PURE CUSTOM CAPSULES

No Fillers · No Dyes · No Unnecessary Excipients · Exact Dose

Prescriber Reference Guide · The Medicine Shoppe, York PA

Excipient Sensitivity · Custom Dose · Combination Capsules · Pediatric & Geriatric · Gluten-Free · Vegan Shell Options

Program Overview

Commercial tablets and capsules routinely contain a broad array of inactive ingredients -- binders, fillers, dyes, coatings, preservatives, and flow agents -- that serve manufacturing purposes but provide no therapeutic benefit to the patient. For a significant subset of patients, these excipients are not clinically inert: they trigger reactions, worsen sensitivities, or create barriers to adherence. Compounded pure custom capsules contain only the active pharmaceutical ingredient(s) at the exact prescribed dose, in a clean shell, with minimal or no added excipients. This guide describes the clinical applications, formulation considerations, and prescribing workflow for pure custom capsule compounding at The Medicine Shoppe.

When Pure Custom Capsules Add Clinical Value

- Excipient sensitivity or intolerance -- documented or suspected reactions to dyes, lactose, gluten, corn starch, talc, PEG, magnesium stearate, or other common inactive ingredients
- Unavailable commercial dose -- the prescribed strength simply does not exist in any commercial product; compounding provides the exact dose without splitting, crushing, or approximating
- Combination capsules -- two or more compatible medications combined in a single capsule to reduce pill burden and improve adherence
- Gluten or lactose intolerance -- many commercial medications contain hidden gluten or lactose; pure capsules eliminate this exposure entirely
- Dye-free requirement -- FD&C dyes (Red 40, Blue 2, Yellow 6) are present in numerous commercial products; some patients with dye sensitivity or MCAS react to these; pure capsules use no colorants
- Pediatric and geriatric dosing -- commercially unavailable dose strengths formulated in capsules sized and dosed appropriately for the patient
- Vegan or dietary preference -- HPMC (hydroxypropyl methylcellulose) capsule shells available as an alternative to gelatin for patients with dietary or religious restrictions

The Problem with Commercial Excipients

FDA regulations require commercial drug manufacturers to list inactive ingredients, but do not require that these be clinically inert for all patients. The following are among the most clinically significant excipients in terms of patient reactivity:

Dyes & Colorants

FD&C Dyes (Red 40, Blue 2, Yellow 6)	Synthetic azo dyes used for tablet and capsule color identification. Documented to cause adverse reactions in sensitive individuals -- urticaria, angioedema, and exacerbation of ADHD symptoms in children (UK regulatory action). Patients with aspirin hypersensitivity frequently cross-react with azo dyes. MCAS patients are particularly sensitive. No therapeutic purpose.
Titanium Dioxide	White colorant and coating agent. Classified as a possible human carcinogen (Group 2B, IARC) when inhaled; the EU banned it as a food additive in 2022 due to genotoxicity concerns. Present in coatings of many commercial tablets. No therapeutic role.
Iron Oxide Pigments	Used in capsule shell colorants; generally lower reactivity than azo dyes but can contribute to excipient load in sensitive patients.

Fillers & Binders

Lactose	Among the most common tablet fillers; problematic for lactose-intolerant patients. Even sub-gram amounts in daily medications can accumulate to clinically relevant lactose exposure in patients who take multiple lactose-containing tablets daily. Many patients and prescribers are unaware their medications contain lactose.
Gluten / Wheat Starch	Present in some commercial formulations as binder or disintegrant. Critical issue for patients with celiac disease or non-celiac gluten sensitivity. Commercial products are not required to label for gluten in the US; determining whether a specific lot is gluten-free requires direct manufacturer inquiry.
Corn Starch	Common disintegrant; relevant for patients with corn allergy or intolerance -- an underrecognized but clinically significant sensitivity in some patients, particularly those with MCAS or multiple food sensitivities.
Magnesium Stearate	Flow agent used in virtually all commercial tablets. Some functional medicine practitioners cite concerns about biofilm formation and immune effects at high doses; evidence is limited, but sensitive patients sometimes report reactions. Low concern at standard pharmaceutical doses in most patients.
Talc (Magnesium Silicate)	Used as glidant and anti-caking agent. Inhalation concerns well-documented; oral exposure in medication context is at low doses but is an unnecessary additive for most patients. Some concern about contamination with asbestos-related minerals in certain talc sources.

Coatings & Preservatives

PEG (Polyethylene Glycol)	Used as tablet coating and solubilizer. Increasingly recognized as a source of hypersensitivity reactions and anaphylaxis, particularly with growing PEG exposure from vaccines, medications, and consumer products. Patients with PEG allergy may react to numerous commercial medications without realizing PEG is the culprit.
Shellac (Pharmaceutical Glaze)	Enteric coating derived from lac insect secretions; relevant for vegan patients and those with shellac hypersensitivity. Not labeled as an allergen in pharmaceutical products.

