

CUSTOM



## TOXIKON AT A GLANCE

### Ocular Testing Capabilities

- » Dry Eye
- » EAU Uveitis
- » Glaucoma/IOP
- » CNV/AMD
- » PK/PD
- » Ocular Toxicology
- » IND/NDA Enabling Studies

### Locations:

#### Corporate Headquarters

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As part of its extensive custom research and testing portfolio for drug discovery and development, Toxikon offers life science companies a variety of ophthalmic preclinical services.

Our multidisciplinary team provides expertise in the scientific and technical disciplines of ophthalmology, pharmacology, analytical and bioanalytical chemistry, and toxicology. Performed in a variety of models, Toxikon's preclinical ocular studies include acute irritation, ocular tissue distribution, pharmacokinetic/pharmacodynamic (PK/PD), dose escalation, acute and repeat dose toxicity, required ISO and OECD/ICH guideline testing programs, implantation, and drug screening and efficacy. Additionally, ocular protocols can be customized for targeted therapeutics, including such ocular disease models as dry eye, corneal wound healing, inflammation and uveitis, lens opacity, neovascularization and age-related macular degeneration, glaucoma and neuroprotection.

As a leading preclinical contract research organization, Toxikon has built strong partnerships with many life science companies. One of those partnerships is with Andover, MA-based Ora. For more than 30 years, Ora has been at the forefront of ophthalmic product development, providing turnkey clinical services for 32 product approvals within the category and having direct involvement in the development of more than a third of the world's currently marketed ophthalmic pharmaceutical products.



### Ophthalmic Development Capabilities

While our reputation has been built on our vast toxicology and chemistry experience, Toxikon's Ocular Program capabilities include:

- » Intra-vitreous injections, stereotaxic surgery
- » Specialized surgeries (e.g. episcleral vein injections to induce elevated IOP)
- » Aesthesiometry, tonometry, pupilometry; and electroretinography (ERG)
- » Slit-Lamp exams and Draize and McDonald-Shadduck scoring systems
- » Direct and indirect ophthalmoscopy
- » Anterior/posterior segment and fundus photography
- » Ocular tissue dissection, distribution and PK/PD/ADME
- » Retina/choroid flat-whole mounting, confocal microscopy, and RGC quantitation
- » Ocular histology/pathology and clinical support
- » Stereo and fluorescent microscopy
- » Optic nerve damage assessment



## Services and a Glance

Toxikon is an ISO/IEC 17025-accredited Contract Research Organization (CRO) that is registered for drug, biologic, and medical device testing. With approximately 200 employees, Toxikon is committed to staying at the forefront of ophthalmic product development. Toxikon's safety services include toxicology (acute, subchronic, and chronic toxicity, reproductive toxicity, genetic toxicology, carcinogenicity), pharmacokinetics, toxicokinetics, bioavailability, ADME, chemical characterization, impurities analysis and synthesis, bioanalysis, and microbiology. Additionally, full IND/NDA enabling studies are performed with a multidisciplinary approach to program management. Toxikon's extensive certifications and licenses allow it to meet international regulatory requirements for data acceptability and harmonization.

To meet all applicable international GxP requirements, Toxikon's facilities are fully registered with FDA and USDA, and accredited with the Association for the Assessment and Accreditation of Laboratory and Animal Care International (AAALAC), and the International Organization for Standardization (ISO). Toxikon also has assurance with the National Institutes of Health so federally funded work can be performed at our facilities in compliance with NIH's Public Health Service Policy on Human Care and Use of Laboratory Animals (PHS Policy).

Model/Diseases	Procedure/Mechanism	Animal/Species	Model Period
Dry Eye	Short term-Botulinum Toxin B into the lacrimal gland	Mouse/Rat	Short Term: Immediately 12 weeks
	Long term-cutting or injuring the facial nerve	Rabbits	Long Term: > 1 week
EAU/Uveitis	Interphotoreceptor retinoid-binding protein (IRBP) peptide 161-180/ Pertussis Toxin	Mouse/Rat	2 weeks - 16 weeks
Glaucoma/IOP	Ocular hypertension (OHT)	Rat	2 weeks - 16 weeks
	Retinal ischemia	Rat	24 hours - 16 weeks
	Scleral scarring	Mouse	4 weeks - 16 weeks
Corneal NV/AMD	Alkali cauterization (NaOH)	Mouse/Rat	1 week - 4 weeks
	Epithelial wound healing	Mouse/Rat	1 week - 4 weeks
	Suture	Rat	1 week - 4 weeks
Choroidal NV /AMD (Subretinal NV)	Laser photocoagulation neovascularization (Argon laser photocoagulation, 50µm, 400mW, 0.05s)	Mouse/Rat	4 weeks - 16 weeks
Retinal NV/AMD, DR	Retinopathy of prematurity (ROP) - (low oxygen environment)	Mouse/Rat	4 weeks - 8 weeks
	Lipid hydroperoxide (LHP) - (Intravitreal injection)	Rabbit	1 week - 8 weeks
	Streptozotocin (STZ) - (Diabetic retinopathy, i.m.)	Rat	2 weeks - 16 weeks

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Visit [www.toxikon.com](http://www.toxikon.com) to learn more about our Ocular development capabilities.