

# Pharmaceutical Extemporaneous Preparations Guideline

General Administration of Pharmaceutical Care Deputyship for Medical Support Services Ministry of Health



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#### Introduction:

Compounding is the formation of a pharmaceutical preparation—a medication—by a licensed pharmacist to fulfill the specific requirements of an individual patient when a commercially available medication does not meet those needs, in situations such as when the strength or dosage form of a medication needs to be customized. For example, compounding may be helpful when patients need an individualized dose or patients with dysphagia who cannot swallow whole solid medications or when medications must be administered via nasogastric or gastrostomy tube. Additionally, when a suitable dose or dosage form is not commercially available, or a patient may require a medication that is currently in shortage or discontinued.

#### Aim and Purpose:

This evidence-based guideline is developed to provide formulations of extemporaneously compounded medications most commonly prepared. It is helpful when a particular dose or dosage form is unavailable commercially, for individualized dosing, or for patients with special needs to ensure safety for both patients and personnel involved in the compounding process. Pharmacists, healthcare professionals, and others engaged in compounding drug preparations should comply with applicable Ministry of Health and Saudi Food and Drug Authority compounding laws and regulations in addition to the pharmaceutical compounding (USP) standards.

## **Target Population:**

Patients (of special populations) with prescriptions of:

- Medications that are not commercially available.
- Commercially available medications but out of stock.

### **Targeted End users:**

The guideline is developed to provide directions to pharmacists and assistant pharmacists involved in the health care of special populations.

#### Methodology:

The guideline is created by pharmacists and clinical pharmacists who have experience in compounding areas.

#### **Conflict of Interest:**

No financial relationships with pharmaceutical, biotechnology, or medical device companies.

## **Funding:**

No fund was provided.

## **Updating:**

The guideline will be updated annually if any updates or changes in the international/national guidelines occur.

## **General Guidance for Extemporaneous Preparations**

### What is Compounding?

- Compounding (according to FDA) is a practice in which a licensed pharmacist or licensed physician mixes or adjusts the ingredients of a drug to produce a medication tailored to a specific patient's needs.
- Compounding (according to USP) is the process of preparing, mixing, gathering, modifying, packaging, and labeling a drug, device, or drug-delivery device, complying with a licensed practitioner's prescription, medication order, or action plan, depending on the practitioner/pharmacist/compounder/patient relationship in the professional practice.

#### **Compounding Categories:**

There are three general categories of nonsterile compounding, different levels of experience, training, and physical facilities are associated with each category. Compounders must earn and keep knowledge and skills in all areas for which they compound (e.g., dosage form, medical specialty, and patient population).

#### The following factors are used to determine overall classification:

- Complexity or difficulty degree of the compounding process.
- Warnings and stability information and warnings.
- Storage and packaging requirements.
- Dosage forms.
- The complexity of calculations.
- Local versus systemic biological disposition.
- The compounders exposure to risk.
- Risk of potential harm to the patient.

#### **Description of Categories:**

According to USP 795, the categories of the compounding process consist of the following:

#### 1. Simple

Starting to prepare with a compounding monograph or found in a peer-reviewed journal article that includes specific amounts of all ingredients, compounding method, and equipment, as well as stability information for the formulation with appropriate BUDs; or reconstituting or trying to manipulate items that may need an addition of one or more ingredients as instructed by the manufacturer. Example: Captopril Oral Solution.

#### 2. Moderate

Making a preparation that needs specific calculations or procedures (such as dosage unit mold cavities calibration) to assess the quantities of ingredients per preparation or per individualized dosage units; or attempting to prepare for a specific formulation with no available stability data. For example: mixing two manufactured cream products or more when the mixture's stability is unknown.

#### 3. Complex

Making preparations that necessitate specialized training, facilities, environment, equipment, and procedures to achieve the best therapeutic outcomes. Transdermal dosage forms, modified-release preparations, and systemic inserts and suppositories are examples of possible complex preparations.

### Principles for sterile and non-sterile preparations:

Standards in compounding nonsterile and sterile medications developed by the United States Pharmacopeia USP-NF guideline on implementing good compounding practices to ensure the patient benefit and reduce risks, including contamination, infection, or incorrect dosing.

The compounder pharmacist is responsible for compounding preparations of adequate strength, quality, and purity in accordance with the prescription or medication order. It also includes dispensing the finished preparation with appropriate packaging and labeling.

#### The following are the general principles of compounding:

- 1. Personnel should be appropriately trained and qualified to perform their assigned duties.
- 2. Ingredients for compounding with the proper identity, purity, and quality are obtained from reliable sources and stored in accordance with manufacturer guidelines.
- 3. Material Safety Data Sheets (MSDSs) are available to compounding staffs for all drugs and chemicals used in compounding. Bulk component containers are labeled with the proper Occupational Safety and Health Administration (OSHA) hazard labels.
- 4. All compounding equipment is clean, well-maintained, and used correctly.
- 5. The compounding environment is appropriate for its intended purpose and procedures to prevent cross-contamination, particularly when compounding with medications that require special precautions, such as hazardous medications.
- 6. Only authorized personnel are allowed in the close medication compounding operations.
- 7. Processes are assured to be reproducible and always carried out as intended or specified.
- 8. Procedures and compounding conditions are provided for error prevention.
- 9. All compounding aspects are appropriately documented.

