optimal drug delivery solutions. better treatments.
better treatments with optimal drug delivery technologies.

We are your catalyst for creating better treatments. Our deep expertise in drug development, delivery and supply can help improve the bioavailability of your compound, enhance therapeutic profiles, improve patient adherence, and enhance safety and convenience.

As a global leader in drug delivery solutions, we have the deepest expertise, the broadest offerings and the most innovative technologies to improve the performance of your products from discovery to market and beyond.

**IMPROVED BIOAVAILABILITY**
We have the broadest range of proven solutions to improve the bioavailability of your treatments, including API optimization, expert formulation, softgel, hot melt extrusion and controlled release technologies.

**IMPROVED PATIENT ADHERENCE**
With the superior therapeutic performance of our softgel technology and Zydis® fast-dissolve technologies, we can help improve patient adherence.

**IMPROVED THERAPEUTIC PROFILES**
Our softgel, controlled release, and GMS™, Optide® Technologies help deliver better absorption, controlled API in blood levels, faster onset, extended release and targeted delivery.

**SUPERIOR CONVENIENCE & SAFETY**
Our drug delivery technologies help optimize the dosing and route of administration of your products, for a patient and doctor-preferred choice with reduced pill burden or combination product delivery.

**OPTIFORM™ TECHNOLOGIES & SOLID STATE SERVICES**
Optiform™ technologies, developed by GlaxoSmithKline, help select the most suitable salt, crystalline and co-crystal forms to solve your bioavailability challenges. With proven technologies, industrial expertise and high-throughput workflows, we can help you discover and evaluate the diversity of solid-state forms of your API, enable the selection of the most suitable form to meet your development needs and ensure a successful, timely and cost-effective progression from pre-clinical and clinical development through commercialization.

**MORE PRODUCTS TO MARKET, FASTER**
As the #1 global partner in the development and formulation of drugs, biologics and consumer health products, we help bring more compounds and better treatments to market faster.

**PRE-FORMULATION & FORMULATION**
For both small and large molecules, we have the analytical and drug development expertise to provide market-leading, full CMC services for oral, inhalation and sterile products from pre-formulation and formulation through clinical supply, including scale-up and technology transfer to our commercial manufacturing facilities.

**SOLUBILITY SCREENING**
Our scientists have extensive experience developing market-ready softgel fill formulations that include solutions, suspensions, self-emulsifying/micro-emulsion concentrates and lipolyzing formulations.

**MINI-ENCAPSULATION**
Our mini-encapsulation capabilities provide early stability data as well as animal and human testing supplies, speeding your development timeline.

Discover more solutions with Catalent. Call: +1 866 720 3148 Email: solutions@catalent.com Visit: www.catalent.com
SOFTGEL TECHNOLOGIES
The leading solution to improve the bioavailability of your poorly water-soluble compounds.

Softgel technology benefits go beyond the dosage form itself to leverage exceptional formulation capabilities that deliver more products into your development pipeline. Softgel technology delivers:

• Improved bioavailability over other oral solid options
• Enhanced pharmacokinetic profile with the application of film coatings for targeted delivery and improved therapeutic profiles
• Better permeability with the use of lipid-based fills containing permeability enhancers
• Improved stability overcoming oxidation and light sensitivity challenges
• Excellent dose uniformity with highly potent, low-dose compounds

IMPROVED BIOAVAILABILITY
As the commercially-proven solution to help enhance the oral bioavailability of your products, softgel technology can optimize the pharmacokinetic performance of your compound and provide better absorption, leading to higher blood levels and quicker onset of action to improve the therapeutic profile and deliver better treatments to the patients you serve. Using numerous lipid-based fill formulations to find the best solution for optimizing bioavailability of your unique compound, we can enable the advancement of more products in your development pipeline.

VEGICAPS® CAPSULES SOLVE BIOAVAILABILITY CHALLENGES FOR MORE APIs

Vegetable capsules are an easy-to-swallow, plant-based shell, free from animal derivatives, gluten and modified sugars, featuring unique shell formulations containing modified starch, carrageenan (red seaweed extract), disodium phosphate, glycerol and/or sorbitol and purified water. An optimal solution for highly-viscous and/or semi-solid fill formulations, with higher melting points, VEGICAPS® capsules provide a solution beyond traditional gelatin capsules, and can help you bring more products to market.

