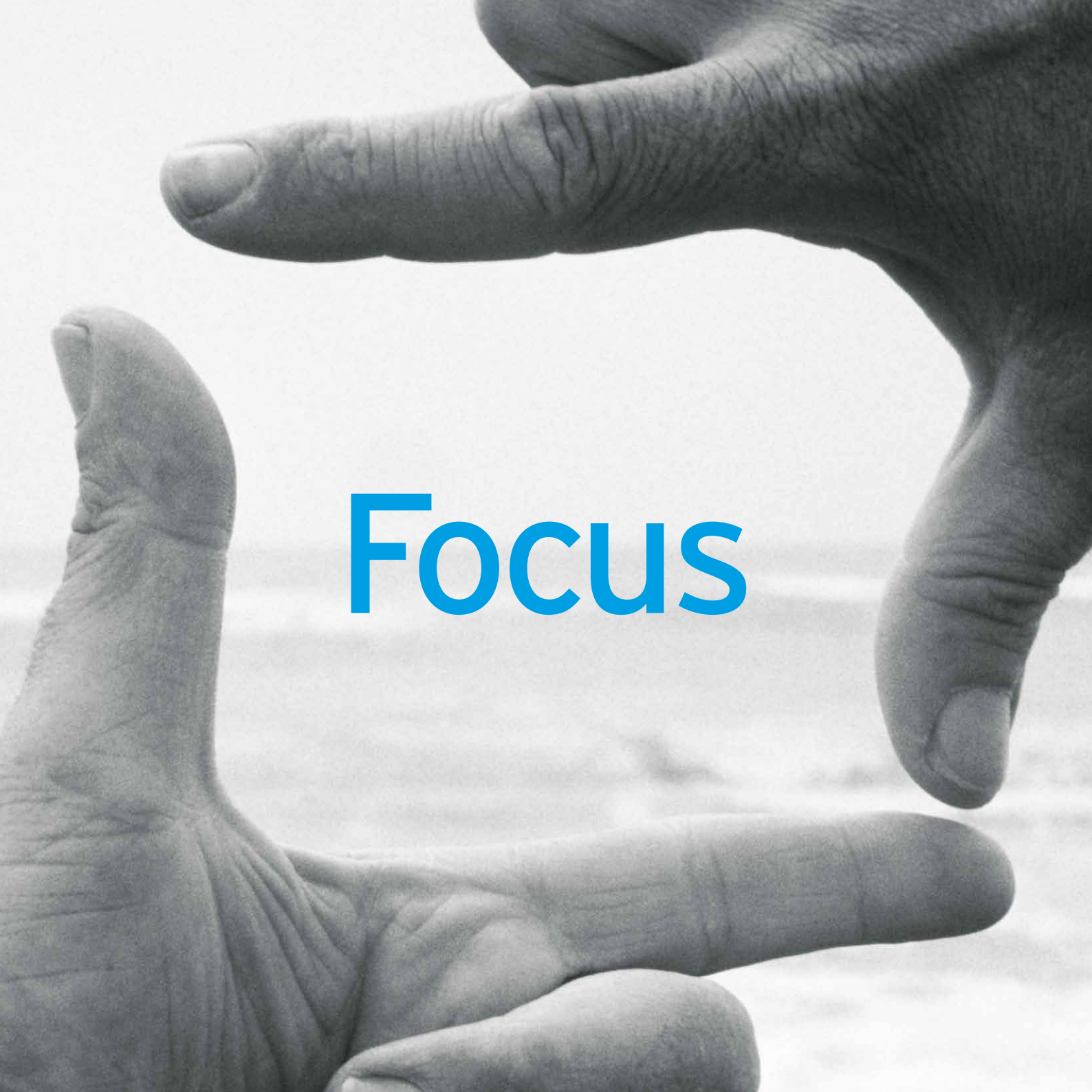
Genepharm's origins date back to 1971. A privately held pharmaceutical company, Genepharm has been committed to the development, manufacturing, marketing and distribution of a premium range of generic pharmaceutical products. Genepharm was originally focused on the Greek Market, where direct market sales under its own brand are made. The company has expanded and is now selling its products across Europe, the Middle East, Africa, Asia and the Americas. In 2019 MS Pharma, a fast growing pharmaceutical company based in Jordan, acquired Genepharm. In 2021, GMS Holdings, acquired Genepharm.

