

**THE MEDICINE SHOPPE**

1698 S Queen St · York, PA 17403



# Specialty Ophthalmic Compounding

*Prescriber Reference Guide*

Sterile 503A Compounding

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*Compounded sterile preparations for ophthalmic use.*

Phone: (717) 846-0500 · Fax: (717) 845-8767 · E-prescribe available

## A Note to Our Prescribing Partners

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We created this guide to reflect how we approach ophthalmic compounding: with a working clinical understanding of what's being prescribed and why. From fortified antibiotics to alternative anti-inflammatory pathways to urgent infectious cases, we're aligned with the therapeutic intent—not just the formulation. This is meant to be more than a product list.

The Medicine Shoppe in York, PA is a USP <797>-compliant sterile compounding pharmacy. Our ophthalmic lineup covers the compounds most commonly needed in anterior segment and corneal practice — most of which are **not commercially available in any formulation**, and all of which are compounded in our ISO-classified cleanroom as preservative-free preparations where clinically appropriate.

This guide is organized around clinical problems rather than compound names. Each section covers the mechanism, the evidence, the practical formulation details, and the clinical pearls that matter for that category of disease. We've kept it lean — you already know the ophthalmology. We just want you to know what we carry and why it's worth a call.

**What we compound for ophthalmic use:** Fortified tobramycin 14 mg/mL · Vancomycin 25 mg/mL · Chlorhexidine 0.02% · PHMB 0.02% · Amphotericin B 1.5 mg/mL · Insulin 1 IU/mL · Losartan 0.08% · N-Acetylcysteine 10% · Timolol 0.25%/0.5% PF · Dexamethasone 0.1% PF · Methylprednisolone 1% PF

*We fill urgent ophthalmic prescriptions same day where possible. Call us directly for emergent situations — Acanthamoeba, fungal keratitis, and fortified antibiotic cases get priority handling.*

**(717) 846-0500 · Fax: (717) 845-8767 · E-prescribe via any major platform**

## Quick Reference: Full Ophthalmic Lineup

All preparations are sterile, preservative-free (where clinically appropriate), and dispensed per individual patient prescription. Most preparations can be frozen and are provided as 3ml vials that can be thawed individually. Insulin cannot be frozen and can only be provided with a 10-day BUD.

Compound	Concentration	Primary Indication(s)	Typical Dosing	Notes
<b>Fortified Tobramycin</b>	14 mg/mL	Bacterial keratitis (gram-neg, Pseudomonas)	1 drop q1–2h initial, taper	Refrigerate · 10d BUD
<b>Fortified Vancomycin</b>	25 mg/mL	Bacterial keratitis, MRSA, gram-positive	1 drop q1–2h initial, taper	Refrigerate · 10d BUD
<b>Chlorhexidine</b>	0.02%	Acanthamoeba keratitis (1st line)	1 drop q1h initial, taper	10 × 1 mL PF vials
<b>PHMB</b>	0.02%	Acanthamoeba keratitis (1st line)	1 drop q1h initial, taper	10 × 1 mL PF vials
<b>Amphotericin B</b>	1.5 mg/mL	Fungal keratitis, Candida, Aspergillus	1 drop q1–2h initial, taper	Refrigerate · 10d BUD
<b>Insulin</b>	1 IU/mL	PEDs, neurotrophic keratitis, diabetic keratopathy	1 drop QID or as directed	Refrigerate · 10d BUD
<b>Losartan</b>	0.08% (0.8 mg/mL)	Corneal fibrosis: post-PRK haze, post-infectious scarring	1 drop 6× daily × 4–12 wks	Provided frozen 4d BUD upon thaw (10 x 1ml vials)
<b>N-Acetylcysteine</b>	10%	Filamentary keratitis, SLK, mucous plaques, MGD	1–2 drops QID	Refrigerate · 3 vials=10ml
<b>Timolol (PF)</b>	0.25% or 0.5%	Glaucoma / IOP management (BAK-sensitive patients)	1 drop BID or QD	10 × 1 mL single-dose vials
<b>Dexamethasone (PF)</b>	0.1%	Post-surgical inflammation, anterior uveitis	Per prescriber	10 × 1 mL single-dose vials
<b>Methylprednisolone (PF)</b>	1%	Post-surgical inflammation, dex-intolerant patients	Per prescriber	10 × 1 mL single-dose vials

BUD = beyond-use date per USP <797>. Contact pharmacy for current BUD documentation for your specific preparation.