The VEGICAPS® capsule shell polymer system undergoes thermal transitions at higher temperatures than traditional, gelatin-shell systems and can tolerate high-temperature filling, allowing encapsulation of:

• Heated fill materials for highly viscous or semi-solid fill systems
• Chemically aggressive fill systems with high alkalinity
• API or excipients that cross-link with traditional gelatin soft capsules

VEGICAPS® FORMULATIONS

<table>
<thead>
<tr>
<th>Formula</th>
<th>Base Vehicle</th>
<th>Vehicle Characteristics at Room Temperature</th>
<th>Drug Loading</th>
<th>Physical State of the Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Physical State of the Formulation</td>
<td></td>
<td>20°C</td>
</tr>
<tr>
<td>1</td>
<td>PEG 6000</td>
<td>hydrophilic, solid</td>
<td>solid</td>
<td>solid</td>
</tr>
<tr>
<td>2</td>
<td>Sucrose Acetate Isobutylate</td>
<td>isoparaffinic</td>
<td>extremely viscous fluid</td>
<td>extremely viscous fluid</td>
</tr>
</tbody>
</table>

As the leading solution to improve the bioavailability of your poorly water-soluble compounds.

DISCOVER MORE SOLUTIONS WITH CATALENT. Call +1 866 720 3148 Email: solutions@catalent.com Visit: www.catalent.com

SOFTGEL TECHNOLOGY INNOVATIONS

We have successfully launched hundreds of new Rx products around the world and produce over 80% of Rx softgel capsules worldwide. Softgel technology is the commercially-proven drug delivery choice for solutions, suspensions, self-emulsifying/ microemulsion concentrates and lipolyzing formulations, and provides the ability to deliver stable, uniform doses as well as:

• Product Differentiation A wide array of available shapes and colors ensures your product has the look and feel you want for your brand.

• Product Lifecycle Management Developing a softgel formulation of your product helps manage the lifecycle of your brand and can help delay brand erosion upon competitive entry.

• Enhanced pharmacokinetic profile with the application of film coatings for targeted delivery and improved therapeutic profiles

• Patient Convenience Aesthetically-pleasing, easy-to-swallow softgels are more likely to be taken as directed and therefore deliver the full efficacy benefit.

VAGINAL OVULES

Elevate your brand and improve patient compliance with vaginally-delivered softgel ovules.

CHEWABLE SOFTGELS

Ideal for the pediatric and geriatric markets, our chewable capsules accommodate a wide range of formulations and can be customized to meet the needs of your patients.

TWIST-OFF SOFTGELS

A unique softgel delivery system ideal for ophthalmic and dermatological products.

EXPERT SOFTGEL SOLUTIONS. RELIABLY SUPPLIED.

Our expertise in softgel technology development, delivery and supply is backed by an excellent regulatory compliance track record, with more products to market than other enabling technologies. With our integrated global network of state-of-the-art cGMP facilities on five continents, we can move your product from clinic to market with superior quality and reliability.

• Containment facilities for potent compounds and cytotoxic products
• FDA-approved pilot plants that meet cGMP requirements
• Manufacturing options in a Foreign Trade Zone to provide potential savings on API import duty
• Innovative in-line gel ribbon printing can help differentiate your product in the global marketplace (FIGURE 2)
MODIFIED RELEASE TECHNOLOGIES

Formulation solutions to maximize product differentiation and address your patients’ needs for prescription or OTC products in development, mid-lifecycle or post-patent expiry.

 OUR DIFFERENCE

Our unmatched range of innovative technologies, combined with our formulation, production scale-up, regulatory and commercial expertise can optimize your therapeutic profile, get your product to market faster and reduce your development risk. With high market share, high brand retention rates, strong growth, and notable contribution to overall brand sales for numerous prescription and consumer drugs, our controlled release and orally-disintegrating technologies can optimize product performance, maximize product differentiation and increase your return on investment.

Catalent modified release technologies help provide:

- Improved bioavailability
- Enhanced therapeutic profiles
- Improved patient adherence
- Superior convenience and safety

TABLETS
- Matrix tablet
- Osmotic tablets
- Bi-layer tablets, including immediate, sustained and delayed-release combos
- Dividable tablets
- Combination product tablets
- Multi-care tablets
- Direct compression orally-disintegrating tablets (ODT)
- Traditional tablets

COPAED PELLETS/BEADS
- High-potency pellets
- Drug-layered spheres
- Taste mask particles

CAPSULES
- IR powder in a capsule (Xcelodose®)
- API in a capsule (Xcelodose®)
- Beads for controlled release, including multiparticulate
- Tablets in capsules

CONTROLLED RELEASE PILLS, TABLETS & CAPSULES

Deliver your drug when it’s needed, how it’s needed. We can optimize your drug-release profile to provide the most effective treatments for your target patients. We utilize polymers to coat tablets and beads, or drug particles in capsules. Dissolution of the coating releases the API over a controlled period of time.

