# Capsugel®

High-quality capsules, excipients and formulations for the medicines



Made better. By science.™

## QUALITY AS A MINDSET

We are focused on quality and compliance in everything we do, from raw material sourcing to manufacturing and follow-up service. Our ongoing commitment to Six Sigma principles helps to minimize variability, improve the quality of our processes, and lead us toward the ultimate goal of zero defects for our products. The Capsugel® product portfolio is engineered to help overcome key product challenges with proven performance in products you trust.

- Immediate release: Coni-Snap® Gelatin, Vcaps® Plus, Plantcaps®
- Modified release: Vcaps® Enteric, DRcaps®
- Dry-Powder Inhalation: Zephyr™ portfolio
- R&D Clinical: PCcaps®, DBcaps®, Colorista®\*
  - Patient-centric End to end: Coni-Snap® Sprinkle, Press-Fit®, Licaps®
- \* Colorista® is a trademark of Lonza or its affiliates registered in the US and/or EU





## CONI-SNAP® HARD GELATIN

The reliable and outstanding performance of Coni-Snap® hard gelatin capsules has made them a product of choice for biopharmaceutical companies since their unique locking closure was introduced. Designed and engineered to perform, they are a reliable and widely used capsule.



#### DRCAPS®

DRcaps® are made with an innovative HPMC formulation that can help protect sensitive ingredients from the low pH environment of the stomach. The low-moisture level of DRcaps® provides enhanced stability for hygroscopic ingredients.



#### **CONI-SNAP® SPRINKLE**

Designed to be easily opened by patients and caregivers, these capsules are ideal for pediatric and geriatric populations.

Available in gelatin and HPMC.



#### **VCAPS® PLUS**

An immediate-release HPMC¹ capsule, without gelling agents. Vcaps® Plus capsules offer excellent dissolution profile with pH-independent performance, standard or low-moisture content, great machinability and visual quality.



## ZEPHYR™ DRY-POWDER INHALATION CAPSULES

Custom inner surface properties, customized moisture levels and strict microbial limits all designed to optimize inhalant end-product performance.

Available in Coni-Snap® Gelatin,
Coni-Snap® Gelatin-PEG, Vcaps® and
Vcaps® Plus.



#### **COLORISTA®**

An optimized tool for formulation development enabling compatibility studies before deciding on the final color for the commercial drug products. Available in gelatin and HPMC.



#### **PLANTCAPS®**

Plantcaps® are plant-based capsules produced from tapioca pullulan. They are starch-free, gluten-free, preservative-free and non-GMO. They offer fast disintegration and excellent oxygen barrier properties in a non-reactive shell.



#### **PCCAPS®**

PCcaps® provide a simple way for pre-clinical oral administration of pharmaceutical actives and formulations to rodents. These small gelatin capsules have been designed for performing pre-clinical trials such as pharmacokinetic, pharmacodynamic and animal safety studies.



## LICAPS® LIQUID-FILLED HARD CAPSULES

Licaps® two-piece capsules are an advanced dosage form for liquid, semi-solid, paste and multi-particulate applications. This unique and elegant dosage form has a proven track record for addressing complex formulation challenges and improving / repositioning existing formulations.

Available in gelatin and HPMC.



#### **VCAPS® ENTERIC**

Capsule technology that simplifies enteric drug delivery implementation. It offers an enteric-release profile to the upper gastro-intestinal tract that meets the disintegration requirements for delayed-release capsules from the European, US and Japanese Pharmacopoeia. The pharmaceutical grades of cellulosic derivatives used in Vcaps® Enteric capsules have extensive market precedence for use in providing enteric protection.



#### **DBCAPS®**

DBcaps® capsules were developed with a tamper-evident design to specifically address the clinical trial challenges of testing without bias. The wider diameter of opaque DBcaps® allows containment and blinding of large-diameter or uniquely-shaped tablets or other comparator products, while their shorter length makes them easier to swallow. Available in gelatin and HPMC.



#### PRESS-FIT® GELCAPS

Press-Fit® Gelcaps utilizes a Capsugel® technology that is difficult to mimic and enables brands to create a new product look without having to reformulate their product. Flexible gelcaps are stretched around a caplet of specified shape and dimension using a patented cold-shrink process.

#### **R&D SAMPLE SUPPLIES**

We offer R&D Sample Bottles and the Capsugel® CapsuleCaddy™ container to support and expedite the R&D process. Contact your representative to order. Refer to the back of this brochure for further details.

<sup>&</sup>lt;sup>1</sup> HydroxyPropyIMethylCellulose or Hypromellose

## OUR EQUIPMENT

#### Our dedicated Technical Support team offers:

Operational overview and assessment, guidance workshops,

targeted support, success measures

The Lonza Engine™ portfolio includes equipment for micronization, capsule filling and sealing and powder micro-dosing. It supports bioavailability enhancement, encapsulation and early-phase clinical development technologies. Our global technical support service team works with customers to increase production efficiency and improve equipment yields by tailoring services to customer needs.