10. There are adequate processes and documentation for investigating and correcting errors or issues with compounding, testing, or preparation.

### Criteria when compounding drug preparation:

- 1. Evaluate the dose, safety, and proposed use of the preparation for suitability in regard to:
  - The components' physical and chemical characteristics
  - Dosage form
  - Route of administration and therapeutic appropriateness, as well as systemic and local biological disposition
  - Legal limitations, if any.
- Before compounding for the first time, a Master Formulation Record must be created and followed each time in addition to a Compounding Record completed after each preparation.
- 3. The formulation's ingredients are of the expected identity, quality, and purity, not withdrawn from the market due to concerns about safety or efficacy. For each ingredient used, certificates of analysis and MSDSs are consulted, as appropriate.
- 4. The compounding area must be kept clean and sanitized.
- 5. In a specific workspace, only one preparation is compounded at a time.
- 6. The proper compounding equipment must be chosen and checked for cleanliness, correct functioning, and use.
- 7. Establish a reliable BUD for the finished preparation to ensure its characteristics, purity, and quality is acceptable, at least until the labeled BUD.
- 8. When compounding, staff engaged must keep their hands clean and wear clean clothing that is appropriate for the method of compounding being selected (such as facemasks, hair bonnets, gloves, coats, gowns, aprons, shoes, or other items as needed), to protect them from chemical exposure and prevent drug contamination.
- 9. Preparations must be made following the Saudi FDA standards, USP 795 standards, and other official standards, with relevant scientific information.
- 10. The compounder verifies essential steps (such as but not limited to weighing, measuring, and mixing) to ensure that when followed, they will consistently produce the desired qualities in the finished preparation.
- 11. The final preparation is evaluated using elements such as weight, clarity, adequacy of mixing, color, odor, PH, consistency, and analytical testing when appropriate.
- 12. The preparation is packaged according to the Packaging and Drug Preparation Containers' recommendation.
- 13. The preparation container's label complies with all relevant SFDA regulations. The BUD and information about handling and storage must be included on the label with indicating" This is a compounded preparation."

- 14. The compounder must check the Master Formulation Record and the Compounding Record to make sure that no errors have been made during the compounding process and that the preparation is appropriate for use.
- 15. The preparation is given to the patient or caregiver with providing the necessary counseling.

### **Beyond-Use Dating and Stability Criteria:**

The BUD, which starts counting from the date the preparation is compounded, is the date after which it may no longer be used. BUDs are assigned using different standards than those used to give an expiration date to manufactured drug products. The following considerations should be taken into account when determining a BUD:

- The drug's nature and its degradation mechanism.
- The dosage form components.
- The preparation's potential for microbial proliferation.
- The package container.
- The storage conditions.
- The duration of therapy.

In the absence of stability information, maximum BUDs for nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and kept at controlled room temperature as recommended by USP 795, are as follows:

Non-preserved aqueous	Preserved aqueous	Nonaqueous dosage forms	Solid dosage forms
14 days	35 days	90 days	180 days

#### **Containers for Packaging and Drug Preparation:**

- The compounder must make sure that the packaging for compounded preparations (containers and container closures) complies with USP requirements and, if available, compounding monographs.
- Container suppliers are required to supply and provide verification of USP container compliance upon request.
- Containers and closures must be made of suitable clean material to avoid affecting the compounded drug preparation's strength, quality, or purity.
- The physical and chemical properties of the compounded preparation determine the container used.

- For substances with sportive or leaching properties, container-drug interaction should be considered.
- Containers and closures must be kept off the floor, handled and stored carefully to avoid contamination, and adjusted so that the oldest stock will be first used.
- Containers and closures must be stored in a way to enable inspection and cleaning of the storage area.

## **Sterile Preparations Pharmaceutical Compounding:**

Sterile compounding, such as ophthalmic preparations, differs from nonsterile compounding primarily by requiring strict adherence and maintenance of sterility when compounding. Some differences between standards for sterile compounding and those for nonsterile compounding include ISO-classified air environments; personnel garbing and gloving; personnel training and testing in principles and practices of aseptic manipulations and sterilization; environmental quality specifications and monitoring; and disinfection of gloves and surfaces of ISO Class 5 sources.

## 1) Responsibility of Compounding Personnel:

- Compounding personnel must make sure that compounding of sterile preparations CSPs are correctly identified, measured, diluted, and mixed and accurately purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed. A qualified licensed healthcare professional who manages and controls the compounding and dispensing of sterile preparations (CSPs) must achieve the following objectives:
- Compounding staff members are appropriately qualified, educated, instructed, and trained to carry out tasks in sterile compounding environments.
- Ingredients have a correct identity, purity, and quality.
- Partially used packages or opened ingredients for subsequent use in CSPs are appropriately stored.
- During any phase of the compounding process, nonsterile water-containing CSPs are sterilized within 6 hours after preparation completion to minimize bacterial endotoxins generation.
- Devices for measuring, mixing, sterilizing, and purifying are clean, accurate, and effective for their intended use.
- Prior to dispensing and administration of CSPs, carefully evaluate the potential harm from added substances.
- The packaging selected for CSPs is suitable to keep sterility and strength until the beyond-use date (BUD).
- BUDs are assigned based on direct testing or extrapolation from trustworthy literature sources and documentation.