The Areas

- Greece: manufacturing, sales and marketing of its own branded generic pharmaceutical products
- Europe: product development and out-licensing of its product dossiers, intellectual property, and regulatory affairs.
- International: out-licensing, technology transfers and distribution of its pharmaceutical products.

The Milestones

- 1971: Establishment
- 1974: First manufacturing facility inaugurated
- 2001: Manufacturing facilities are upgraded according to the EU GMPs
- 2005: Approved as supplier by TGA (Australian Health Authorities)
- 2006: Product Development Focus and Upgrade of Development Centre to EU GMP
- 2007: Genepharm establishes two new oncology facilities for sterile liquid and solid oral dosage forms
- 2009 GCC initial Accreditation, last renewal 2024
- 2009 Syria initial Accreditation, last renewal 2024
- 2010: GMP certified from Health Canada as supplier
- 2011: GMP certificate from Turkish Authorities
- 2011 Sales from Exports surpass local Sales
- 2011: Certified manufacturer for Korea
- 2012: GMP certified from Taiwan Authorities
- 2014: Opening key markets in South America and launch of Generic plus molecule
- 2016: UAE initial Accreditation, last renewal 2021
- 2017: JFDA company accreditation
- 2019 Russian Federation Accreditation
- 2019: ANVISA initial Accreditation, last renewal 2023
- 2019: Acquired by MS Pharma
- 2021: Acquired by GMS Holdings
- 2022: EAEU Accreditation
- 2022: Discontinuation of the Cyto Sterile Production and Expansion of Conventional Facility
- 2023: New Research and Development Center
- 2024: ZAZIBONA Accreditation


Focus

Our Business

Product Development

- Experienced Scientific Team focus on delivering several new generic products every year
- Targeted Product Development, including “generic plus” products
- Full Patent Search and Assessment, Formulation and Analytical Development. Pilot Scale Production and Stability Trials ensuring industrial application
- Strategic Partnerships and Co-Developments
- Newly completed Product Development laboratory expansion to allow more generic products delivery every year

Achievements

- Having secured agreements for its products with the leading generic companies in Europe and around the world, Genepharm is focused on forging strong and long-lasting relationships with its partners. Genepharm aims to deliver several new generic products per year to its customers. Complex Drug Development will be key to our success in the future and our aim is to be a supplier of choice for quality generic products.

Regulatory Affairs

- Preparing and coordinating documentation
- Ensuring product compliance with the latest regulations
- Vast knowledge and database, collating a wide range of information from around the globe
- Compilation and submission of eCTD dossiers to Regulatory Authorities
- Extensive experience and knowledge base to reply to deficiency letters and efficient support to all regulatory procedures
- Communication with Regulatory Authorities for DCP’s, MRP’s and National Procedures to facilitate Marketing Authorizations
- Maintenance of eCTD dossiers
- Maintenance of the life cycle of the Product

Accreditations

- ISO 9001:2015
- EU GMP
- GCC GMP
- Health Canada
- Taiwan GMP
- Korea Ministry of Health
- Kazakhstan GMP
- Pakistan GMP
- Sudan GMP
- Jordanian GMP
- Philippines GMP
- ZAZIBONA GMP
- ANVISA GMP
- EAEU GMP
- ISO 50001:2018
- ISO 14001:2015


Create

Our Products

Products

Available EU-CTD Dossiers across various therapeutic categories:

- Alimentary Tract and Metabolism
- Anti-Parathyroidism
- Cardiology
- CNS
- Dermatology
- Diabetes Mellitus
- Erectile Dysfunction
- Immunosuppressant
- Iron chelating agent
- Oncology
- Respiratory
- Urology

For any collaboration inquiry please contact us at: *bd@genepharm.com* or *info@genepharm.com*