With development and manufacturing services for a broad range of formulations, our technologies can help deliver the following benefits:

- Optimized drug delivery profiles by ‘gaining a dose’
- Differentiated products, reduced pill burden and improved reimbursement potential through less frequent dosing
- Improved compliance through convenient dosing regimens
- Target drug delivery to specific parts of the body to optimize efficacy, and safety, and reduce side effects
- Same fast onset of action with an IR, while reducing pill burden with continued and extended release
- Ability to deliver poly-therapy by designing a ‘pill within a pill’
- Faster time to market and higher probability of success by selecting our experience and capabilities

EXTENDED & SUSTAINED RELEASE

Decrease dosing frequency compared to immediate-release form or a specific amount of drug released at specific timed intervals.

DELAYED (ENTERIC) RELEASE

Drug released at specific points in the body, based on pH or other characteristics.

PULSED (REPEAT ACTION) RELEASE

Short- and long-term combined drug release (immediate plus extended release) in one dose form.

OSDc® OPTIDOSE™

Optimized dose delivery technology offers the broadest range of controlled release, combination (tablet-within-a-tablet) products and orally-disintegrating tablets to optimize dosing, therapeutic, and plasma release profiles to meet patient needs in a high quality, one-step manufacturing process.

ORTHOMELT EXTENSION

Hot melt extension (HME) increases solubility, and improves therapeutic efficacy for poorly soluble compounds.

ORALLY-DISINTEGRATING TABLETS

Deliver your drug where it is needed, faster. Our orally-disintegrating technologies can help deliver the following benefits:

- Increased bioavailability through pre-gastric absorption
- Faster orally-dissolving formulation marketed (less than 3 seconds)
- Improved safety by limiting first-pass metabolism through liver
- Convenience, with no water required, benefiting elderly and pediatric patients, and patients on the go
- Patient satisfaction, with 93% preferring our Zydis® formulations vs. standard tablets (figure 3)
- Significantly improved patient compliance vs. standard tablets

STICK PACK FAST-DISSOLVE LOOSE POWDER GRANULES

Loose, free-flowing powder granules in a convenient unit-dose pack that dissolve instantly without water, providing an alternative formulation to tablets or pills.

ZYDIS® FAST-DISSOLVE TABLETS

Lyophilized orally disintegrating tablets that disperse instantly (in as little as 3 seconds) without the need for water. Taste-masking can be integrated into tablet formulation if needed.

LOYPAN® FAST-DISSOLVE TABLETS

Increases the range of prescription and consumer drug products that can be formulated in lyophilized fast-dissolve dosage form because it uses less water. This proprietary technology may be applicable to the formulation of higher doses of soluble drugs that is currently feasible, and may enable incorporation of coated API for enhanced taste-masking and controlled release.

FIGURE 3: PATIENT PREFERENCE & COMPLIANCE

<table>
<thead>
<tr>
<th>Disease</th>
<th>Study Type</th>
<th>Patient Number</th>
<th>Patients Preferring Zydis® ODT vs. Standard Tablets</th>
<th>Compliance: Zydis® ODT vs. Standard Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parkinson’s Disease</td>
<td>12-month longitudinal patient records</td>
<td>1520</td>
<td>N/A</td>
<td>98.5% vs. 81.0% Medicare patients</td>
</tr>
<tr>
<td>Parkinson’s Disease</td>
<td>12-week investigator study</td>
<td>197</td>
<td>86% preferred Zydis® ODT</td>
<td>N/A</td>
</tr>
<tr>
<td>Allergy Rhinitis</td>
<td>patient preference survey</td>
<td>420</td>
<td>83% preferred Zydis® ODT</td>
<td>N/A</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>16-week investigator study</td>
<td>149</td>
<td>N/A</td>
<td>92.9% vs. 78.5% (P&lt;0.05)</td>
</tr>
<tr>
<td>Allergy (Antihistamine)</td>
<td>patient preference study</td>
<td>&gt;750</td>
<td>94.3% preferred Zydis® ODT to lessen side effects of</td>
<td>95.3% Zydis® ODT easy to take &amp; did not cause</td>
</tr>
</tbody>
</table>
INHALATION & STERILE TECHNOLOGIES

Deep expertise and a wide range of inhalation, parenteral and injectable dosage forms for better treatments with improved safety and convenience.