### 2) Personnel Training and Evaluation:

When preparing CSPs, personnel must initially undergo thorough training from experts, complete a didactic review, and pass written and media-fill tests of aseptic skills. This testing must thereafter be taken twice a year for high-risk level compounding and at least yearly for low- and medium-risk level compounding.

### 3) CSP Microbial Contamination Risk Levels:

The three contamination categories for CSPs described according to the potential for microbial contamination during the compounding of low-risk level CSPs and medium-risk level CSPs or the potential for not sterilizing high-risk level CSPs.

#### Low risk Level:

- o Manipulations with <u>sterile</u>, <u>non-hazardous</u> ingredients under <u>ISO Class 5</u>.
- Compounding includes only transferring, measuring, and mixing manipulations with no more than two entries and no more than three commercially manufactured sterile product packages.
- Manipulation is limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile syringes and needles, & passing sterile liquids in sterile syringes to sterile administration devices, package containers of another sterile product, and containers for dispensing and storage.
- Example: Single-volume transfers of sterile dosage forms from ampules, using sterile syringes with sterile needles to another sterile container.

#### Medium-Risk Level CSPs:

- Multiple small or individual doses of sterile products are combined to create a CSP that will be given to various patients or a single patient on multiple occasions.
- Other than the single-volume transfer, complex aseptic manipulations are also a part of the compounding process.
- When it comes to homogeneous mixing or complete dissolution, the compounding process requires an unusually long-time frame.
- Example: using manual or automated devices for compounding total parenteral nutrition fluids.

### High-Risk Level CSPs:

 Nonsterile components, such as manufactured products not designed for sterile administration routes (e.g., oral), are incorporated, or a nonsterile device is used before final sterilization.

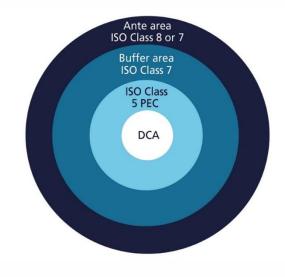
- CSPs exposed for more than an hour to air quality worse than ISO Class
   5 Compounding personnel is improperly garbed and gloved.
- Preparations containing non-sterile water are stored for more than six hours before being sterilized.
- Example: Dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized.

## 4) Environmental Control and Quality:

A CSP's ability to achieve and maintain sterility and overall freedom from contamination depend on the components used, the process utilized, the performance of the staff, and the environmental conditions in which the process is done. Sterile compounding area shall be physically designed and environmentally controlled for maintaining at least ISO Class 5 conditions to minimize air-borne contamination from contacting critical sites. Devices that shall be capable of maintaining ISO Class 5 conditions during all

Compounding activities include laminar airflow hoods and unidirectional zonal laminar flow of High- Efficiency Particulate Air (HEPA) filtered air. To achieve the desired environmental conditions, the compounding process must follow the principles of HEPA-filtered unidirectional airflow.

(The most common sources of ISO Class 5 air quality for exposure of critical sites are horizontal and vertical LAFWs, CAIs, and CACIs. A clean room is a compounding environment that is



supplied with HEPA or HEPA-filtered air that meets ISO Class 7, the access to which is limited to personnel trained and authorized to perform sterile compounding and facility cleaning. A buffer area is a location that gives air quality that is at least ISO Class 7).

## 5) Personnel Garbing and Cleansing:

The first important step in preventing microbial contamination in CSPs is for compounding personnel to properly wash their hands and arms with the correct donning of PPE. Compounding personnel must remove all personal outerwear, including coats, jackets, bandannas, scarves, hats, sweaters, and vests, as well as all cosmetics because they shed

particles and flakes, as well as all hand, wrist, and other visible jewelry or piercings that could interfere with the PPE effectiveness, before approaching the buffer area or segregated compounding area (see Low-Risk Level CSPs with 12-Hour or Less BUD) (e.g., fit of gloves and cuffs of sleeves). The following PPE must be worn by personnel in the order that proceeds from activities considered the dirtiest to those considered the cleanest. Wearing special shoes or shoe covers, covering one's head and facial hair (such as by wearing a beard cover and a face mask), and wearing face masks or eye shields are among the garbing practices that are considered to be the dirtiest. Then, a thorough hand wash must be performed after clearing away debris from under the fingernails with a nail cleaner while standing in warm running water.

## 6) Single-dose and Multiple-dose Containers:

Needle-punctured or open single-dose containers, such as bottles, bags, syringes, and vials of sterile products and CSPs, must be used within one hour if opened in worse than ISO Class 5 air quality and must discard any remaining contents. After the initial needle puncture, it is possible to use single-dose vials that have been exposed to ISO Class 5 or cleaner air for up to six hours. Single-dose ampules shall not be stored for any time period when opened. Multiple-dose containers (e.g., vials) are designed for the removal of quantities on multiple occasions since they contain antimicrobial preservatives. The BUD following initial entry or opening (e.g., needle punctured) of multiple-dose containers is 28 days, unless the manufacturer specifies otherwise.