## Section 1 — Infectious Keratitis

Infectious keratitis is among the most time-sensitive conditions in ophthalmic practice — hours matter, and first-line commercial products frequently fall short of the concentrations needed to achieve therapeutic levels in corneal stroma. The Medicine Shoppe carries the full suite of compounded agents for bacterial, fungal, and amoebic corneal infections, with same-day priority dispensing for emergent cases.

### 1a. Bacterial Keratitis — Fortified Antibiotic Drops

#### Clinical Context

Bacterial keratitis requires antibiotic concentrations that commercial topical preparations cannot deliver. Standard tobramycin 0.3% ophthalmic (3 mg/mL) does not achieve adequate corneal stromal levels for *Pseudomonas* keratitis. Commercial preparations also lack any vancomycin formulation — leaving gram-positive and MRSA keratitis without a commercially available topical option.

#### Formulations

Agent	Our Concentration	Target Organisms	Commercial Comparator
<b>Tobramycin</b>	14 mg/mL	<i>Pseudomonas aeruginosa</i> (leading cause in CL wearers), other gram-negatives	3 mg/mL commercially — 4.7× lower concentration
<b>Vancomycin</b>	25 mg/mL	MRSA, <i>S. epidermidis</i> , resistant gram-positives, post-surgical endophthalmitis	Not commercially available as ophthalmic — compounding only

#### Dosing Protocol

Standard fortified drop protocol: **1 drop every 1–2 hours while awake for the first 24–48 hours**, alternating tobramycin and vancomycin where both are prescribed (every 30–60 min). Frequency is then reduced based on clinical response, typically to QID–Q2H over the course of treatment. Dosing is entirely at prescriber discretion based on severity and organism.

#### Dispensing

Dispensed as 10 mL, typically in sets of 3 bottles. Refrigerate; do not freeze. Tobramycin: 14-day BUD refrigerated. Vancomycin: 7-day BUD refrigerated (shorter due to stability). Contact pharmacy for current BUD documentation.

**Clinical Note:** Tobramycin and vancomycin fortified drops cover the two most common serious bacterial keratitis scenarios — gram-negative (especially *Pseudomonas* in contact lens wearers) and gram-positive/MRSA. For coverage overlap or mixed infections, alternating both agents is standard practice. If moxifloxacin or other fluoroquinolone fortified drops are needed, contact us to discuss.

## 1b. Acanthamoeba Keratitis — Chlorhexidine 0.02% & PHMB 0.02%

### Clinical Context

Acanthamoeba keratitis requires early, aggressive, and prolonged anti-amoebic therapy. The two gold-standard first-line agents — chlorhexidine 0.02% and PHMB 0.02% — are **not commercially manufactured as ophthalmic preparations**. Compounding is the only legal source. Treatment duration is typically months, not weeks, with intensive initial dosing that makes preservative-free formulation clinically essential — cumulative BAK exposure on an already-compromised corneal surface is not acceptable.

### Mechanism

Both agents are cationic biguanides that disrupt cell membrane integrity in both *trophozoites* and *cysts*. Cyst-stage activity is critical — Acanthamoeba cysts are highly resistant to most antiseptics, and inadequate cysticidal activity is a primary driver of treatment failure. Chlorhexidine and PHMB at 0.02% have established cysticidal efficacy at concentrations that are tolerable on the ocular surface.

