

Enabling the Next Generation of Complex Medicines
High Potency | Oral Solid Dose | Softgel





Pharmaceutical Pipelines Are Evolving Rapidly.

New therapies are increasingly potent, targeted, and technically complex - placing greater demands on development, manufacturing, and supply.

Bringing these products to market requires specialist expertise, advanced containment, and a partner who can deliver with precision and consistency at every stage.

Behind every programme is a patient - often relying on complex medicines to extend treatment options, manage symptoms, and, in many cases, gain valuable time.

**Supporting these therapies requires a partner who understands what is at stake.
This is where Eirgen Pharma operates.**

We specialize in the development and manufacture of complex oral solid dose and softgel medicines, supporting you from early development through to global commercial supply. By investing in our capabilities, infrastructure, and people, we are strengthening our position in high-potency and complex medicines and becoming the go-to long-term partner for increasingly demanding pharmaceutical programmes.



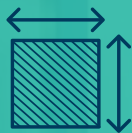
WHO WE ARE



Based in Waterford, Ireland, Eirgen Pharma is a research-driven company that specializes in the development, manufacture, and supply of a broad range of High Potency Oral Solid Dose (OSD) and advanced softgel, Human and Veterinary products to over 60 countries, including the United States, Japan, France, Germany, and the UAE.

Our proven expertise to support our customers in quality and reliability standards simplifies the journey from molecule to market through cutting edge research, development and manufacture.

We continue to invest in leading production technologies for end-to-end oral solid dose drug development and services that continue to complement our purpose-built centre of excellence. We have specialist facilities and expertise for handling high-potency compounds and controlled substances.



Over 70,000ft2
Dedicated High-
Potency Facility



ISO 14644 Class 8
Clean-Room
Standard



Single-Pass Double
HEPA Filtered Air



Fully Segregated
Processing Rooms



Low Humidity
Capability
(<30%RH)



Full Body
Air-Suit Capability



Fully Equipped
Analytical Labs



Equipment to
Support OSD
Manufacturing &
Packaging

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PHARMA



CONTRACT DEVELOPMENT & MANUFACTURING (CDMO)



Eirgen Pharma understands the need for faster innovation and development to bring pharmaceutical innovations to market more quickly.

We create product-specific development strategies tailored to meet your goals and deadlines, ensuring a seamless path from concept to commercialization.

Through our work with current partners, we have;

- Demonstrated proficiency in utilizing FDA-approved drugs as a foundation for innovative product development via the 505(b)(2) pathway.
- Developed like-for-like drug products.
- Formulated softgel solutions
- Created new presentations such as;
 - Modified Release Systems
 - Multi-particulate
 - New Strengths
 - Conversion of solvent-based processes to direct compression processes

Our expertise enables us to deliver tailored, effective service offerings that drive your project forward.



CONTRACT MANUFACTURING (CMO)



Eirgen Pharma has a proven track record of over 20 years in successful technology transfers and new product introductions across Europe, Asia, the Middle East, the United States, and Africa. Our Molecule-to-Market approach ensures that customer timelines for commercial success are met with efficiency, on time, and within budget.

We offer a range of platforms with batch sizes from 5kg to 500kg and 10,000 to 1 million units, including;

- Softgel Capsules
- Film-Coated Tablets
- Hard-Shell Capsules
- Powder
- Combination Products
- Liquid-Filled Products
- Multi-Particulate Systems

With these capabilities, we deliver reliable and scalable solutions to meet your product needs.



CONTRACT PACKAGING (IN-HOUSE)



Eirgen Pharma’s in-house packaging facility offers a full customized packaging process for all forms of single-dose oral drugs. This facility aligns with our CDMO/CMO philosophy; providing a seamless molecule-to-market solution, all under one roof.

Blister	Bottle	Sachet
Cold or Thermoforming	Multiple Product Capability	Multiple Sachet Size Formats
Multiple Blister Formats	Multiple Bottle Size/Types	Tablet/Capsule Pack Capability
Tablet/Capsule Capabilities	Metal Detection	
Vision System Detection	Induction Heating Sealing	
	Labelling (including leaflet booklet)	
	Unit Level Serialisation (Track & Trace)	
	PIL Topsert Application	

SERIALISATION

We provide full compliant unit-of-sale serialization, applying a unique identifier to each product at the pack level. Eirgen Pharma recognizes that serialization is a critical strategic function and integrates it as a key component within the overall production environment to ensure compliance and traceability.

AGGREGATION

Aggregation enables tracking of individual components within the carton through barcodes at the pallet level, creating a sophisticated parent-to-child relationship from pallet to case, and down to the individual pack. Eirgen Pharma currently administers aggregation for US and Saudi-based customers, enhancing the efficiency of the distribution chain and stock level management.



TABLETS

Oral Solid Dose products come in various forms, each requiring unique production techniques and facility designs.

Eirgen Pharma utilizes advanced processing platforms and specialized methods to meet these diverse needs. Our primary processing platforms include

- Wet Granulation
- Dry Granulation
- Direct Compression
- Film Coated Tableting

ENCAPSULATING - HARD SHELL

Hard Shell Capsules offer a cost-effective and convenient solution for reliable dosing and portability. Eirgen Pharma's advanced technology allows for flexible fill formats, including powder fill and liquid fill, ensuring versatility in meeting diverse product requirements.