#### 7) Storage and Beyond-Use Dating:

Personnel who prepare, administer, and dispense CSPs must store them strictly in accordance with the instructions listed on the labels of finished CSPs and ingredient products. Suppose CSPs are known to have been exposed to temperatures for more than 4 hours at temperatures above 40 C or warmer than the warmest labeled limit. In that case, they should be discarded unless direct assay data or the relevant documentation shows that they are still stable.

8) Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs: Compounding personnel must ensure that CSPs prepared or dispensed by the compounding unit are properly stored and secured until either the BUDs are reached or administered to patients. The compounding unit is also responsible for establishing, maintaining, and ensuring compliance with the detailed written policies and procedures. When non-compounding personnel are assigned to tasks that include any of these responsibilities, compounding supervisors should develop policies and procedures encompassing their duties.

## **Ensuring Patient Safety in Compounding:**

Compounding remains an essential practice for meeting unique or specific patient needs—providing special formulations for individual patients in situations where commercially available medications may not be appropriate (e.g., dosing for pediatric, geriatric, and other vulnerable populations). However, injuries and deaths caused by substandard quality compounded preparations have increased the focus on patient safety and urged changes in oversight.

#### Why Should We Be Concerned?

- Increasing population needs have highlighted the importance of patient access to compounded preparations, including those used for pediatric, geriatric, and other purposes.
- Quality failures and a better understanding of the compounding practice environment prompted the FDA to make a clear regulatory and statutory landscape and reconfirm the critical role of quality standards and other requirements in ensuring safe, quality compounded preparations. Although progress is being made, there are remaining gaps in quality and regulation. As a result, maintaining a commitment to quality is essential.
- Guidance on the management of risks associated with extemporaneous preparation:
- 1- Extemporaneous preparation should be considered only when an equivalent licensed product is not available or not suitable for use and if the use can be clinically and pharmaceutically justified. Before selecting this option, all alternatives should be considered.
- 2- The selected preparation should be licensed for use in a country with licensing arrangements and regulatory standards that are equivalent to or similar to the FDA. This assures the requesting pharmacist that a competent regulatory authority has reviewed the medication's quality, efficacy, and safety.
- 3- From a clinical standpoint, the procuring pharmacist should be aware that if the medication is used for a purpose other than its intended one, the efficacy and safety review may not apply to their specific clinical indication. As a result, the procuring pharmacist must review the Summary of Product Characteristics (SPC) and patient information leaflet (PIL) to make sure that they are suitable for the intended use and to provide alternative guidance as needed.
- 4- The use of a licensed medication from the same therapeutic class should be considered a better clinical alternative than the use of an extemporaneously prepared medication with limited evidence to support its formulation and stability.

- 5- However, the choice to switch to a different medication should take into account the patient's condition as well as the drug's relative toxicity.
- 6- Since stability cannot be ensured when dispersing tablets, the dose should be prepared and given right away. However, it should be noted that preparations for modified or slow releases shouldn't be used in this manner.
- 7- When using tablets as ingredients in the preparation of an oral liquid, many excipients are going to be insoluble, even if the drug is soluble. However, because these excipients can bind some of the drugs, it is prudent to use a suspending agent as the drug vehicle to guarantee dose uniformity. As a result, filtration of this type of preparation should not be performed.
- 8- To limit microbial growth, unpreserved preparations should be kept in the refrigerator and assigned a short shelf life. Unpreserved oral liquid preparations should have a maximum shelf-life of 7 days at 2-8 C unless sufficient validation work has been completed to support an extended shelf-life.
- 9- Consideration must be given to the palatability and presentation of oral liquid medications as there is an argument that taste is essential to achieve good compliance in pediatrics, especially for treating longstanding conditions such as cardiology.
- 10- In order to reduce the risk of cross-contamination when handling hazardous products, systems should be in place, and units should be equipped with the appropriate containment devices.
- 11- All alternative options should be explored; extemporaneous preparations should only be used as a last choice when there is a significant risk of morbidity associated with a non-standard or complex formulation.

- 1. Falconer, J. R., & Steadman, K. J. (2017). Extemporaneously compounded medicines. Australian prescriber, 40(1), 5–8. https://doi.org/10.18773/austprescr.2017.001
- 2. Frequently Asked Questions About Pharmaceutical Compounding. (n.d.). American Pharmacists Association. Retrieved September 13, 2022, from <a href="https://aphanet.pharmacist.com/frequently-asked-questions-about-pharmaceutical-compounding">https://aphanet.pharmacist.com/frequently-asked-questions-about-pharmaceutical-compounding</a>.
- 3. <u>Center for Drug Evaluation and Research</u>. (2021, April 26). *Human Drug Compounding*. U.S. Food And Drug Administration. Retrieved September 13, 2022, from <a href="https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding">https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding</a>.
- 4. *Pharmaceutical Compounding Nonsterile Preparations | USP.* (n.d.). Retrieved September 13, 2022, from <a href="https://www.usp.org/compounding/general-chapter-795">https://www.usp.org/compounding/general-chapter-795</a>.
- 5. Saudi food and drug.(2010). Manufacturing and Compounding of Medications.
- 6. Saudi food and drug. (2010). Pharmaceutical Compounding Nonsterile Preparations.