### Formulations & Dispensing

We dispense both agents as **10 × 1 mL preservative-free single-use vials**. The unit-dose format is essential for this indication: treatment requires hourly (or more frequent) dosing initially, and cumulative preservative exposure from a multi-dose bottle is not tolerable over months of therapy. Can be used as monotherapy or in alternation — prescriber preference based on severity and response.

### Dosing

Initial phase (first 2–3 days): typically 1 drop every 1–2 hours around the clock, then gradual taper based on response. Some protocols use QID–Q2H for the first week, then taper over months. Always prescriber-directed based on response, stage, and extent of disease.

**Note on combination therapy:** Chlorhexidine and PHMB have overlapping but not identical spectra. Many corneal specialists use both agents in alternation, particularly in severe or advanced disease. Both agents are also active against certain bacterial and fungal pathogens, which may be relevant in mixed or secondary infection scenarios.

## 1c. Fungal Keratitis — Amphotericin B 1.5 mg/mL

### Clinical Context

Fungal keratitis remains difficult to treat and carries a significant risk of permanent vision loss. Amphotericin B ophthalmic is not commercially available as a topical preparation — the only approved formulations are IV-grade products not suitable for ocular surface use. Compounding provides access to the appropriate concentration in an ophthalmic vehicle at the dose your clinical judgment requires.

### Spectrum of Activity

Organism	Relevance
<b>Candida spp.</b>	Most common fungal keratitis in immunocompromised patients and those with prior steroid use
<b>Fusarium spp.</b>	Common in contact lens wearers and after ocular trauma; also covered by our Acanthamoeba suite if co-infection
<b>Aspergillus spp.</b>	Post-traumatic or post-surgical; amphotericin B provides meaningful activity against most strains
<b>Other molds</b>	Amphotericin B has broad polyene activity via ergosterol membrane disruption across most fungal pathogens

### Dispensing

Dispensed as 10 mL in 3 bottles. Refrigerate; protect from light. BUD 7 days refrigerated. Initial dosing is typically intensive — 1 drop every 1–2 hours — with gradual taper based on clinical response. Duration often 6–12 weeks for fungal keratitis. Entirely prescriber-directed.

**Relationship to natamycin:** Natamycin (natamycin 5%) is commercially available but frequently backordered and expensive. Amphotericin B provides complementary antifungal coverage — particularly stronger activity against *Candida* and *Aspergillus*, with less activity against *Fusarium* compared to natamycin. For *Fusarium* keratitis, natamycin remains the preferred agent where available; amphotericin B is the primary alternative and is stronger for yeast-form infections.

## Section 2 — Corneal Healing & Repair

Two of our compounds address the biology of corneal wound healing through fundamentally different mechanisms — insulin targeting re-epithelialization via growth factor signaling, and losartan targeting stromal fibrosis via TGF- $\beta$  suppression. Neither is commercially available as an ophthalmic preparation, and neither duplicates the mechanism of any other agent in typical post-surgical or post-infectious protocols.

### 2a. Insulin 1 IU/mL — Re-Epithelialization & Growth Factor Signaling

#### Mechanism

Corneal epithelial cells express functional **insulin receptors**. Topical insulin stimulates these receptors directly at the ocular surface, activating downstream signaling (PI3K/Akt pathway) that promotes epithelial cell **proliferation, migration, and survival**. At 1 IU/mL applied topically, systemic absorption is clinically negligible — blood glucose is not meaningfully affected. This makes topical insulin safe in both diabetic and non-diabetic patients.

#### Evidence Base

The evidence for topical insulin is primarily in case series and small prospective studies, but the consistency of the signal is notable. Published reports document defect closure in patients with persistent epithelial defects (PEDs) refractory to lubricants, bandage contact lenses, amniotic membrane, and autologous serum tears. A 2022 case series by Fraunfelder and Cabezas-Leon in *Cornea* reported complete or near-complete healing in the majority of refractory PED cases. The mechanism is well-characterized; RCT data are pending but the safety profile is sufficiently favorable to support off-label use in refractory cases.