Powder Fill - Hard Shell Capsule

Hard Shell Capsules are the preferred choice for filling a variety of formulations, including;

- Powders
- Granules
- Pellets
- Micro-Tablets
- Combination Formulations

Liquid Fill - Hard Shell Capsule

Liquid-Filled Hard Capsule Technology offers distinct advantages over other solid dosage forms, making it ideal for delivering APIs that are oily, waxy, or challenging to formulate in traditional solid systems. Key benefits include;

- Improved content uniformity for low-dose, highly-potent APIs
- Enhanced stability and improved bioavailability
- Hermetically sealed with banding for added protection
- Lower moisture content, making it suitable for moisture-sensitive compounds

PLATFORMS CONTINUED..



SOFTGEL

Softgel capsules remain a preferred choice for pharmaceutical companies due to their hermetically sealed designs, which protect against oxidation and degradation while accommodating a wide range of formulations.

Eirgen Pharma partners with customers to develop high-potency softgel products, particularly small-dose APIs used in chronic condition treatments. Our expertise spans all OEB bands, ensuring safe and compliant high-potency softgel manufacturing.

Key benefits of softgel technology include:

- Enhanced solubility and bioavailability
- Customizable formulations, including liquids, suspensions, and semi-solids
- Improved patient compliance through taste-making
- Controlled release for sustained therapeutic effects
- Combination formulations in a single dosage form
- Superior stability for sensitive or light-sensitive compounds



CONTRACT STABILITY



For life science companies, allocating space and personnel for stability storage can be a significant expense, diverting valuable resources from core operations.

Eirgen Pharma's state-of-the-art controlled stability storage facility, located at our Waterford City Campus, is designed to meet ICH requirements and the highest industry standards.

We provide full lifecycle stability storage solutions, ensuring your samples are securely maintained under precise temperature and humidity-controlled solutions.

With comprehensive onsite program management, we offer stability storage across all ICH zones (I to IV A & B), along with full stability testing services. Our expertise and infrastructure allow you to optimize costs while maintaining complete confidence in the integrity of your products.

Partner with Eirgen Pharma for reliable, cost-effective stability storage solutions.



PROCESS & ACCREDITATION



At Eirgen Pharma, we combine our industry-leading expertise with a streamlined development and manufacturing process to bring your pharmaceutical products from pre-formulation to full-scale commercialization - efficiently and cost-effectively.

Our customized, end-to-end solutions support every stage of the journey, including formulation development, clinical, and commercial manufacturing, and packaging for global distribution. With a focus on quality, flexibility, and scalability, we work as an extension of your team, ensuring your product reached the market seamlessly and successfully.



Eirgen develops and supplies high-potency specialty therapies and non high-potent treatments and generics to over 60 countries worldwide. Our commitment to exceeding industry standards has earned approval from leading regulatory authorities, including;

- Ireland’s Health Products Regulatory Authority (HPRA)
- European Medicines Agency (EMA)
- The U.S. Food and Drug Authority
- Japan’s Pharmaceuticals and Medical Devices Agency (PMDA)





PRODUCT PORTFOLIO



With decades of collective industry experience and over 15 years of seamless collaboration, the Eirgen Pharma team has played a pivotal role in the development and launch of life-changing medications across global markets.

Eirgen currently holds the production rights for numerous OSD products and has the capacity to manufacture each of these products at scale.

Product	Dosage	Therapeutic Area
Anastrozole	1mg Film-Coated Tablets	Oncology
Letrozole	2.5mg Film-Coated Tablets	Oncology
Exemestane	25mg Film-Coated Tablets	Oncology
Temozolomide	5 / 20 / 100 / 140 / 180 / 250mg Capsules	Oncology
Dutasteride	0.5mg Soft Gelatin Capsule	Urology
Rayaldee		Nephrology & Endocrinology
Valganciclovir	450mg Film-Coated Tablets	HIV
Entecavir	0.5 / 1.0mg Tablets	HIV

Our expanding pipeline is strategically designed to ensure access to affordable and effective advanced therapies worldwide. This includes high-potency medicines in various formats, targeting therapeutic areas such as **cancer chemotherapy, HIV, and veterinary services, with a focus on animal health.**



We are actively seeking strategic partners for both our current and pipeline products and invite companies interested in becoming market authorization holders to connect with us. Reach out to our Business Development team to learn more about our existing offerings and upcoming products.



Eirgen Pharma is evolving with purpose.

As pharmaceutical development continues to shift towards more potent, targeted, and technically complex therapies, we are shaping our organisation to support this transformation - strengthening our capabilities in high-potency and complex medicines, expanding our ability to deliver at scale.

Our long-term investment strategy is focused on building a platform that can support increasingly demanding programmes, from early development through to sustained commercial supply. This includes continued expansion of our infrastructure, supported by partnerships such as IDA Ireland, alongside the development of advanced manufacturing environments designed for high-containment and specialist production.

The introduction of additional production capabilities, including Building 4, represents an important step in this evolution. It reflects not only increased capacity, but a deeper capability to transition complex products efficiently into commercial operations, with the consistency and control required for long-term supply.

This development is part of a broader, forward-looking approach.

We are continually investing in our facilities, technologies, and technical expertise to ensure alignment with the future direction of the pharmaceutical industry - where complexity, precision, and reliability will define success.

At the same time, we recognise that growth must be sustainable.

Our expansion is guided by responsible design and long-term thinking, from energy-efficient infrastructure to operating models that support environmental stewardship and resilience over time.

As the organisation grows, so too does our culture.

The introduction of refreshed company values reflects our business that is becoming more focused, more aligned, and more deliberate in how it operates - reinforcing our commitment to accountability, collaboration, and consistent delivery.

Together, these developments represent a clear trajectory,

Eirgen Pharma is building the capabilities, scale, and expertise required to support the future of complex medicines - and strengthening its position as a long-term partner for you, operating at the forefront of modern therapeutics.

CONTACT US

All great partnerships start with a conversation.

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