# **Topical/Ophthalmic Solutions**

## **Acetylcysteine 10% Ophthalmic Solution**

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	10%	- Must be prepared in a laminar
Ingredients	Quantity		flow hood
Acetylcysteine 20% ampoule	7.5 mL		
Sodium Chloride 0.9% (Preservative free)	qs. 15 mL		

## **Equipment Needed**

0.22-µm filter needle, and sterile amber dropper bottle plastic or glass

## **Directions**

- 1. Withdraw 7.5 mL of Acetylcysteine 20% ampoule through 0.22-μm filter needle under a laminar air flow hood using an aseptic technique.
- 2. Withdraw 7.5 mL of sodium chloride 0.9% (Preservative Free).
- 3. Transfer to a sterile ophthalmic dropper bottle.
- 4. Close the dropper bottle.
- 5. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
15 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
4 days	Ophthalmic sterile amber dropper bottle (plastic or	For ophthalmic use only and protect from light

- 1. Anaizi NH, Swenson CF, Dentinger PJ. Stability of acetylcysteine in an extemporaneously compounded ophthalmic solution. Am J Health Syst Pharm. 1997;54(5):549–53.
- 2. Akyol-Salman I, Azizi S, Mumcu U, Baykal O. Efficacy of topical N-acetylcysteine in the treatment of meibomian gland dysfunction. J Ocul Pharmacol Ther. 2010;26(4):329–33.
- 3. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

## **Acetylcysteine 20% Ophthalmic Solution**

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	20%	- Must be prepared in a laminar
Ingredients	Quantity		flow hood
Acetylcysteine 20% ampule (2g /10 mL)	10 mL		

## **Equipment Needed**

Sterile dropper bottle, and 0.22-µm filter needle

## **Directions**

- 1. Withdraw 10 mL of Acetylcysteine 20% ampule via 0.22-μm filter needle under a laminar air flow hood using an aseptic technique.
- 2. Replace the filter needle with a new regular needle.
- 3. Transfer to a sterile ophthalmic dropper bottle.
- 4. Close the dropper bottle.
- 5. Shake well to mix.
- 6. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
4 days	Plastic ophthalmic sterile amber dropper bottle	For ophthalmic use only and protect from light

- 1. Anaizi NH, Swenson CF, Dentinger PJ. Stability of acetylcysteine in an extemporaneously compounded ophthalmic solution. Am J Health Syst Pharm. 1997;54(5):549–53.
- 2. Akyol-Salman I, Azizi S, Mumcu U, Baykal O. Efficacy of topical N-acetylcysteine in the treatment of meibomian gland dysfunction. J Ocul Pharmacol Ther. 2010;26(4):329–33
- 3. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

## Amikacin Ophthalmic Solution 25 mg/mL 2.5%

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye Drop	25 mg/mL	- Must be prepared in a laminar
Ingredients	Quantity		flow hood.
Amikacin 500 mg /2 mL Injection	1 mL		
Artificial tears	qs. 10 mL		

## **Equipment Needed**

Sterile dropper bottle, and 0.22-µm filter needle

## **Directions**

- 1. Withdraw 1 mL (250mg) of amikacin 500 mg/2 mL injection via a 0.22- $\mu$ m filter needle under a laminar air flow hood using an aseptic technique.
- 2. Transfer to a sterile ophthalmic dropper bottle.
- 3. Add 9 mL artificial tears to make a final concentration of 250 mg/10 mL (25 mg/mL).
- 4. Close the dropper bottle.
- 5. Shake well to mix.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
7 days	Plastic ophthalmic sterile dropper bottle	For ophthalmic use only

## **References:**

1. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). *Extemporaneous Ophthalmic Preparations* (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

# Amphotericin B Ophthalmic Solution 1.5 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye Drop	1.5 mg/mL	- Must be prepared in a laminar air
Ingredients	Quar	ntity	flow hood.
Amphotericin B (Fungizone) 50 mg vial	1 Vial		<ul> <li>Do NOT FILTER - Colliodal suspenssion</li> <li>Fungizone, containing</li> </ul>
Sterile Water for Injection (SWFI)	qs. 10	) mL	deoxycholate, is an irritant for the cornea, which reduces patient compliance  Eye drops based on liposomal amphotericin B (AmBisome would be a convenient alternative)  Require use of a 5-micron filter upon transferring to a sterile ophthalmic dropper bottle