#### Key Indications

- Persistent corneal epithelial defects (PEDs) refractory to conventional therapy
- Neurotrophic keratitis (stages 1–3) — alone or adjunct to cenegermin
- Diabetic keratopathy — particularly relevant given the known impairment of corneal nerve and epithelial function in diabetes
- Post-PRK, post-corneal surgery healing — especially where re-epithelialization is delayed
- Severe dry eye with compromised epithelial integrity

#### Practical Notes

Typical regimen: 1 drop QID. Refrigerate. Compared to autologous serum tears: no blood draw required, standardized concentration, immediate availability, lower cost. Consider as an accessible first-line option before escalating to autologous serum or amniotic membrane in refractory PEDs.

**Combination with other agents:** Insulin can be used concurrently with any of our anti-infective drops. Its healing-promotion role is complementary to the antimicrobial role of fortified antibiotics or amphotericin B — if post-infectious corneal healing is delayed, insulin may be added once active infection is controlled.

## 2b. Losartan 0.08% — Anti-Fibrotic / TGF- $\beta$ Signaling

### Mechanism

Corneal fibrosis is driven by TGF- $\beta$ , which signals keratocytes to differentiate into **myofibroblasts** — cells that produce disorganized collagen responsible for stromal opacification. Losartan, an angiotensin II type 1 receptor blocker (ARB), **indirectly suppresses TGF- $\beta$  signaling** by blocking angiotensin II AT1 receptor activation. This both prevents myofibroblast generation and induces apoptosis of existing myofibroblasts. Topically applied at 0.08%, losartan penetrates full-thickness cornea with negligible systemic absorption and no meaningful effect on blood pressure.

### Key Point: What Losartan Does That Steroids Don't

Feature	Topical Losartan 0.08%	Topical Corticosteroids
Mechanism	Blocks myofibroblast generation + induces apoptosis	Anti-inflammatory; does not target fibrosis pathway
Remodels established scar	Yes — promotes myofibroblast apoptosis	No — does not reverse established fibrosis
IOP / cataract risk	None	Both — limiting factors for long-term use
Synergy with steroids	Additive in animal models (Sampaio et al. 2022)	—

### Key Indications

- Post-refractive haze (PRK, PTK, LASIK) — especially breakthrough haze despite mitomycin C at time of surgery
- Post-infectious corneal leukomas — after bacterial, fungal, herpetic, or Acanthamoeba keratitis once infection is cleared
- Chemical and thermal burns — alkali and acid injury scarring in the post-acute healing phase
- Conjunctival fibrosis conditions — Stevens-Johnson syndrome, cicatricial pemphigoid, GVHD, pterygium recurrence prophylaxis

### Evidence Base

The evidence base is primarily experimental (rabbit models, ex vivo) with growing clinical case series. Steven E. Wilson, MD at Cleveland Clinic is the primary investigator driving this literature. Published studies demonstrate myofibroblast suppression and reduced haze formation after PRK, alkali burn, and descemetorhexis in animal models. Early clinical case reports (including traumatic LASIK flap cases and post-PRK breakthrough haze) report meaningful improvement. A 2025 review in the *Journal of Clinical Medicine* summarized current evidence as promising but noted that well-powered RCTs remain needed. Off-label use is supported by a sound mechanistic rationale and favorable safety profile.

### Practical Notes

Typical regimen: 0.8 mg/mL (0.08%), 1 drop 6× daily, duration 4–12 weeks per prescriber judgment and response. Refrigerate. **Can be prescribed concurrently with topical steroids** — the combination appears additive in animal models and makes clinical sense given complementary mechanisms. When steroids need to be tapered due to IOP concerns, losartan can continue as the fibrosis-modulating agent.

**Compounding Note: Losartan is made from pure powder and as such is limited to a 4-day BUD upon thawing. Prescriptions are dispensed at 10x1ml vials which are appropriate for freezing with a 45-day expiration.**

## Section 3 — Mucolytic Therapy: N-Acetylcysteine 10%

N-Acetylcysteine (NAC) is the only mucolytic agent available for the ocular surface — and it works through a mechanism that no lubricant, steroid, or anti-infective agent touches. For the subset of ocular surface disease patients where **abnormal mucus, not dryness or inflammation, is the primary driver**, NAC 10% is often the compound that finally provides relief. It is not commercially available as an ophthalmic preparation.

