



# CHEMISTRY RX

**INNOVATIVE** SKIN THERAPIES

"Enhancing the Lives of Mitochondrial  
Disease Patients Through Compounded  
Treatment Options"

# "Traditional Pharmacy" vs. "Compounding Pharmacy"

## Traditional Pharmacy:

- Dispenses **pre-manufactured medications** from pharmaceutical companies.
- Offers a wide variety of **commercially available** drugs in standard dosages and forms (tablets, capsules, etc.).
- May offer some basic compounding services, but not the extent of a dedicated compounding pharmacy.

## Compounding Pharmacy:

- Creates **custom-made medications** by combining ingredients to meet a patient's specific needs.
- Can adjust **dosage**, change the **form** (liquid, cream, etc.) of a medication, or address allergies by using alternative ingredients.
- Often caters to patients who can't tolerate commercially available medications or require unique formulations.
- May have **higher costs** due to the personalized nature of the medication.

## "Traditional Pharmacy" vs. "Compounding Pharmacy"


	Traditional Pharmacy	Compounding Pharmacy
<b>Medication Source</b>	Pre-manufactured	Custom-made
<b>Medication Availability</b>	Mostly only commercially-available options	Can meet any patient-specific needs (allergies, dietary or religious restrictions, etc)
<b>Dosage &amp; Form</b>	Standardized (and therefore limited)	Unlimited variety in dosages & forms
<b>Services</b>	Focuses on dispensing	Focuses on compounding
<b>Cost</b>	Generally lower due to mass production	May be higher due to customization



# Mitochondrial Disease

A disease affecting the mitochondria of cells in the body resulting from genetic mutations and environmental toxins, with increasing prevalence due to better diagnostics and increased awareness.

## Symptoms include:

- Poor growth, muscle weakness and loss of muscle coordination
  - Neurological problems, including seizures
  - Autism spectrum disorder
  - Visual and hearing problems
  - Developmental delays
  - Heart, liver, and kidney disease
  - GI disorders
  - Diabetes
  - Respiratory Disorders
  - Increased risk of infection
  - Thyroid and/or adrenal dysfunction
  - Dysfunction of the nervous system
  - Neurophysiological changes
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# Commonly Prescribed Medications for Mitochondrial Disease Patients

- Mito-Cocktails
- Folinic Acid Capsules
- Hydroxocobalamin Injections
- Dye-Free Medications
- Maintenance Medications for patients that have allergies to certain fillers



# Background on "Mito-Cocktails"

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- Over the last 20 years, research opinions, abstracts, and articles written in collaboration by researchers and physicians from leading genetic institutional centers have documented medications and vitamin supplements associated with treating the symptoms of Mitochondrial Disease.
- Genetic mutation(s) cause disruption to the mitochondria of certain cells. Customized Mito-Cocktails, consisting of a combination of various medications/amino acids/vitamins, differing from patient to patient, with individualized doses of each ingredient have become widely prescribed.
- Ingredients selected for treatment not only need to be specific to each patient's symptom(s), but consideration must be taken regarding absorption and the patient's ability to undergo biochemical reactions in the body to convert inactive forms of these ingredients to the active forms.
- Mitochondrial cocktails, or Mito-Cocktails have become widely used based on the ability to individualize treatment for these patients, allowing compounding pharmacies to play a vital role to patients suffering from Mitochondrial Disease.

# Principles of "Mito-Cocktails"

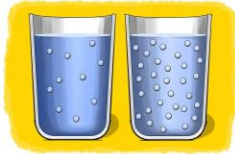
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- **Mito Cocktail** is a term for a prescription of blended medications/amino acids/vitamins prescribed by doctors for patients suffering from mitochondrial disorders
- **Mito-Cocktails** can simplify the administration process associated with complex medication regimens.
- Can be compounded into a variety of dosage forms, assisting with the required administration route of the patient (oral suspension, capsules, powder in jar with scoops)

Mito Cocktails undergo an extensive process when being formulated, based on each ingredients physical properties included in these prescriptions and a multitude of patient factors.

Properties that need to be considered:

**Solubility** - wide range of concentrations of ingredients:



**Palatability** - each "Mito-Cocktail" is comprised of different ratios of ingredients, leading to high variability in the process for making them palatable, while always adhering to all USP standards (consistency, color, trying to cancel out bitterness or spiciness):



**Stability** - ensuring that stability guidelines are always adhered to for patient and product safety:



**Route of Administration** - disease manifestations require a wide array of possible dosage forms:

**Oral Route**





## Properties that need to be considered (continued):

**Allergies** (dyes, etc):




**Dietary Restrictions** (keto – zero carb, diabetic – low carb, Kosher, sugar alcohol intolerances):



**Patients' Personal Preferences** (flavors):



# Compounded "Mito Cocktail" vs. Commercially Available Supplements

- Crucial to customize the compounded "Mito Cocktail" to each patient's clinical genotype and phenotype
  - Usually much higher doses than you can find OTC
  - Pill burden when using OTC options can be tremendous
  - Fillers and other additives, which may not be compatible with dietary restrictions have the potential to cause adverse effects, such as GI upset (difficulty going to the bathroom, upset stomach, etc)
  - Dietary supplements that are found over the counter do not undergo the same testing as pharmaceutical-grade bulk powders
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# Benefits of Using a Compounding Pharmacy for Mitochondrial Disease

- **Customized "Mito Cocktails":** Mitochondrial disease treatment often involves a combination of medications, amino acids, vitamins, and other supplements. A compounding pharmacy can create a personalized "Mito Cocktail" that combines all the necessary ingredients in the right dosages for each patient. This can simplify medication management and improve adherence.
- **Dosage Flexibility:** Standardized dosages of commercially available options might not be optimal for patients with mitochondrial disease. A compounding pharmacist can customize doses to meet individual needs.
- **Discontinued Medications:** If a specific supplement or medication beneficial for mitochondrial disease gets discontinued, a compounding pharmacy might be able to recreate it.

