COMPANY PROFILE: ENCOMPASS OPHTHALMIC DRUG DEVELOPMENT SERVICES

ENCOMPASS

The direction you need. The service you deserve.

Encompass Pharma was formed in 2004 by a highly experienced team of ophthalmic development and analytical scientists. Based in Norcross, GA, US, we are a global leader in ophthalmic drug development, formulation, and analytical services for the ophthalmic pharmaceutical market. We offer a full range of ophthalmic development and formulation services from pre-formulation through clinical supplies manufacturing and scale-up.

PRECLINICAL SUPPORT

We have a strong knowledge base of existing ophthalmic compounds, excipients, and drug delivery technology. Our dedicated staff and state-of-the-art, cGMP compliant laboratory is dedicated to supplying preclinical screening studies.

OPHTHALMIC FORMULATION

We have significant experience in the optimisation of ophthalmic drug forms and delivery technologies for your product and as such we understand the unique challenges presented in ophthalmic development and formulation. We have formulation experience with all ophthalmic dosage forms including solutions/suspensions; ointments/gels; emulsions; depot and sustained-release technologies; and lyophilized products.

Topical delivery of medications to the eye is challenged by the elimination of drug formulations from the pre-corneal area by tear flow. We utilise our proprietary *in vitro* formulation evaluation tool named the DiffER (diffusion/erosion) model to evaluate topical ocular drug and drug delivery characteristics. The DiffER model was developed to offer clients an *in vitro* model to optimise the formulation prior to *in vivo* studies. It utilises a modified Franz diffusion cell to include simulated tear flow to assess the impact of formulation changes on the diffusion of active moieties better, across isolated rabbit corneas and sclera. The amount of drug that diffused across the cornea (or sclera), as well as the amount of drug eliminated in the pre-corneal or scleral (donor) area, are compared to evaluate the effects of various formulations on diffusion /delivery.

OPTIMISING OPHTHALMIC DRUG DELIVERY

We have an extensive working knowledge of currently available and new ophthalmic drug delivery systems and technologies which can be used to meet the unique delivery and therapeutic objective established by our clients. In past projects we have assisted our partners to enhance ophthalmic drug delivery by increasing ocular surface/tear residence; improving therapeutic efficacy; optimising active ingredient concentration; reducing systemic exposure/increasing safety; extending product lifecycles; and enhancing delivery to the posterior of the eye.

PROLOC BIOADHESIVE OCULAR DRUG DELIVERY SYSTEM

PROLOC bioadhesive minitablets are inserted into the cul-de-sac of the eye and rapidly adhere to the ocular mucosa and remain in place until fully eroded. Typically, the drug is released for a period of eight hours or more. PROLOC is easy to insert. Directly after insertion, the tablet hydrates rapidly (in approximately one minute) and creates a comfortable viscoelastic outer surface. It becomes completely hydrated within 2-3 hours after application, and is subsequently transformed into a highly concentrated gel (see Figure 1).

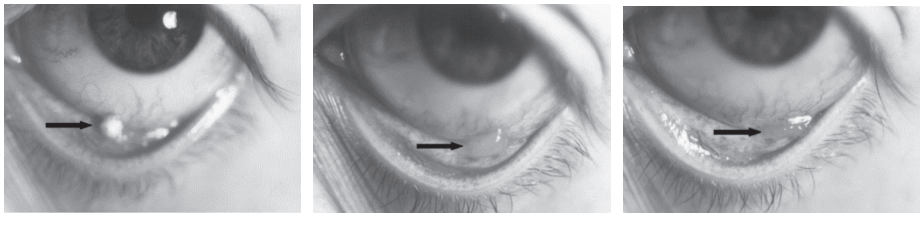
PROLOC offers intellectual property protection and provides the opportunity to expand a current drug franchise or to open new possibilities for new drug molecules and uniquely delivered therapies. Clinical trials have been conducted to support ocular delivery as well as vaginal, buccal and intranasal delivery.

ANALYTICAL SERVICES

Encompass provides state-of-the-art analytical services to some of the leading pharmaceutical companies in the world. Our extensive experience provides for regulatory GMP compliance along with scientific excellence. We bring you results with the interpretation and direction to ensure your products successful completion. Our analytical services include method development and testing; stability services; packaging system characterisation; and cleaning validation.

CLINICAL SUPPLIES & MANUFACTURING SUPPORT

We currently produce pilot-scale manufacturing to support preclinical animal studies, we are currently in the process of expanding our capabilities to produce clinical supplies for Phase I clinical trials. We have a long history of working with commercial-scale aseptic contract manufacturing facilities worldwide and will assist in the selection and transfer of your formulation to a contract manufacturing organisation with a current understanding of today's regulatory needs. From quality and manufacturing agreements we have the expertise to help our clients scale-up and navigate formulation and regulatory requirements.



Insertion 2 hours 4.5 hour

Figure 1: PROLOC bioadhesive minitablet completely transforms into a highly concentrated gel at 4.5 hours.

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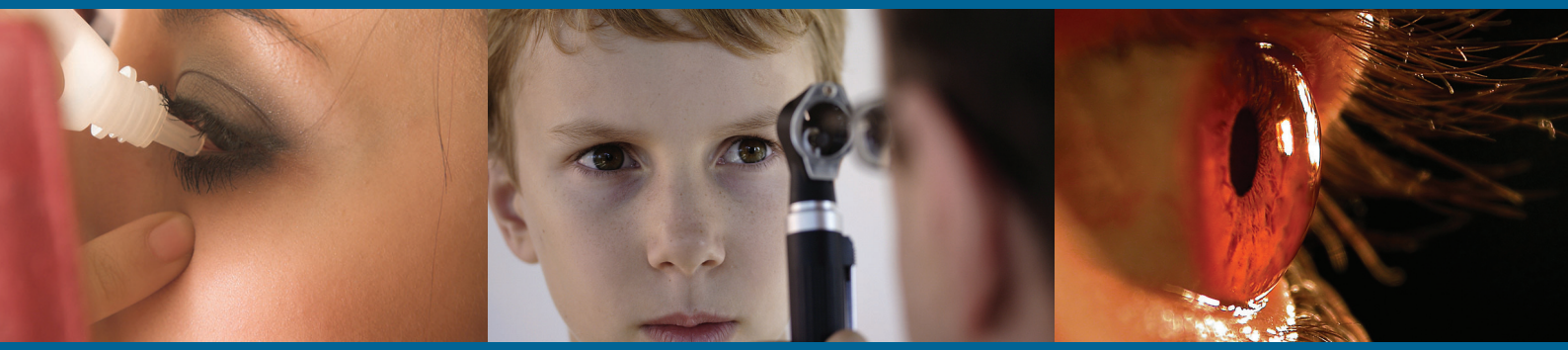

A new direction in OPHTHALMIC DRUG DEVELOPMENT.

Ophthalmic development and formulation services are our focus. We provide a wide range of product development services, including formulation and regulatory consulting, formulation optimization utilizing in vitro permeation models, analytical support, and coming soon GMP clinical manufacturing, and clinical labeling.

- Innovative development process combining state-of-the-art in-vitro/in-vivo screening studies to efficiently and effectively speed ophthalmic drug evaluation & development.
- Preclinical formulation support & evaluation
- Formulation, drug delivery, drug delivery optimization
- Clinical supplies & manufacturing support
- Analytical services

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