LUBRIZOL LIFE SCIENCE

Ophthalmic CDMO Services and Excipients

INTRODUCTION

The inherent nature of the eye presents challenges when it comes to developing ocular drug products. Partnering with an organization that has ophthalmic expertise and the right infrastructure is essential to successfully taking on ocular drug delivery and bringing ophthalmic products to market.

At LLS Health, our team has decades of experience providing complete ophthalmic drug product services to meet your needs for all ocular dosage forms – topical, implantable, and injectable.

In this brochure, you can explore the extent of our competencies for ocular drug product development and manufacturing, both clinical and commercial, for a range of batch sizes, as well as our ophthalmic excipient offerings.

- Support NCEs, ANDAs, 505(b)(2)s, and OTC drug products – containing either small molecules or biologics
- Specialize in the complex delivery of BCS II and IV molecules
- Handle DEA-controlled substances (Schedules I-V) and HPAPIs
- Nanoparticulate and microparticle formulation expertise

SOLUBILITY AND BIOAVAILABILITY ENHANCEMENT

Difficult-to-formulate active pharmaceutical ingredients (APIs) are a specialty of ours. We have years of experience in maximizing bioavailability for ocular drug delivery, controlling drug release rate, and enhancing drug stability.

- NANOMILLING CAPABILITY – we have industry-leading expertise and capability in nanomilling to reduce API particle sizes into the nanoscale to produce nanoparticulate suspensions. Such particles provide a substantially greater surface area-to-volume ratio, which improves the dissolution rate of poorly-water soluble APIs (BCS Class II and IV compounds) and enables more effective ocular formulations. In addition to commercially available nanomilling equipment, our proprietary SteriMill™ nanomilling technology enables aseptic processing in our clinical and commercial cleanrooms.
- LYOCELL® TECHNOLOGY – a patented drug delivery technology based on the use of reverse cubic phase lyotropic liquid crystals. This unique particle structure gives LyoCells powerful drug-solubilizing properties for a variety of APIs, whether small molecule or biologics. LyoCell technology can also enhance controlled drug release compared to other technologies and can handle a high payload of API.

DRUG FORMULATION AND DOSAGE FORM SUPPORT

At LLS Health we can support you in identifying the ideal excipients and formulation techniques needed to achieve precise and effective release of an API over the lifecycle of the product. We support the development and manufacturing of:

- Topical formulations
- Long-acting injectables
- Drug-device combination products
- Ocular implants

We use innovative modeling and Design of Experiment (DoE) approaches in line with Quality by Design (QbD) principles to help develop your ocular drug formulation. In doing so, we create robust, effective, and scalable techniques to produce the optimal drug formulation.

We can offer a range of conventional and proprietary development methods and technologies to deliver your drug product's target product profile, whatever that might be.

ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

We offer method development capabilities that may incorporate complicated multi-step sample preparations and complex technologies. Conscious of cost and timing, we validate these methods in a phase appropriate manner. Methods include the recovery of APIs, impurities, as well as the dissolution performance of your product. Our team has supported the development of hundreds of small and large molecules such as peptides, proteins, and oligonucleotides. Our physical and chemical characterization labs are well-equipped and well-staffed to support these efforts.

ASEPTIC MANUFACTURING

We provide a broad range of clinical trial and commercial manufacturing services to complement our formulation expertise. Our integrated approach offers a smooth transition from the bench to production for sterile solutions, suspensions, emulsions, and a variety of dosage forms. Our FDA-inspected manufacturing facility features aseptic filling with no minimum batch sizes, meaning we are positioned to take on the manufacturing projects that other CDMOs may shy away from.

- **DEDICATED CAPACITY –** our commercial manufacturing facility is qualified for aseptic vial and bottle filling, and our clinical cleanrooms offer flexible manufacturing for sterile filling and complex formulations.
- **FLEXIBILITY –** our facilities and cleanroom space have been specially designed for versatility, enabling production of various ophthalmic products, including topical solutions and long-acting injectables.
- **TRANSPARENCY –** we will provide you with timely and accurate information so we can make informed decisions, together. Our team guarantees honest, two-way collaboration throughout your project.