### Mechanism

NAC cleaves the **disulfide bonds within mucoproteins**, reducing their chain length and viscosity. This directly dissolves the mucin-epithelial debris complexes that form corneal filaments and plaques. As a precursor to **glutathione**, NAC also replenishes the ocular surface's primary antioxidant defense, which is particularly relevant in chronic inflammation, post-infectious eyes, and chemical injury recovery.

### Indications and Evidence

#### Filamentary Keratitis

This is the primary evidence-based indication. A 2017 study in *Korean Journal of Ophthalmology* (Koh et al.) demonstrated significant symptom improvement and filament resolution with topical 10% NAC QID in patients refractory to conventional therapy including steroids, cyclosporine, and punctal plugs. The AAO *EyeWiki* lists 10% NAC as a standard mucolytic option in filamentary keratitis management, and it is endorsed in *Review of Optometry* clinical protocols for refractory cases.

#### Superior Limbic Keratoconjunctivitis (SLK)

NAC 10% QID is explicitly recommended by corneal specialists (including Christopher Rapuano, MD at Wills Eye) as a component of stepwise SLK management when filaments are present — alongside preservative-free lubricants, cyclosporine, and punctal plugs.

#### Corneal Mucous Plaques & Keratoconjunctivitis Sicca

In severe aqueous-deficient dry eye, Sjögren's syndrome, and GVHD, thick mucous plaques can form on the corneal surface that do not respond to lubricants. NAC's mucolytic action on the mucoproteins making up these plaques provides a mechanistic rationale and is supported by a *Survey of Ophthalmology* review (2021) covering NAC's role across multiple ocular surface disease categories.

#### Meibomian Gland Dysfunction

A study by Akyol-Salman et al. (*Journal of Ocular Pharmacology and Therapeutics*, 2010) reported significant improvement in MGD symptoms and signs with topical NAC — attributed to reduction in viscous meibomian secretions contributing to ocular surface disease.

### Practical Notes

Concentration: 10% standard; 5% available per prescriber preference (some patients report stinging with 10% that resolves at 5%). Typical regimen: 1–2 drops QID. Refrigerate. Duration per prescriber — typically weeks to months. No commercial equivalent. Safe to use concurrently with other ocular surface agents.

**Clinical tip:** In patients who present with filamentary keratitis that recurs despite treatment, consider whether the underlying cause (dry eye, Sjögren's, SLK, GVHD) has been adequately addressed. NAC provides relief of the mucin-filament problem but the etiology driving ongoing mucus abnormality may require systemic or immunologic management.

## Section 4 — Preservative-Free Unit-Dose Preparations

Benzalkonium chloride (BAK) is the most widely used ophthalmic preservative, and its cumulative toxicity to the ocular surface is well-established. In patients using drops long-term — glaucoma patients, those with chronic inflammation, post-surgical patients — BAK exposure adds up, disrupts the tear film, and damages corneal epithelial cells. For these patients, preservative-free compounding provides a meaningfully better option.

We dispense our preservative-free preparations as **10 × 1 mL single-use vials** — one vial per use, no BAK, no contamination risk. This format is also ideal for post-surgical patients whose healing corneal epithelium is especially vulnerable to preservative toxicity.