Knowledge

Our Services

Development

Pharmaceutical development services including turn-key solutions for product realization, from conception to submission. Our competitive advantages include:

Wide formulation expertise ranging from conventional dosage forms to advanced technology platforms

- QbD based formulation and process development assuring compliance with the current ICH Q8 guideline and trouble-free scale up and technology transfer
- End-to-end product development, including CMO identification and tech transfer activities
- Stand-alone activities such as feasibility studies, troubleshooting (and tech transfer of existing products), consultation and identification of Freedom To Operate (FTO) in cooperation with client's IP Department

Genepharm's analytical R&D offers a wide range of services including:

- Development of analytical methods, QbD approach upon request
- Analytical Method validation as per ICH guidelines
- Method transfer procedures to and from external laboratories
- Analytical support of formulation development
- Support of process validation and evaluation activities
- Stability testing in zones I-IV
- IVIVC studies upon request through co-operating parties

Regulatory Affairs

Genepharm's team has extensive experience in the regulatory affairs domain within EU and global markets having successfully finalised over 2700 MA sets for its products. Regulatory services offered include evaluation of scientific and technical data and guidance through development, dossier compilation (including eCTD sequences), submission via DCP/MRP, maintenance of marketing authorizations within EU (renewals, variations), liaison with competent authorities and keeping abreast of relevant legislation.


Excellence
JACKET
CHAMBER
GENEPHARM S.A
ID No: MVC
CERTIFICATE No: GEN 2_03.11a
CALIBRATION DATE: 27-May-11
NEXT CALIBRATION November-11
THERMOMETER
RECORDER
YOKOGAWA

Our Production

The Facilities

The company has two dedicated state-of-the-art production facilities located in Athens, Greece, designed in accordance with EU cGMP requirements:

Oncology/High Potent Oral Solid Dosage Forms (inaugurated in 2007)

- Product Form: tablets (uncoated or coated) & hard gelatin capsules
- Molecules handled: Afatinib, Anastrozole, Bicalutamide, Exemestane, Finasteride, Fingolimod, Gefitinib, Hydroxyurea, Letrozole, Ruxolitinib, Tamoxifen, Thioguanine
- Granulation Capacity: up to 150 kg
- Primary Packaging: blisters
- Full Capacity: 130 million tablets, 10 million capsules
- Accreditations: EU GMP, Gulf Countries Council (GCC), Health Canada, Therapeutic Goods Administration (TGA - Australia),
- Anvisa accreditation

Conventional Solid Dosage Forms (renovated in 2005)

- Product Forms: tablets (uncoated, coated, oral dispersible and chewable), hard gelatin capsules
- Molecules handled: more than thirty-five (35)
- Primary Packaging: blisters
- Full Capacity: 590 million tablets, 40 million capsules
- Accreditations: EU GMP, Gulf Countries Council (GCC), Health Canada Anvisa, EAEU, and more


Grow

Our Activities

Greece

Direct Sales & Marketing of own branded generics, covering more than 8.000 doctors, across various therapeutic areas:

- Antithrombotic agents
- Cardiology
- Dermatology
- Diabetes
- Gastroenterology
- Iron chelating agent
- Neurology
- Oncology
- Orthopaedics
- Pathology
- Pneumonology
- Respiratory
- Urology

Around the Globe

- Experienced Management Team in the areas of Formulation & Analytical Development, Intellectual Property, Regulatory Affairs, Manufacturing, Supply Chain, Quality Assurance and Business Development
- Extensive customer network with over 320 partners in 78 countries worldwide
- Regulatory expertise gained by working closely with health authorities around the world
- Out-licensing of its product dossiers, linked to supply agreements from own manufacturing and/or CMO facilities
- More than 2000 MA sets have been obtained in EU and 200 MA sets currently in progress
- 760 valid Marketing Approval sets in Rest of the World, another 350 on-going
- Over 1000 agreements for its products with major generic companies
- Sales and Distribution of own branded products in Africa, Asia, Balkans, the Middle East and LatAm

Care

genepharm

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