ICH STABILITY PROGRAMS

We offer ICH stability programs tailored for the needs of ocular drug development projects.

Our pharmaceutical stability programs are set up with your unique requirements in mind, operating under ICH guidelines for GMP batches. We can design programs that address the required time and temperature considerations for both your API and finished dosage form, including custom programs that are developed as needed.

With our support, you can be confident you have the stability data required for every stage of regulatory submission from Phase I to filing for marketing authorization.

EXCIPIENTS

LLS Health is a leader in supplying high-quality, high-performance excipients that are ideal for use in ocular drug formulations, due to their ability to optimize the performance of the final drug product.

Our excipient offerings include:

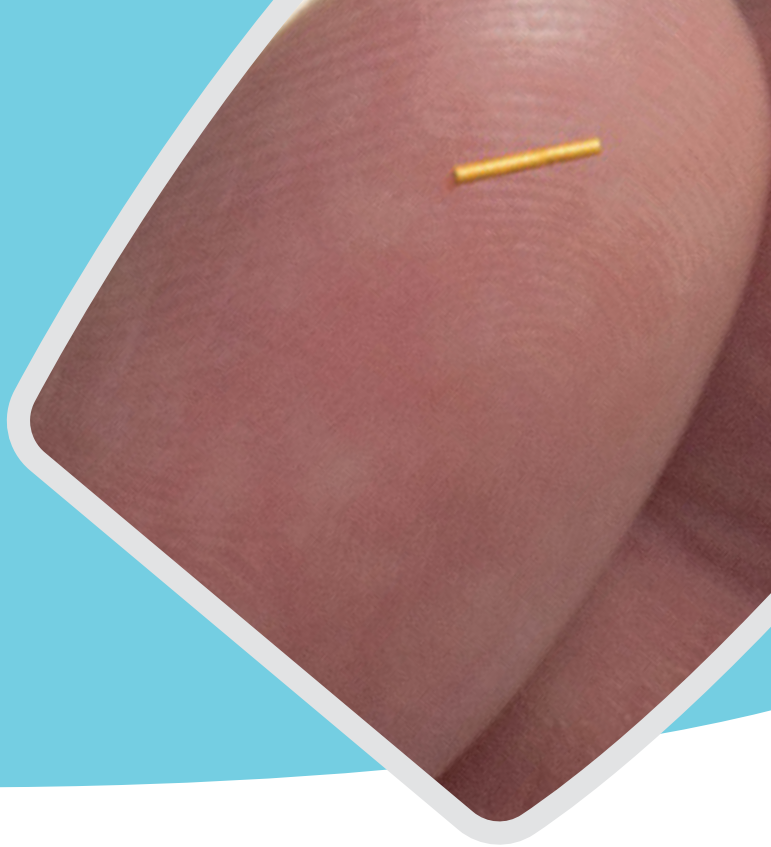
- Polymers for ocular topicals:
  - Carbopol® polymers
  - Noveon® polycarbophil
  - Pemulen™ polymers

Our excipients for ocular topicals have delivered trusted quality to the pharmaceutical industry for more than 40 years. They can instil essential properties for effective ocular delivery, including permanent drug suspension, emulsification, mucoadhesion, and rheology control.

Pathway™ thermoplastic polyurethane (TPU) excipients

Our Pathway™ TPU excipients are ideal for ocular implants and drug-device combination products, such as punctal plugs and non-biodegradable inserts. Pathway excipients offer customizable mechanical properties, controlled drug release, and compatibility with a wide range of APIs including anti-inflammatory agents. Pathway TPU excipients are manufactured according to IPEC-GMP guidelines and have established Drug Master Files (DMFs) with the FDA.

Learn more and request a sample today.



CONTACT US TODAY

LLS Health has a wide range of capabilities in ophthalmic drug development, manufacturing and analytical support, making us an ideal single partner to meet all of your project's needs.

To find out more about how we can support you in addressing your unique ocular drug development or manufacturing needs, contact us today.

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