Oral Drug Delivery Solutions

An integrated portfolio of functional excipients, delivery technologies and services to release the true value of your oral solid dosage forms

EVONIK
Leading Beyond Chemistry

Make Evonik Health Care Your Competitive Advantage

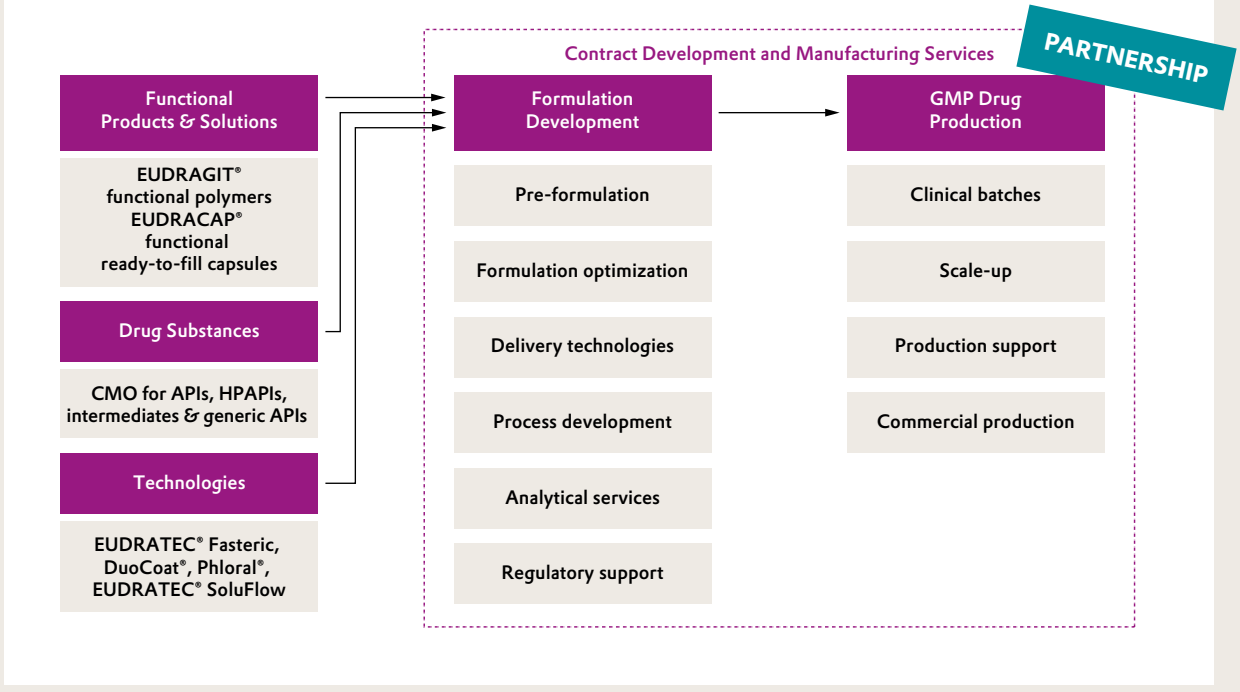
Evonik is one of the world's leading specialty chemical companies. In 2021, our more than 33,000 employees produced sales of more than €15 billion and an operating result (EBITDA) of €2.4 billion. We hold market leading positions in 80 % of our businesses, and are active across more than 100 countries and 175 sites globally.

Evonik Health Care is a global strategic partner for advanced drug delivery solutions. We combine highly versatile platforms of functional excipients for oral and parenteral dosage forms, with innovative technologies and best-in-class formulation development, manufacturing and regulatory services.

Pharmaceutical companies worldwide leverage our distinctive products and value-adding services to enhance drug effectiveness, reduce project complexity, increase speed to market and strengthen supply security.

By helping to transform your APIs into high-performance medicines, we can become Your Competitive Advantage.