INHALATION

For respiratory conditions, such as asthma, sinusitis and chronic obstructive pulmonary disease (COPD), drug delivery by inhalation helps target the diseased area precisely and bypasses the gastrointestinal tract to minimize systemic absorption and improve bioavailability for effective treatment. With over twenty years in inhalation product development for all inhalable dose forms, we have the broadest range of development services from dosage form selection, technology assessment, formulation development, stability, extractable and leachable testing to clinical manufacturing and packaging.

STERILE TECHNOLOGIES

Through our diverse range of injectable delivery platforms, unit and multi-dose blow/fill/seal configurations, and our innovative self-injection solutions through our collaboration with Bespak, Catalent can enhance product performance and provide more convenient, safer dosing options to improve patient outcomes.

• Extensively customizable pre-filled syringe offerings to support multiple therapeutic areas
• Variety of innovative technologies, improving safety and patient outcomes
• Reliable, flexible supply with syringe-filling capacity of up to 200 million units
• Formulation development
• Blow/fill/seal technologies
• Pre-filled syringes
• Autoinjector
• Phase 1/II Vials

PRESSURIZED Metered-dose Inhalers
DRY POWDER Inhalers
NEBULIZED SOLUTIONS/SUSPENSIONS

INTEGRATED SERVICES, RELIABLY SUPPLIED

Customized, integrated solutions to solve your most complex challenges, from development and delivery to manufacturing and packaging.

We are a global leader in customized integrated service solutions. Whether you need a single solution or an end-to-end partner, our team of scientific, regulatory, manufacturing and operations professionals can develop a tailored proposal that will put you on track to faster, more efficient drug development and commercialization pathways.

REGULATORY SERVICES

With over 50 years of experience across a wide range of therapeutic areas for global markets, we help you maximize your product value with expert development solutions. From pre-clinical to life-cycle maintenance, we help ensure accurate, timely regulatory submissions, which can minimize development timelines and maximize probability of success.

CLINICAL SUPPLY SERVICES

We ensure the successful flow of your trial to clinic with integrated services that include global comparator sourcing, clinical manufacturing and blinding, clinical packaging and labeling, analytical services, and distribution and warehousing. Our reliable and flexible project management teams will help you reach your development milestones on time and get more products to market faster.

ORAL & PARENTERAL DRUG MANUFACTURING

With over 75 years of manufacturing expertise, consistent quality and reliable product supply, our global infrastructure of GMP FDA, EMA and locally accredited facilities can provide you with a tailored drug manufacturing solution.

PACKAGING

A broad range of packaging solutions can be integrated with our global manufacturing options for a tailored solution that helps optimize your supply chain, reduce cycle time and inventory levels, and simplify release and invoicing procedures for lower overall supply chain costs.
WHY CATALENT?
Unrivaled experience, deepest expertise and a track record of market success on a global scale.

- We are the #1 global partner in the development and formulation of drugs, biologics and consumer health products
- We are a world leader in drug delivery technology
- We serve 90 of the top 100 pharmaceutical and 44 out of the top 50 biotech companies
- We operate 20+ global sites serving 1,000+ customers in over 100+ countries
- We create expert solutions from over 1,000 scientists, including key opinion leaders in drug development and delivery
- We've supported over 40% of recent U.S. drug approvals as well as multiple approvals around the world, and are now working on 500+ new development programs
- We manufacture or package 100 billion units annually
- We use a multi-faceted approach to solve bioavailability and patient adherence challenges
- We have had no critical observations in over 50 regulatory inspections globally last year
- We offer fully-integrated medication supply chain solutions
- We have a proven track record in regulatory compliance in all key jurisdictions
- We are fully dedicated to high standards of quality, cGMP leadership, and LEAN operational excellence

Catalyst + Talent. Our name combines these ideas. From drug and biologic development to delivery technologies and supply solutions, we are the catalyst for your success. With over 75 years of experience, we have the deepest expertise, the broadest offerings, and the most innovative technologies in brand and generic pharmaceuticals, veterinary medicine, consumer health, and biologics. Whether you are looking for a single, tailored solution or multiple answers throughout your product's lifecycle, we can improve the total value of your treatments—from discovery to market and beyond. Catalent. More products. Better treatments. Reliably supplied.™

To learn more about Catalent drug delivery solutions, contact us today.
www.catalent.com
more products.
better treatments.
reliably supplied.™

Challenge us. Let us help you get your products to market faster, stay there longer, and be more successful. Catalent Pharma Solutions. We are the catalyst for your success.

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