## **Equipment Needed**

Sterile dropper bottle, and 5-micron filter needle

## Directions

- 1. Reconstitute 50 mg of the vial powder with 10 mL SWFI under a laminar air flow hood using an aseptic technique to make 5 mg/mL.
- 2. Shake the vial rapidly for 30 seconds to completely disperse the powder.
- 3. Withdraw 3 mL (15mg) of the reconstituted solution via a 0.22-micron filter needle.
- 4. Remove the filter needle and transfer the reconstituted solution into a sterile, pyrogen- free ophthalmic dropper bottle.
- 5. Add 7 mL of sterile water for injection to give final concentration of 15mg/10mL (1.5mg/mL).
- 6. Close the dropper bottle.
- 7. Shake well to mix.
- 8. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Colliodal suspenssion	Refrigerate
Shelf life	Container Type	Special Instructions
7 days	Plastic ophthalmic sterile amber dropper bottle	For ophthalmic use only, shake well before use and protect from light

- 1. Morand K, Bartoletti AC, Bochot A, et al. Liposomal amphotericin B eye drops to treat fungal keratitis: physico-chemical and formulation stability. International Journal of Pharmaceutics. 2007 Nov;344(1-2):150-153. DOI: 10.1016/j.ijpharm.2007.04.028.
- 2. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

## Amphotericin B Ophthalmic Solution 2.5 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye Drop	2.5 mg/mL	- Must be prepared in a laminar
Ingredients	Quan	itity	flow hood.
Amphotericin B (Fungizone) 50 mg vial	1 Vial		<ul> <li>Do NOT FILTER - Colliodal suspenssion</li> <li>Fungizone, containing</li> </ul>
Sterile Water for Injection (SWFI)	qs. 10	) mL	<ul> <li>Fungizone, containing deoxycholate, is an irritant for the cornea, which reduces patient compliance</li> <li>Eye drops based on liposomal amphotericin B (AmBisome would be a convenient alternative) require the use of a 5-micron filter upon transferring to a sterile ophthalmic dropper bottle</li> </ul>

## **Equipment Needed**

Sterile dropper bottle, and 5-micron filter needle

## Directions

- 1. Reconstitute 50 mg of the vial powder with 10 mL SWFI under a laminar air flow hood using an aseptic technique to make 5 mg/mL.
- 2. Shake the vial rapidly for 30 seconds to completely disperse the powder.
- 3. Withdraw 5 mL (25 mg) of the reconstituted solution via a 5-micron filter needle.
- 4. Remove the filter needle and transfer the reconstituted solution into a sterile, pyrogen-free ophthalmic dropper bottle.
- 5. Add 5 mL SWFI to give a final concentration of 2.5 mg/mL.
- 6. Close the dropper bottle.
- 7. Shake well to mix.
- 8. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Colliodal suspenssion	Refrigerate
Shelf life	Container Type	Special Instructions

- 1. Morand K, Bartoletti AC, Bochot A, et al. Liposomal amphotericin B eye drops to treat fungal keratitis: physico-chemical and formulation stability. International Journal of Pharmaceutics. 2007 Nov;344(1-2):150-153. DOI: 10.1016/j.ijpharm.2007.04.028.
- 2. Allen LV. Amphotericin B 2mg/ml ophthalmic solution. Int J Pharm Compound. 1998; (2):223.
- 3. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

## Amphotericin B Ophthalmic Solution 5 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye Drop	5 mg/mL	- Must be prepared in a laminar
Ingredients	Quantity		flow hood.
Amphotericin B (Fungizone) 50 mg vial	1 Vial		<ul> <li>Do NOT FILTER - Colliodal suspenssion</li> <li>Fungizone, containing</li> </ul>
Sterile Water for Injection (SWFI)	qs. 10	) mL	deoxycholate, is an irritant for the cornea, which reduces patient compliance  Eye drops based on liposomal amphotericin B (AmBisome would be a convenient alternative)  Require the use of a 5-micron filter upon transferring to a sterile ophthalmic dropper bottle

## **Equipment Needed**

Sterile dropper bottle, and 5-micron filter needle

## **Directions**

- 1. Reconstitute 50 mg of the vial powder with 10 mL SWFI under a laminar air flow hood using an aseptic technique to make 5 mg/mL.
- 2. Shake the vial rapidly for 30 seconds to completely disperse the powder.
- 3. Withdraw all the reconstituted solution via a 5-micron filter needle.
- 4. Remove the filter needle and transfer the reconstituted solution into a sterile, pyrogen-free ophthalmic dropper bottle.
- 5. Close the dropper bottle.
- 6. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Colliodal suspenssion	Refrigerate
Shelf life	Container Type	Special Instructions
7 days	Plastic ophthalmic sterile amber	For Ophthalmic use only, shake well before use and protect from light

#### References:

1. Morand K, Bartoletti AC, Bochot A, et al. Liposomal amphotericin B eye drops to treat fungal keratitis: physico-chemical and formulation stability. International Journal of Pharmaceutics. 2007 Nov;344(1-2):150-153. DOI: 10.1016/j.ijpharm.2007.04.028.

2.	Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4_9.

## **Cefazolin 5% Ophthalmic Solution**

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	50 mg/mL	- Must Be Prepared in a laminar
Ingredients	Quantity		flow hood
Cefazoline 1000 mg vial	1 Vial		<ul> <li>When adding cefazolin to the artificial tears, aseptically</li> </ul>
Distilled water used for injection (preservative-free)	4.5 mL		remove the dropper head in
Artificial tears—Tears Naturale II (Alcon) or Natear (Silom Medical)	qs. 4 mL		LAFH.