YOUR GLOBAL PARTNER FOR ADVANCED ORAL DRUG DELIVERY



RELEASE THE TRUE VALUE OF YOUR ORAL SOLID DOSAGE FORMS

1

EUDRAGIT® functional polymers

The versatility and reliability to protect the API, boost drug performance and reduce formulation risk

EUDRACAP® functional ready-to-fill capsules

The fast and reliable solution to optimize the release profile of your drug, protect active ingredients, and help accelerate speed to market

2

Delivery Technologies

Differentiated solutions for modified release to enhance drug efficacy and generate superior targeting outcomes

3

Formulation Services

Best-in-class services to reduce project complexity from concept to the final dosage form to increase speed to market

4

PARTNERSHIP

Clinical and Commercial Supply

High-quality GMP clinical production, robust scale-up to commercialization through partner with on-site production support and trouble-shooting

5

Regulatory Support

Leverage the worldwide monograph status of our excipients and local market expertise for regulatory 'peace of mind'

UNRIVALLED VERSATILITY TO UNLOCK THE POTENTIAL OF YOUR API

Our platform of polymers can be used individually or combined to match virtually any target release profile

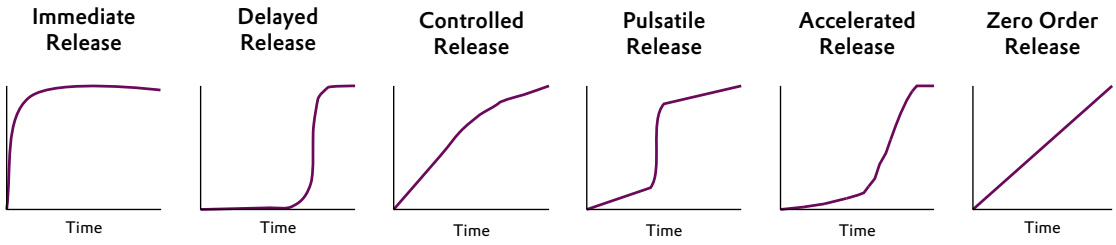
EUDRAGIT® formulations to design individual immediate, delayed or sustained release profiles

- Single or multiple EUDRAGIT® polymer layers
- Combination of EUDRAGIT® polymers
- Combination of EUDRAGIT® polymers and other excipients or substances
- Inert core with combination of EUDRAGIT® polymers and API layer
- Ready-to-use mixtures

EUDRACAP®

Optimize gastric resistance, boost intestinal absorption and enhance bioavailability with EUDRACAP® functional, ready-to-fill capsules.

- An effective, precisely tailored functional coating
- Easy to open and close on standard equipment
- Reliable protection and precise, rapid release



THE FLEXIBILITY TO ADDRESS SPECIFIC FUNCTIONALITY REQUIREMENTS

THE EUDRAGIT® ADVANTAGE

- A proven record for safety and performance in marketed oral solid dosage forms spanning more than 70 years
- Ideal for all oral solid dosage forms including tablets, capsules, and multiparticulates
- Easy to handle and compatible with all relevant process technologies
- Consistent quality and global supply security at any clinical or commercial scale
- Unparalleled technical application and formulation expertise across coatings, formulations and finished dosage forms

IMMEDIATE RELEASE

Protect the Drug. Boost Patient Compliance.

- High-gloss easy to process cosmetic and functional coatings
- Neutral in taste and smell to mask API bitterness or unpleasant odors
- Smooth surfaces as thin as 10 – 20 µm to improve swallowability
- Reliable protection and stability for APIs sensitive to light, moisture and oxygen
- Insoluble in saliva and readily soluble in the stomach for improved absorption
- Custom-made, easy-to-mix powder blends for rapid suspension preparation

DELAYED RELEASE

Protect the API. Avoid Discomfort. Improve Absorption.