Propylene Glycol	Solubilizer and preservative; contact sensitizer in susceptible individuals; relevant in topical formulations but also present in some oral liquid formulations.
Sodium Benzoate / Parabens	Preservatives in liquid formulations; recognized contact and systemic sensitizers in predisposed individuals, particularly relevant in MCAS patients and those with multiple chemical sensitivities.

Pure Capsule Construction

A pure custom capsule contains only what the prescription requires -- the active ingredient(s) at the specified dose, in a capsule shell, with microcrystalline cellulose (MCC) added only as needed to achieve appropriate fill volume. MCC is among the most inert pharmaceutical excipients available -- no known allergenicity, no dyes, no animal products, gluten-free, and widely accepted even by highly sensitive patients.

Capsule Shell Options

Gelatin (Standard)	Hard gelatin capsules are the standard pharmaceutical shell; derived from bovine or porcine collagen hydrolysis. Excellent moisture barrier, easy to swallow, widely accepted. Appropriate for most patients. Not suitable for vegans, vegetarians, or those with religious dietary restrictions (halal/kosher concerns with porcine gelatin).
HPMC (Vegan)	Hydroxypropyl methylcellulose capsule shells -- fully plant-derived, no animal products. Suitable for vegans, vegetarians, and patients with religious dietary restrictions. Slightly different dissolution kinetics than gelatin in some formulations (generally not clinically significant at compounded doses). Available in same sizes as gelatin shells.
Size Selection	Capsule size (000, 00, 0, 1, 2, 3, 4) determined by fill volume of the active ingredient(s) plus any MCC needed. Compounding pharmacist selects appropriate size; smaller sizes preferred for pediatric patients and those with dysphagia.

The Role of MCC (Microcrystalline Cellulose)

What Is MCC	Microcrystalline cellulose is a purified, partially depolymerized cellulose derived from plant sources. It is pharmacopoeially recognized (USP/NF), widely used as the most inert pharmaceutical filler, and is free from dyes, lactose, gluten, animal products, and common allergens.
When It Is Added	MCC is added only when the active ingredient dose is too small to fill the capsule shell adequately without it -- ensuring consistent fill and accurate dosing. For medications with larger doses, MCC may not be needed at all.
When MCC Is Omitted	For patients who specifically request MCC-free capsules (extremely sensitive patients, MCAS), the compounding pharmacist can minimize or eliminate MCC by selecting the smallest appropriate capsule size for the active ingredient volume. This may result in a very small capsule for low-dose medications.
MCC vs. Commercial Fillers	MCC is categorically cleaner than the filler matrix in most commercial tablets -- which typically contain lactose, corn starch, magnesium stearate, and other excipients in addition to any binders and coatings.

Clinical Applications by Category

Thyroid Medications

T3 (Liothyronine)	Commercial liothyronine (Cytomel) contains corn starch, magnesium stearate, and dextrose -- relevant for corn-sensitive and sugar-sensitive patients. Compounded pure T3 capsules allow exact dosing (including very low doses like 2.5-5 mcg not commercially available) and clean excipient profile. Sustained-release T3 formulations also available.
T4 (Levothyroxine)	Commercial levothyroxine tablets contain acacia, lactose, magnesium stearate, and povidone. Patients sensitive to these excipients or who need non-standard doses benefit from pure compounded T4 capsules.
NDT (Natural Desiccated Thyroid)	Desiccated thyroid (T3+T4 from porcine thyroid) can be compounded in pure capsules with clean excipients at custom doses -- relevant for patients intolerant of Armour Thyroid or NP Thyroid excipients (corn starch, dextrose, opadry coating). Custom T3:T4 ratio capsules also available.
Combination T3+T4	Custom ratio combination capsules -- prescriber specifies exact mcg of each; compounded in a single capsule; useful for patients requiring individualized ratio titration not available in commercial products.

Low Dose Naltrexone (LDN)

Why Compounded	Commercial naltrexone is 50 mg -- LDN (1.5-4.5 mg) requires compounding. Pure capsules are particularly important for LDN patients, many of whom have MCAS, autoimmune conditions, or chemical sensitivities where commercial excipient tolerance is poor.
Excipient-Free LDN	Pure LDN capsules: naltrexone at prescribed dose + minimal or no MCC; no dyes, no lactose, no fillers beyond what is necessary. Specify gelatin or HPMC shell per patient need.
Dosing	1.5 mg, 3.0 mg, 4.5 mg standard; any custom strength available; titration packs (multiple strengths in one order) available on request

Bioidentical Hormones

Progesterone	Commercial progesterone (Prometrium) contains peanut oil -- contraindicated in peanut allergy. Compounded pure progesterone capsules use no peanut oil; sesame oil or dry powder fill available. Custom doses (25 mg, 50 mg, 75 mg) not commercially available.
DHEA	OTC DHEA supplements contain variable excipient loads; compounded DHEA capsules at precise low doses (5 mg, 10 mg, 15 mg) in pure shell provide exact dosing without supplement-grade filler uncertainty.
Thyroid + Hormone Combinations	Combination capsules containing, e.g., LDN + DHEA, or T3 + T4, or progesterone + DHEA -- reduce pill burden for patients on multiple compounded agents; compatibility confirmed by the compounding pharmacist.