## **Equipment Needed**

Sterile dropper bottle, and 0.22-µm filter needle

## **Directions**

- 1. Reconstitute 1 gm cefazolin vial powder with 4.5 mL of distilled water used for injection (preservative-free) under a laminar air flow h ood using an aseptic technique, then shake to mix. Label it as vial A.
- 2. Shake well to dissolve the powder.
- 3. From vial A, withdraw 1 mL and dilute it in 3 mL of artificial tears vehicle and label it as vial B.
- 4. Withdraw the content of vial B into a syringe with a 0.22-µm filter needle
- 5. Remove the filter needle and transfer the solution to a sterile ophthalmic dropper bottle.
- 6. Shake well to mix.
- 7. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
4 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
28 days	Plastic amber	

- 1. Rojanarata T, Tankul J, Woranaipinich C, Potawanich P, Plianwong S, Sakulma S, Saehuan C. J Ocul Pharmacol Ther. 2010 Oct;26(5):485-90. doi: 10.1089/jop.2010.0036
- 2. Valiev, Abdujabborkh & Zdoryk, Oleksandr & Georgiyants, Victoriya. (2015). Chemical Stability of Pharmacy-Compounded Cefazolin Sodium Eye Drops. Pharmaceutical Chemistry Journal. 48. 759-761. 10.1007/s11094-015-1188-x.
- 3. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). *Extemporaneous Ophthalmic Preparations* (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

## Ceftazidime (Fortaz) Ophthalmic Solution 50 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye Drop	50 mg/mL	- Must Be Prepared in a laminar
Ingredients	Quantity		flow hood
Ceftazidime 1 g vial	1 Vial		
Distilled water used for injection (Preservative free)	qs. 10 mL		

## **Equipment Needed**

Sterile glass dropper bottle ,and 0.22-µm filter needle

## **Directions**

- 1. Reconstitute 1 gm of the Ceftazidime vial powder with 9.5 mL of distilled water used for injection (preservative-free) under a laminar air flow hood using an aseptic technique to make 1 gm/10mL.
- 2. Withdraw 5 mL from the reconstituted solution (500 mg) via 0.22-micron filter needle.
- 3. Remove the filter needle and transfer the solution into a sterile, pyrogen free ophthalmic dropper bottle.
- 4. Add 5 mL of distilled water used for injection (preservative-free) to the bottle to make the final concentration of 500 mg/10 mL (50 mg/mL).
- 5. Close the dropper bottle.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
7 days	Sterile glass or plastic amber dropper bottle	For ophthalmic use only

- 1. Gautier, Eric & Justine, Saillard & Deshayes, Caroline & Vrignaud, Sandy & Lagarce, Frederic & Briot, Thomas. (2018). Stability of a 50 mg/mL Ceftazidime Eye-Drops Formulation. Pharmaceutical Technology in Hospital Pharmacy. 3. 10.1515/pthp-2018-0025.
- 2. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

# Ceftriaxone 50 mg/mL 5%

Route	<b>Dosage Form</b>	Concentration	Note	
Topical ophthalmic	Eye drop	50 mg/mL	- Must be prepared in a laminar	
Ingredients	Quantity		flow hood	
Ceftriaxone 1 g vial for injection	500 mg			
0.9% Sodium chloride (preservative-free)	9.6 mL			

## **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

## **Directions**

- 1. Reconstitute 1 g Ceftriaxone vial with 9.6 ml of 0.9% sodium chloride (used for injection) to prepare 100 mg/mL using an aseptic technique.
- 2. Withdraw 5 mL (500 mg) and transfer to an empty dropper bottle via a 0.22-μm filter needle.
- 3. Add 5 mL sodium chloride 0.9% to constitute Ceftriaxone to give the final concentration of 500 mg/10 mL = 50 mg/mL.
- 4. Transfer to a sterile ophthalmic dropper bottle via a 0.22-µm filter needle.
- 5. Label the bottle.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Solution	Refrigerator or room temperature
Shelf life	Container Type	Special Instructions
	Sterile dropper	

#### References:

1. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

## Clindamycin Ophthalmic Solution 50 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	50 mg/mL	- Must Be Prepared in a laminar
Ingredients	Quantity		flow hood
Clindamycin 300 mg/ 2 mL	5 mL		
Distilled water used for injection (preservative free)	qs. 15 mL		

## **Equipment Needed**

Sterile dropper bottle, and 0.22-µm filter needle

## **Directions**

- 1. Withdraw 5 mL (750 mg) of Clindamycin 300 mg/ 2 mL ampule via a 0.22- $\mu$ m filter needle under a laminar air flow hood using an aseptic technique.
- 2. Remove the filter needle and transfer it ito a sterile ophthalmic dropper bottle.
- 3. Add 10 mL distilled water used for injection (preservative free) to make the final concentration (50 mg/mL).
- 4. Close the dropper bottle.
- 5. Shake well to mix.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition	
15 mL	Clear solution	Refrigerate	
Shelf life	Container Type	Special Instructions	
24 hours	Plastic ophthalmic sterile dropper bottle	For ophthalmic use only	