### Available Preservative-Free Preparations

Preparation	Concentration(s)	Indication	Why Compounded PF?
<b>Timolol PF</b>	0.25% or 0.5%	Glaucoma / ocular hypertension in patients who are BAK-sensitive or on multiple drops	Timoptic Ocudose is commercially available but often less accessible and more expensive than compounded; unit-dose format reduces cumulative BAK burden
<b>Dexamethasone Sodium Phosphate PF</b>	0.1%	Post-surgical inflammation, anterior uveitis, chronic anterior segment inflammatory conditions	Commercial dexamethasone drops contain BAK. PF formulation preferred for inflamed/healing post-surgical eyes and patients on long-term steroid therapy
<b>Methylprednisolone PF</b>	1%	Post-surgical inflammation; useful alternative where dexamethasone is not tolerated or where methylprednisolone is preferred	Not commercially available as an ophthalmic preparation; compounding only. Preferred by some surgeons for specific post-surgical protocols

### Which Patients Benefit Most

- Glaucoma patients on multiple agents — each bottle typically contains BAK, and the cumulative exposure from 2–3 daily topical medications is clinically meaningful
- Post-surgical patients — the healing epithelium and compromised surface are particularly vulnerable to preservative toxicity; PF is standard of care in many practices
- Dry eye disease — BAK disrupts the tear film and worsens dry eye. Patients on chronic drops should be on PF formulations wherever possible
- Frequent drop users — anyone using drops more than BID benefits from reducing preservative burden
- Contact lens wearers — BAK is toxic to contact lens materials and the epithelium beneath

**Note on methylprednisolone:** Unlike dexamethasone and prednisolone, methylprednisolone 1% ophthalmic has no commercial equivalent whatsoever — it is not available from any manufacturer as an eye drop. Prescribers who prefer it for specific post-surgical protocols or who have patients with dexamethasone tolerance issues must use compounded product.

## Section 5 — Clinical Decision Guide

A quick reference for selecting the right compound by clinical presentation.

Clinical Presentation	Compound to Consider	Rationale
Contact lens wearer with corneal ulcer, culture pending	<b>Fortified tobramycin 14 mg/mL ± vancomycin 25 mg/mL</b>	Cover Pseudomonas (gram-neg dominant) ± gram-positive empirically while awaiting culture
Corneal ulcer with dendritic pattern, gram-positive organisms	<b>Vancomycin 25 mg/mL</b>	Gram-positive/MRSA coverage; no commercial equivalent
Ring infiltrate, pain out of proportion, contact lens wearer	<b>Chlorhexidine 0.02% + PHMB 0.02%</b>	Acanthamoeba pattern — start biguanides immediately pending scraping/PCR
Fungal keratitis (feathery borders, trauma history, steroid use)	<b>Amphotericin B 1.5 mg/mL</b>	Compounded antifungal; covers Candida, Aspergillus, Fusarium
Non-healing PED, neurotrophic keratitis, post-PRK delayed re-epi	<b>Insulin 1 IU/mL QID</b>	Growth factor signaling at corneal epithelial insulin receptors
Post-PRK late haze despite MMC, or breakthrough haze post-infective	<b>Losartan 0.08% 6× daily</b>	Myofibroblast suppression via TGF-β pathway; no IOP/cataract risk
Active scarring from SJS/OCP/GVHD, pterygium recurrence prophylaxis	<b>Losartan 0.08% ± steroid taper</b>	Anti-fibrotic; additive with steroids in animal models
Corneal filaments, mucous plaques, refractory filamentary keratitis	<b>NAC 10% QID</b>	Only mucolytic option; cleaves mucoproteins directly; compounding only
SLK with filaments present	<b>NAC 10% QID as component of stepwise SLK management</b>	Endorsed by corneal specialists including Rapuano at Wills Eye
Glaucoma patient with BAK intolerance or multiple drops	<b>Timolol 0.25% or 0.5% PF vials</b>	Single-use vials eliminate BAK exposure entirely
Post-surgical inflammation, BAK-sensitive or healing cornea	<b>Dexamethasone 0.1% PF or methylprednisolone 1% PF</b>	PF formulation protects healing epithelium from preservative toxicity

## Section 6 — How to Order / Prescribe

We work with both individual prescribers and practices. For most ophthalmic compounds, a standard Rx transmitted via any of the methods below is all that's needed. For urgent cases, call us directly.