Psychiatric & Neurological Medications

Low-Dose Custom Strengths	Psychiatric titration often requires doses not commercially available -- e.g., very low-dose antidepressants for hypersensitive patients, micro-dose lithium orotate, or sub-therapeutic doses during taper protocols. Compounded pure capsules enable precise low-dose titration.
Dye-Sensitive Patients	Many psychiatric medications are heavily dyed (capsule colors used for dose identification); patients with dye sensitivity or MCAS who require these medications benefit significantly from dye-free compounded equivalents.
Micro-Dosing Protocols	Emerging clinical interest in very low-dose psychiatric medications (e.g., ultra-low-dose naltrexone, micro-dose lithium, sub-milligram doses of SSRIs) that are not commercially viable; compounding enables these protocols.

GI & Metabolic Medications

Mast Cell / Histamine Conditions	Patients with MCAS often react to multiple commercial excipients simultaneously. Pure capsule compounding of antihistamines (ketotifen, hydroxyzine, cromolyn), mast cell stabilizers, and GI medications at custom doses provides tolerable formulations for this high-sensitivity population.
GI-Specific Compounds	Compounded GI medications (e.g., low-dose naltrexone for Crohn's, oral cromolyn sodium, intestinal anti-inflammatory agents) at doses not commercially available; excipient-free formulations important for patients with inflammatory bowel conditions and food sensitivities.
Supplements at Custom Doses	Vitamins and nutraceuticals (B vitamins, methylfolate, methylcobalamin, magnesium, zinc) at precise therapeutic doses in pure capsules -- without the sugar coatings, artificial colors, and mixed excipients common in supplement products.

Pediatric & Geriatric Applications

Pediatric Dosing	Commercial tablets cannot be reliably split to pediatric doses. Compounded capsules provide exact weight-based doses in appropriate capsule sizes; can be opened and sprinkled into food for children who cannot swallow capsules. Pure excipient profile particularly important for children with food allergies, autism spectrum disorders with sensory sensitivities, or MCAS.
Geriatric Polypharmacy	Combination capsules reduce pill burden in geriatric patients on multiple medications. Smaller capsule sizes (size 3 or 4) available for patients with dysphagia. Excipient-free formulations particularly relevant for frail elderly patients with multiple drug sensitivities.
Dose Unavailability	Many medications have no pediatric commercial formulation; geriatric patients often need doses lower than the lowest commercial tablet. Compounding fills these gaps with exact dose specification.

Combination Capsules

Combining two or more compatible medications in a single capsule is one of the most clinically valuable applications of custom capsule compounding. Before combining, the compounding pharmacist confirms chemical compatibility and stability of the combined ingredients.

Clinical Benefit	Reduces daily pill count; simplifies complex regimens; improves adherence particularly in patients managing multiple chronic conditions; single prescription for combined agents
Compatibility Assessment	Not all medications can be combined -- some have incompatible pH requirements, react with each other chemically, or have different stability profiles. The compounding pharmacist reviews all requested combinations for compatibility before compounding.
Common Combinations	LDN + DHEA; T3 + T4 (custom ratio); progesterone + DHEA; ketotifen + other antihistamines; methylene blue + other cognitive support agents; custom vitamin/supplement combinations; adrenal support formulas (DHEA + pregnenolone + adaptogenic compounds)
Limitations	Combination capsules are not appropriate if: the medications require different release profiles (e.g., one immediate-release and one sustained-release); the combined dose would require a capsule too large to swallow; or chemical incompatibility is identified by the pharmacist
Prescribing Combination Capsules	List all ingredients and doses on the prescription; pharmacist will confirm compatibility and contact prescriber if any concerns arise before compounding

Common Excipients in Commercial Medications -- Quick Reference

The following table summarizes the most clinically significant commercial excipients, the patient populations most affected, and the pure capsule advantage:

Excipient	Why It Matters	Most Affected Patients	Pure Capsule Advantage
FD&C Dyes	Urticaria, angioedema, ADHD exacerbation, azo dye cross-reactivity with aspirin hypersensitivity	MCAS, aspirin-sensitive asthma, dye-sensitive patients, children	No colorants of any kind
Lactose	GI symptoms in lactose intolerance; cumulative exposure from multiple medications	Lactose intolerance (estimated 65% of global population), IBS	Lactose-free
Gluten / Wheat Starch	Villous atrophy, GI symptoms, systemic inflammation	Celiac disease, NCGS, inflammatory bowel	Gluten-free confirmed
Corn Starch	Corn allergy/intolerance reactions; relevant in MCAS	Corn allergy, MCAS, multiple food sensitivities	Corn-free
PEG (Polyethylene Glycol)	Hypersensitivity reactions, anaphylaxis; increasingly common sensitization	PEG allergy (growing prevalence), MCAS	PEG-free
Titanium Dioxide	Genotoxicity concerns (EU ban as food additive); EU-banned; unnecessary colorant	Patients preferring minimal chemical exposure; EU-informed patients	Titanium dioxide-free
Peanut Oil (Prometrium)	Anaphylaxis in peanut allergy	Peanut-allergic patients on progesterone	Peanut oil-free options for all hormones
Shellac	Not vegan; shellac hypersensitivity; undisclosed animal product	Vegan patients, shellac-sensitive patients	Shellac-free

Prescribing Pure Custom Capsules

Pure custom capsules can be prescribed for virtually any oral medication that can be compounded in capsule form. The prescription should specify the active ingredient(s), dose(s), capsule shell preference, and any specific excipient exclusions. The compounding pharmacist will select the appropriate capsule size and confirm compatibility for combination orders.

What to Specify	Active ingredient(s) and dose(s); capsule shell (gelatin or HPMC/vegan); any specific excipient exclusions (e.g., MCC-free if required); quantity; sig/dosing instructions
Combination Orders	List all ingredients and doses; pharmacist confirms compatibility before compounding and contacts prescriber with any concerns
Shell Default	Gelatin unless patient requests HPMC (vegan); note HPMC preference on prescription or call ahead
MCC-Free Requests	For highly sensitive patients (MCAS, extreme chemical sensitivity) who request no MCC: note on prescription; pharmacist will minimize fill material and select smallest appropriate capsule size
Dose Ranges	Any dose compoundable in capsule form; no minimum or maximum beyond pharmacopeial limits; prescriber specifies exact strength
Quantity	30-day supply standard; 90-day available for stable chronic medications

Prescribing Examples

- LDN: 'Naltrexone 4.5 mg capsule (HPMC shell, no dyes, no lactose) -- take 1 capsule at bedtime; qty 30'
- Thyroid: 'Liothyronine 5 mcg / Levothyroxine 50 mcg capsule (gelatin, MCC only) -- take 1 capsule daily; qty 30'
- Progesterone: 'Progesterone 100 mg capsule (peanut oil-free, gelatin shell) -- take 1 capsule at bedtime; qty 30'
- Combination: 'Ketotifen 0.5 mg / DHEA 10 mg capsule (HPMC shell, no fillers) -- take 1 capsule twice daily; qty 60'
- Pediatric: 'Liothyronine 2.5 mcg capsule (size 4, HPMC shell, MCC only) -- open capsule and mix with small amount of food; qty 30'

Formulation & Dispensing

Capsule Shells	Gelatin (standard, bovine/porcine) or HPMC (vegan/plant-derived) -- prescriber or patient specifies; same sizes available for both
Filler	Microcrystalline cellulose (MCC) only, as needed for fill volume; MCC-free options on request
No Dyes	No FD&C dyes, no iron oxides, no titanium dioxide, no colorants of any kind
No Lactose, No Gluten	Lactose-free and gluten-free confirmed; no corn starch, no wheat starch
No PEG, No Shellac	PEG-free; shellac-free; no peanut oil (relevant for progesterone capsules)
Custom Strengths	Any dose compoundable in capsule form; no commercially available strength required
Combination Capsules	Two or more compatible ingredients in a single capsule; compatibility reviewed by pharmacist
Quantity	30-day standard; 90-day available; titration packs (multiple strengths per order) available on request
Pricing	Cash pay -- contact pharmacy for current pricing; combination capsules priced per formula
BUD / Storage	Per USP compounding standards; labeled on each preparation; most capsules room temperature storage

Ordering & Contact Information

All custom capsules require a valid prescription specifying active ingredient(s), dose(s), and any formulation preferences. The compounding pharmacist is available to discuss ingredient compatibility, shell selection, and excipient-free options for complex patients.

How to Order

- By phone -- call (717) 846-0500; ask for the compounding pharmacist; have patient name, DOB, active ingredient(s), dose(s), shell preference, and any excipient requirements ready; pharmacist available to assist with formulation questions
- By fax -- send prescription to (717) 845-8767; list active ingredient(s) with dose(s); note gelatin or HPMC shell; note any excipient exclusions (MCC-free, etc.); specify quantity and sig
- E-prescribe -- select 'Compound' as medication type; list ingredient(s) and dose(s) in Sig/Comments; note shell preference and any excipient restrictions; include quantity and dosing instructions

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