- A broad, easy-to-combine enteric platform to achieve a specific dissolution pH
- Highly effective and stable polymers for precise targeting and rapid dissolution
- Well-defined solutions to protect the gastric mucosa from aggressive actives
- Strong expertise in safeguarding the transit of APIs sensitive to gastric fluid
- Options to improve coating productivity and reduce process and cleaning time
- Ready-to-fill coated capsules for accelerated time to market

SUSTAINED RELEASE

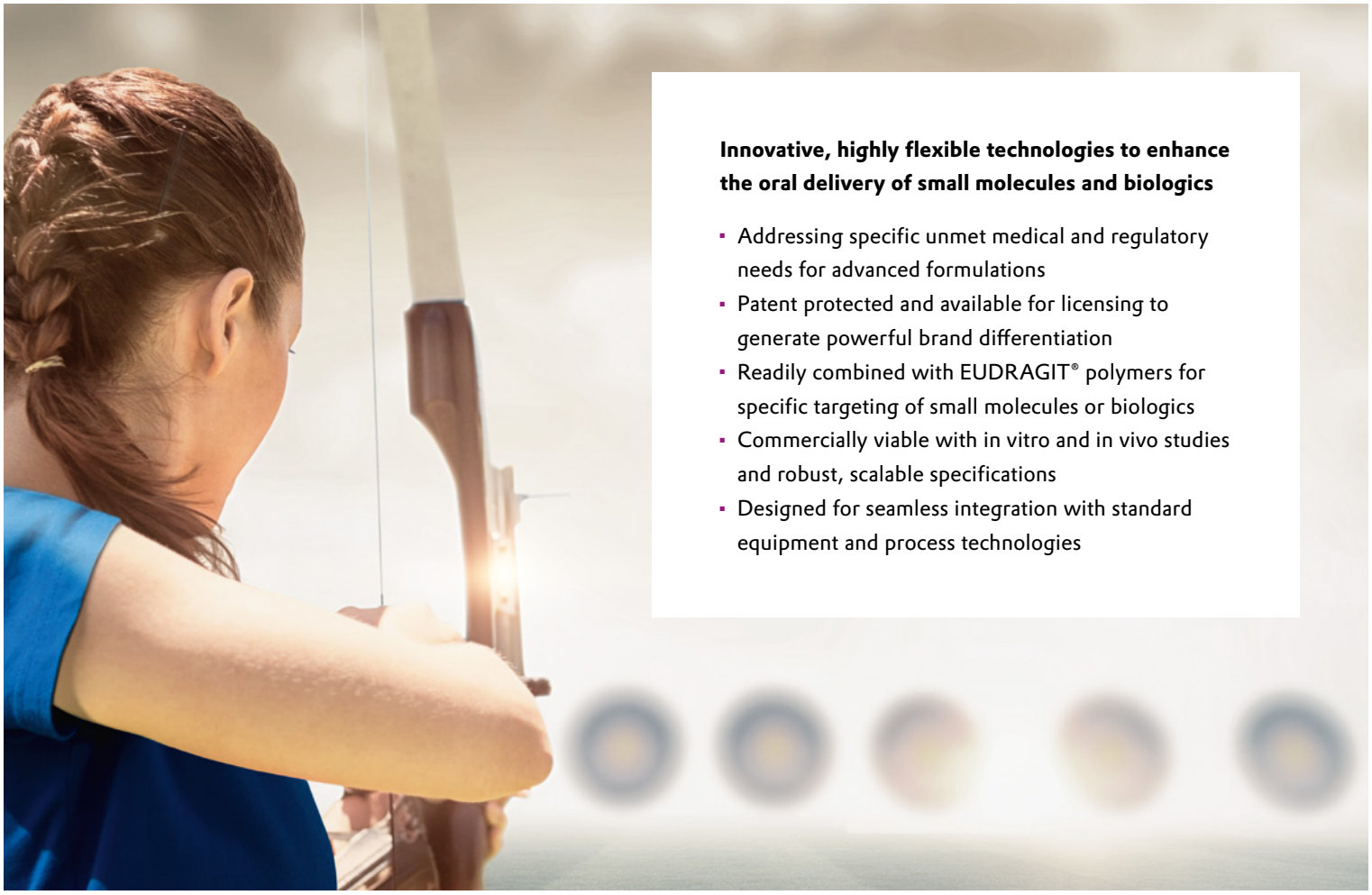
Optimize Drug Effectiveness. Improve Patient Compliance.