### Transmission Methods

Method	Contact	Notes
Phone	(717) 846-0500	Call for urgent cases — Acanthamoeba, fungal keratitis, fortified antibiotics prioritized same-day
Fax	(717) 845-8767	Standard written Rx — include patient DOB, diagnosis/indication, full sig
E-prescribe	Available via major platforms	Search 'Medicine Shoppe York PA' — confirm with pharmacy if not found in your platform
Address	1698 S Queen St, York PA 17403	Walk-in welcome; parking available

### What to Include on the Prescription

- Patient full name, date of birth, and address
- Drug name, concentration, and dosage form (e.g., 'Tobramycin 14 mg/mL ophthalmic solution')
- Sig / dosing instructions (e.g., '1 drop OU q1h while awake × 48h, then taper per MD')
- Quantity (e.g., '10 mL' or '10 × 1 mL vials' for unit-dose)
- Prescriber name, NPI, DEA (if controlled), and signature
- Diagnosis or indication is helpful but not required — especially useful for insurance/prior auth documentation

### Urgent / Emergent Cases

**For Acanthamoeba keratitis, fungal keratitis, and severe bacterial keratitis cases:** call us directly at (717) 846-0500. We prioritize same-day compounding for these cases and can often have drops ready within hours. Fax or phone the Rx while the patient is still in your office when possible.

### Insurance & Payment

Compounded ophthalmic preparations are typically not covered by prescription insurance (they are off-label, non-FDA-approved formulations). Most are cash pay. We price competitively — for the infectious keratitis preparations in particular, the alternative is often IV-grade or inpatient therapy, making outpatient compounded drops a significant cost savings. We can provide a good-faith cost estimate before dispensing.

## Section 7 — Regulatory & Quality Overview

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As a prescriber, you're increasingly asked by patients and institutions about the quality and legitimacy of compounded medications. Here's a brief overview of where we stand.

### 503A Compounding Pharmacy

The Medicine Shoppe is a **503A traditional compounding pharmacy** licensed by the Pennsylvania State Board of Pharmacy. Under 503A of the FD&C Act, we compound **patient-specific prescriptions** — every preparation is made for an identified individual patient based on a valid prescription from a licensed practitioner. We are not a 503B outsourcing facility (which produces bulk, office-use stock without patient-specific Rx's) — everything we compound is for a specific named patient.

### USP <797> Sterile Compounding

All ophthalmic preparations are compounded under USP <797> sterile compounding standards in our **ISO-classified cleanroom**. This means aseptic technique, environmental monitoring, appropriate garbing, and documented quality assurance for every sterile preparation. Ophthalmic preparations — particularly those going on already-compromised corneal surfaces — require this level of sterility control, and we do not cut corners here.

### "Essentially a Copy" — What We Can and Cannot Compound

Under 503A, compounding pharmacies may not routinely compound drugs that are **essentially copies of commercially available products**. This is why most of our ophthalmic lineup consists of compounds with **no commercial equivalent at any concentration** (vancomycin ophthalmic, PHMB, chlorhexidine, amphotericin B ophthalmic, insulin ophthalmic, losartan ophthalmic, NAC ophthalmic, methylprednisolone ophthalmic). For preparations where a commercial product exists (dexamethasone, timolol), we compound the preservative-free formulation — which constitutes a documented clinical difference from the commercial BAK-preserved product.

### Beyond-Use Dating

Beyond-use dates (BUDs) for our preparations are assigned per USP <797> guidelines based on sterility and stability data. Shorter BUDs for some preparations (e.g., vancomycin 7 days refrigerated) reflect the stability characteristics of the compound, not a quality deficiency. We can provide BUD documentation for any preparation upon request for your records or institutional requirements.

**For any quality, regulatory, or clinical questions about our preparations:** call (717) 846-0500 and ask to speak with our compounding pharmacist directly. We are happy to discuss formulation details, stability data, and clinical rationale for any compound we make.

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**Hours**  
Mon–Fri: 9am–6pm  
Sat: 9am–1pm

*For urgent ophthalmic cases, call directly — same-day priority for infectious keratitis.*

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