#### Bioavailability enhancement technologies

- Liquid-filling and sealing equipment: CFS1200<sup>™</sup>, CFS 1500<sup>™</sup>, LEMS<sup>®</sup> 70

#### Technologies for clinical development and small batches

- Powder micro-dosing system: Xcelolab®, Xcelodose® 120S, Xcelodose® 600S
- Hard capsule filing machine: Ultra III™

Lonza's experienced service and support team will provide installation, validation packages and on-site training as requested. Also available are ongoing support and preventive maintenance agreements to keep your Lonza Engine™ equipment operating at optimal efficiency.

## OUR SERVICES



### Security of Supply

All Capsugel® manufacturing equipment is proprietary and sourced from a centralized manufacturing technology center, ensuring global consistency. Our manufacturing capabilities allow us to immediately respond to demand surges and to invest quickly where needed to ensure security of supply for our customers. All manufacturing sites perform to the same specifications, allowing customers to depend on us to maintain daily supply and to source from our other manufacturing sites when needed.



#### **Color Lab**

Our color lab experts can assist with final product color decisions thanks to a wide range of global gelatin or HPMC colors, and a palette of pre-developed ink colors for immediate use. The color lab formulates colors on request to match brand guidelines and meet region-specific regulatory requirements. Our experience in developing and manufacturing thousands of color combinations will give additional assurance that the selected colors have already been validated by the Quality team, thus enabling customers to meet aggressive product launch schedule.



#### **Pre-Sampling Method**

Thanks to the Pre-Sampling Method,
Capsugel® capsules remain hygienically
packed and sealed until they are filled.
Our operational department takes a
representative sample from the entire lot,
that is shipped with the order. Sample
remains unaltered, giving the customer an
objective and representative view of the
capsules delivered.

## OUR REACH

Meeting the needs of customers in over 100 countries requires a reliable and highly efficient integrated global network of manufacturing sites. With our global scale, we have established a rigorous program to certify our vendors and their products that provides a best practice for the industry.





**SPEED TO MARKET** 

FORMULATION KNOWLEDGE

Capsugel Lonza

Pharma & Biotech

REGULATORY EXPERTISE

**GLOBAL RELIABLE SUPPLY** 

**PREMIUM QUALITY** 

## LONZA PHARMA & BIOTECH

#### **CUSTOMIZED API**

#### **DELIVERY & PRODUCT DIFFERENTIATION**



drug substance development

drug substance manufacturing

drug product development drug product manufacturing

#### Small molecules

- early and advanced chemical intermediates
- customized API\*, including HPAPI\*\*
- payloads for ADCs\*\*\*

#### **Biologics**

- mammalian & microbial expression systems
- cell & gene technologies
- bioconjugates

- \*API active pharmaceutical ingredient \*\* HPAPI – highly potent active pharmaceutical ingredient
- \*\*\* ADC antibody drug conjugates

- particle engineering
- oral dosage form and delivery systems solutions
- capsules
- parenteral drug products (injections, infusions)
- delivery systems & device integration
- liquid & lyophilized dosage forms
- parenteral drug products (injections, infusions)

## OUR OFFERING

#### **SALES & MARKETING SUPPORT**

Our team of commercial, business development and marketing experts have strong market expertise. Their industry experience in product development, capsule science and regulatory requirements allow you to go to market safer and faster. Our experienced team of Account Solutions Representatives are here to assist you in every step of the order process.

Lonza Pharma & Biotech is the leader in capsule-based solutions and services, proudly offering Capsugel® products. With an invaluable global production and supply chain foot print, we strive to provide the highest level of quality products and offer regulatory expertise to our 2,000 pharmaceutical customers worldwide.

For more than 100 years, biopharmaceutical companies have relied on the quality, consistency and functional innovations Capsugel® has delivered. Today, we produce more than 200 billion capsules for over 100 countries.

Building on our history of innovation in polymer science and capsule engineering, Lonza Pharma & Biotech continues to launch ground-breaking capsule designs and equipment technologies that are improving drug development and delivery. Whether you are looking to formulate new products or enhance an existing line, we have the right capsule to help you bring improved products to market faster. With a diverse portfolio including HPMC, dry-powder inhalation capsules and specialized clinical capsules, we are a global leader in capsule development and manufacturing, bringing unmatched products and technical support to our worldwide customer base.



All product information corresponds to Lonza's knowledge on the subject at the date of publication, but Lonza makes no warranty as to its accuracy or completeness and Lonza assumes no obligation to update it. All trademarks belong to Lonza and its affiliates. © 2019 Lonza

## CONTACTS









For further information about the products:

Visit: www.capsugel.com

EMEA: solutions.emea@lonza.com / +33 389 205725

AMER: solutions@lonza.com / 800 845 6973

Or contact your Lonza representative