- Sustained, modulated or custom release profiles controlled by diffusion barriers
- Multiple combination options to precisely control passage through the GIT
- Proficient in daily dosage forms including multiparticulates and matrix tablets
- Insoluble with pH-independent swelling and options for high or low permeability
- Options to improve coating productivity and reduce process and cleaning time

SOLUBILITY ENHANCEMENT

Increase bioavailability. Address poor solubility.

- Suitable carriers for all process technologies such as spray drying, HME and top-spray granulation
- Highly specialized in amorphous solid dispersions (ASDs)
- Development and manufacturing service for particle-engineered free flowing ASDs
- Predictive systems to select the best carrier excipient and process parameters
- Various downstreaming options to improve dosage forms and speed to market



Innovative, highly flexible technologies to enhance the oral delivery of small molecules and biologics

- Addressing specific unmet medical and regulatory needs for advanced formulations
- Patent protected and available for licensing to generate powerful brand differentiation
- Readily combined with EUDRAGIT® polymers for specific targeting of small molecules or biologics
- Commercially viable with in vitro and in vivo studies and robust, scalable specifications
- Designed for seamless integration with standard equipment and process technologies

OPTIMIZE DRUG EFFICACY WITH SUPERIOR TARGETING OUTCOMES

Effective targeting of upper small intestine

EUDRATEC® FASTERIC

A dual-layer coating for enteric protection with rapid release at pH 5.5 or below for effective targeting of the upper small intestine

High-precision colon delivery

DUOCOAT®

A dual-layer coating of enteric polymers with an inner layer customized for rapid dissolution in the ileocolonic region

PHLORAL®

A single film coating with a dual action mechanism that combines a pH triggered polymer with a polysaccharide

Phoral® is a proprietary technology from Intract Pharma Ltd.

HARNESS THE VALUE OF OUR BEST-IN-CLASS PROJECT SERVICES

1 COMPREHENSIVE SUPPORT

Extensive polymer and formulation support from the first sample to the final dosage form

2 DECADES OF TECHNICAL EXPERTISE

Projects led by scientists and pharmacists with in depth technical and scientific knowledge

3 GLOBAL LABORATORY NETWORK

Access to nine formulation and application labs worldwide including local onsite support

4 PROCESS TECHNOLOGY EXPERTISE

Strong capabilities across all relevant process technologies and equipment

5 SUPPORTING SCALE-UP AND LAUNCH

Broad knowledge of physiological aspects, clinical requirements and GMP scale-up

6 STRONG RECORD OF ACHIEVEMENT

Decades of commercial project success for small molecules or biologics

7 ANY ORAL SOLID DOSAGE FORM

Deep expertise across complex dosage forms

8 LOCAL MARKET EXPERTISE

Highly familiar with local regulatory processes and requirements

9 QUALITY BY DESIGN APPROACH

QbD principles guide each process step to reduce risk and improve speed to market

10 HANDLING OF SPECIAL SUBSTANCES

HPAPI down to 1 µg/m^3 OEL, biological materials up to biosafety level BSL-2 as well as controlled substances