## Common Ingredients Prescribed in "Mito Cocktails"

- Ubiquinol
- Arginine
- Leucovorin
- Biotin
- B-complex
- Alpha Lipoic Acid
- Levocarnitine
- Thiamine
- Citrulline
- Ascorbic Acid
- Vitamin E
- Niacin
- Niacinamide
- Creatine
- N-Acetylcysteine
- Riboflavin



## Dosage Form Options for Compounded "Mito Cocktails"

Dosage Form	Properties
<b>Oral Suspension</b>	<ul style="list-style-type: none"><li>• Liquid form</li><li>• Great option for patients with different types of feeding tubes</li><li>• Great option for patients who have difficulty swallowing capsules</li><li>• Shorter beyond-use date (14 or 35 days)</li></ul>
<b>Powder in Jar with Scoops</b>	<ul style="list-style-type: none"><li>• Good for active ingredients that are usually prescribed in higher doses (creatine, arginine, citrulline)</li><li>• Can be added to juices, milk, food, etc...</li><li>• Longer beyond-use date (6 months)</li></ul>
<b>Capsules</b>	<ul style="list-style-type: none"><li>• Can be opened up and poured into food or drinks</li><li>• Longer beyond-use date (6 months)</li></ul>



# Flavors!



Hawaiian  
Punch



Tutti Frutti



Raspberry



Strawberry  
Lemonade



Tropical  
Punch



Pineapple



Strawberry



Watermelon



Grape



Orange



Cherry



Mango



Creme de  
Menthe



Bubblegum

## Flavor Options for Patients with Specific Dietary Restrictions



**Strawberry, colorless:  
for patients who do  
not tolerate dyes**



**Bubble gum, colorless:  
for patients who do not  
tolerate dyes**



**Zero dye, zero carb Bubble  
gum: for patients who do  
not tolerate dyes and  
require medications free of  
carbohydrates**

# Considerations When Choosing an Accredited 503A Compounding Pharmacy for "Mito Cocktails"

- **Limited Research:** The efficacy and safety of some compounded medications for mitochondrial disease might not be as well-established compared to FDA-approved drugs. *Does the pharmacy commit to staying informed on the latest studies and publications pertaining to the treatments they compound?*
- **Quality Control:** Compounded medications are not FDA-approved - there's a potential for inconsistencies in dosing or contamination if using a pharmacy with lax quality control procedures. *Does the pharmacy invest in equipment and software that allows for accuracy checks, adhere to current USP regulations, and have a strong compliance department to ensure standards are adhered to?*
- **Clinical Expertise:** Ensuring the compounding pharmacy has a firm understanding of the disease states and the therapeutic options they are providing. *Does the pharmacy have accreditations & staff trained in the disease states it services?*
- **Insurance Coverage:** Insurance coverage for compounded medications can be limited or non-existent. *Does the pharmacy you are considering using have the ability and expertise to bill insurance companies?*
- **Cost:** Compounding medications are generally more expensive than commercially available options because they are custom-made. *Does the pharmacy offer affordable solutions?*



## Additional Considerations When Choosing an Accredited 503A Compounding Pharmacy for "Mito Cocktails"

- **Importance of a Reputable Pharmacy:** It's crucial to choose a compounding pharmacy with a proven track record of quality control and adheres to USP (United States Pharmacopeia) standards.
- **Accredited Pharmacies:** Pharmacies carrying accreditations ensure high standards of care and commitments to continuous quality improvement.
- **Doctor Consultation:** Always discuss using a compounding pharmacy for mitochondrial disease with your doctor. They can assess your needs, recommend the appropriate medications and dosages, and ensure the compounding pharmacy adheres to their specifications.
- **Support Groups:** Mitochondrial disease patient support groups can be a valuable resource for finding reputable compounding pharmacies with experience in creating "Mito Cocktails".



## Licensing & Accreditations


- Licensed in all 50 states plus territories
- 25 Medicaid licenses
- URAC
- ACHC
- PCAB
- NABP



# The Patient's Experience at Chemistry Rx Compounding & Specialty Pharmacy

- 1) Prescription Transmission to Pharmacy
- 2) Initial Outreach
- 3) Prior Authorization
- 4) Appeals (if applicable)
- 5) Confirmation of Payment (if any) & Shipping Address
  - *(will always do this right before shipping any medication)*

## Navigating Insurance Difficulties

- Chemistry Rx has a clinical team (including nurses) dedicated to **communicating with insurance companies to resolve any issues that may arise.**
  - Our clinical pharmacists and nurses work with providers to **navigate any coverage gaps** which commonly arise on compounded medications.
  - Our team works with providers regarding formulations, **educating them on covered ingredients and dosage forms.**
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