



## CAPTISOL, A LIGAND TECHNOLOGY

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[www.captisol.com](http://www.captisol.com)

### CAPTISOL LEGACY

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Captisol was invented and initially developed by scientists at the University of Kansas' Higuchi Biosciences Center, for specific use in drug development and formulation. This unique technology has enabled 15 FDA-approved products, including Gilead's VEKLURY, Amgen's KYPROLIS, Baxter International's NEXTERONE, Acrotech Biopharma L.L.C.'s and CASI Pharmaceuticals' EVOMELA, Melinta Therapeutics' BAXDELA, Pfizer's VFEND IV and Sage Therapeutics' ZULRESSO. The most recent approval in March 2023 was Novartis' MEKINIST, a pediatric oral product. There are many Captisol-enabled products currently in various stages of development.

We maintain broad global patent portfolio for Captisol with approximately 440 issued patents worldwide relating to the technology (including 45 in the U.S.) and with the latest expiration date in 2035. Other patent applications covering methods of making Captisol, if issued, extend to 2041. In addition to solid Captisol powder, we offer our partners access to cGMP manufactured aqueous Captisol concentrate. This product offering was established in 2017 to reduce cycle time and increase Captisol production capacity for large volume drug products. We maintain both Type IV and Type V DMFs with the FDA. These DMFs contain manufacturing and safety information relating to Captisol that our licensees can reference when developing Captisol-enabled drugs. We also have active DMFs in Canada, Japan, and China.

### SEAMLESS TRANSITION TO CLINICAL TRIALS

Captisol may increase systemic exposure for toxicology studies of investigative compounds and has a proven clinical safety record. In early development, Captisol formulation can lead to a seamless transition from nonclinical safety to clinical trials. Captisol has helped more than 10 million patients in over 120 countries.

### MULTIPLE ADMINISTRATION ROUTES ENSURE TARGETED DELIVERY

Captisol's chemical structure was designed to create new products by improving solubility, stability, bioavailability, and dosing of active pharmaceutical ingredients. Routes of administration investigated include parenteral, oral, ophthalmic, nasal, topical, and inhalation

products. Once inside the body, Captisol releases the drug agent, which then travels to its target. The interaction between Captisol and the agent is not permanent, and Captisol is safely expressed from the kidneys.

### PATENTED & VALIDATED MANUFACTURING

Of all modified cyclodextrins, Captisol is an ingredient in the most approved products in the U.S. Manufactured under cGMP, at multiple locations, using a patented and validated all-aqueous process, annual manufacturing capacity has been increased to 500 MT. Captisol is supplied in ultra-low endotoxin, ultra-low bioburden, low-chloride forms. Pack sizes available for R&D use include 100g, 1kg, 5kg, and 20kg. Commercial pack sizes include 1kg, 5kg, and 20kg, with the ability to fill metric-ton orders.

### FORMULATION SERVICES AVAILABLE

The scientists at Ligand Pharmaceuticals have developed in-house and aided clients in developing parenteral, oral, ophthalmic, nasal and inhalation formulations with Captisol and other cyclodextrins. With the recent addition of internal resources and analytical tools, we can provide greater responsiveness for collaborative feasibility and development programs. In addition, the Captisol team have successfully completed or assisted with orphan designations and approvals, preclinical, CMC and clinical development for ANDA, 505b2 and traditional NDA programs.

**Our Team is Ready. Are you? Contact us Today!**





**CAPTISOL®**  
A Ligand<sup>™</sup> TECHNOLOGY

***"With 80 years of combined experience working with Captisol and other cyclodextrins, our team is ready for any formulation challenge and look forward to helping you bring your product to market." – Lian Rajewski, PhD, Sr. Research Investigator***

## Your Partner in Solubility.

The scientists at Ligand Pharmaceuticals are experts at working with Captisol, have developed products in-house and aided clients in developing many successful formulations.

Our expertise in navigating CMC, regulatory, and clinical issues is unparalleled in the industry. Captisol is a solubility enhancing excipient (derivatized cyclodextrin) that has been on the market for over 20 years and is in more than a dozen approved products.

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Our Team is Ready. Are you? Contact us today!

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