CREATING EXCEPTIONAL VALUE FROM FEASIBILITY TO FINAL DOSAGE FORM

PRE-FORMULATION SERVICES	▪ Fast-track feasibility studies ▪ Rapid evaluation of and compatibility with excipients ▪ Selection of formulation technologies
FORMULATION DEVELOPMENT	▪ Formulation and reformulation projects ▪ Technology matching to target release profile ▪ Prototypes for stability or preclinical studies ▪ Process development and scale-up
ANALYTICAL SERVICES	▪ Comprehensive range of analytical methods to support development and manufacturing projects ▪ Stability program testing ▪ Scanning electron microscopy ▪ Dissolution testing using USP I (Basket), USP II (Paddle) and USP IV (Flow Through Cell) and biorelevant media
PRODUCTION, SCALE-UP AND COMMERCIAL SUPPLY	▪ Process technology expertise non-GMP and GMP scale (through partnering) ▪ On-site production support and troubleshooting ▪ CMO review and recommendation for clinical and commercial scale-up ▪ Transfer to production site **PARTNERSHIP**

OUR HIGHLY SPECIALIZED CAPABILITIES ENABLE US TO EFFICIENTLY MANAGE COMPLEX PROJECTS FOR:

- Drug types including small molecules, peptides, nucleic acids, highly potent APIs, controlled substances and BSL-2 microbials
- Specialized oral modified drug release including controlled, sustained, delayed, and pulsatile release
- Bioavailability enhancement of small molecules, oral biologics and microbials
- Regulatory and lifecycle management strategies including expedited approval pathways such as 505(b)(2)

CUSTOM PRODUCTS TO MATCH YOUR SPECIFIC NEEDS

A range of size, color and other tailored options
In addition to our series of standard EUDRACAP® products, our EUDRACAP® Select platform provides you with flexible custom options including:

- **Size:** A range of sizes can be supplied
- **Color:** Transparent, two-tone, full white or full colored
- **Release profile:** Many EUDRAGIT®, drug delivery and process technology options are available to match your specific immediate, delayed, sustained or modulated release profile or solubility enhancement requirements

A best-in-class platform of functional ready-to-fill capsules

EUDRACAP® Select

SOLVE YOUR SOLUBILITY ENHANCEMENT CHALLENGES

Our solubility enhancement service for particle-engineered free-flowing amorphous solid dispersions

- Solubilizes highly challenging compounds
- Creates free-flowing powder through lean process with advanced particle-engineering control
- Leverages full therapeutic potential

Transform poorly soluble drugs into free-flowing amorphous solid dispersions

EUDRATEC® SoluFlow

4 Clinical and Commercial Supply

FAST, FLEXIBLE AND RELIABLE CLINICAL AND COMMERCIAL DRUG SUPPLY

- Sites
  - Germany and the USA
  - GMP system complies with EU guidelines and FDA guidelines
- HPAPI capabilities
  - OEB 3a/3b (OEL 1 µg/cm³ - 10 µg/cm³)
  - OEB 4: select cases (OEL 0.1 µg/cm³ - 1 µg/cm³)
- Controlled substances
- Solvent capabilities

PARTNERSHIP

Capability	GMP Scale
Fluid bed coating	0.005 – 400 kg
Automatic capsule filling	10,000 – 100,000 capsules/hour
High-shear granulation	10 – 100 L
Drug layering	0.004 – 400 kg
Tablet compression	< 150,000 tablets/hour
Tablet and capsule coating (drum coater)	0.8 – 125 L
Direct pelletization (fluid bed technology)	0.004 – 100 kg

5 Regulatory Support

WORLDWIDE MONOGRAPH ACCEPTANCE. LOCAL MARKET EXPERTISE.

PHARMACOPOEIAL MONOGRAPHS AND DMFS

- Global acceptance of monographs for EUDRAGIT® series across key regions including U.S., EU, Japan and China
- EUDRAGIT® types detailed in Type IV U.S. DMFs
- EXCiPACT™ certificate system for audit efficiency

EXTENSIVE DOCUMENTATION SUPPORT

- Global quality systems (IPEC-GMP)
- Robust documentation to support NDAs and marketing authorizations including
  - Safety and toxicology packages
  - Polymer specifications
  - Letters of Authorization for DMFs
  - Detailed statements for special purposes

202210

EVONIK
Leading Beyond Chemistry

EVONIK OPERATIONS GMBH
Health Care Business Line

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