#### References:

1. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). *Extemporaneous Ophthalmic Preparations* (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

## Colistimethate Ophthalmic Solution 16 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	16 mg/mL	- Must Be Prepared in a laminar
Ingredients	Quantity		flow hood
Colistimethate sodium injection 1 million IU/80 mg	1 Vial		
Distilled water used for injection (preservative free)	5 mL		

## **Equipment Needed**

Sterile dropper bottle, and 0.22-µm filter needle

## **Directions**

- 1. With 5 mL of distilled water used for injection (preservative free), reconstitute an 80 mg vial of Colistimethate under a laminar air flow hood using an aseptic technique to make 16 mg/mL.
- 2. Shake well to dissolve the powder.
- 3. Transfer the reconstituted solution into a sterile, pyrogen-free ophthalmic dropper bottle
- 4. Close the dropper bottle.
- 5. Shake well to mix.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition
5 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
1 day	Sterile dropper bottle (plastic or glass	For ophthalmic use only

- 1. Lim LM, Ly N, Anderson D, et al. Resurgence of colistin: a review of resistance, toxicity, pharmacodynamics, and dosing. Pharmacotherapy: J Human Pharm and Drug Ther.2010;30(12):1279–91.
- 2. Chatterjee S, Agrawal D. Multi-drug resistant Pseudomonas aeruginosa keratitis and its effective treatment with topical colistimethate. Indian J Ophthalmol. 2016;64(2):153.
- 3. Loyd V. Allen, Jr, PhDProfessor EmeritusCollege of Pharmacy, University of OklahomaOklahoma City, Oklahoma. (2011, April 20). Colistimethate Sodium 1.2 mg/mL Ophthalmic Solution. Uspharmacist. Retrieved July 19, 2022, from <a href="https://www.uspharmacist.com/article/colistimethate-sodium-12-mgml-ophthalmic-solution">https://www.uspharmacist.com/article/colistimethate-sodium-12-mgml-ophthalmic-solution</a>.
- 4. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [E-book]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

Cyclosporine	1% Oph	thalmic S	Solution

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	10 mg/mL	- Must Be Prepared in a laminar
Ingredients	Quantity		flow hood
Cyclosporine 50 mg/mL Injection (5 mL) Sandimmune®	3 mL		<ul> <li>Hazardous medication must be prepared following (USP 800)</li> </ul>
Liquifilm tears (polyvinyl alcohol and povidone 1.4%, 0.6%)	qs. 15 mL		

# **Equipment Needed**

0.22- $\mu m$  filter needle, and sterile dropper bottle

## **Directions**

- 1. Reconstitute 3 mL of 50 mg/mL Cyclosporine solution with 12 mL of liquifilm tears using an aseptic technique.
- 2. Transfer to a sterile ophthalmic dropper bottle via a 0.22-µm filter needle.
- 3. Close the dropper bottle.
- 4. Shake well to mix.
- 5. Label.

Formula Qty Final	Final Product Description	Storage Condition	
15 mL	Clear solution	Refrigerate	
Shelf life	Container Type	Special Instructions	
30 days	Plastic ophthalmic sterile dropper bottle	For ophthalmic use only  Caution Hazardous, Handle properly	

## **References:**

1. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

## **Cyclosporine 2% Ophthalmic Solution**

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	20 mg/mL	- Must Be Prepared in a laminar
Ingredients	Quantity		flow hood
Cyclosporine 50 mg/mL Injection (5 mL) Sandimmune®	6 mL		<ul> <li>Hazardous medication must be prepared following (USP 800)</li> </ul>
Liquifilm tears (polyvinyl alcohol and povidone 1.4%, 0.6%)	qs. 15 mL		

## **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

## **Directions**

- 1. Reconstitute 6 mL of 50 mg/mL Cyclosporine solution with 9 mL of liquifilm tears using an aseptic technique.
- 2. Transfer to an empty dropper bottle via a 0.22- $\mu m$  filter needle.
- 3. Close the dropper bottle.
- 4. Shake well to mix.
- 5. Label.

Formula Qty Final	Final Product Description	Storage Condition
15 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
30 days	Plastic ophthalmic sterile dropper bottle	For ophthalmic use only  Caution Hazardous, Handle properly

## **References:**

1. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). *Extemporaneous Ophthalmic Preparations* (1st ed. 2020 ed.) [E-book]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

## Fortified Gentamicin Solution 14 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	14 mg/mL	- Must Be Prepared in a laminar
Ingredients	Quar	ntity	flow hood
Gentamicin 80 mg/2mL Ampule	2 m	nL	<ul> <li>When adding Gentamicin to the Gentamicin 0.3% bottle, aseptically remove the dropper</li> </ul>
Gentamicin Ophtalmic Solution 0.3% (15 mg/5 ml)	5 mL		<ul> <li>headthe in laminar flow hood</li> <li>Do not attempt to use a needle through the dropper head, which may alter the intended drop size</li> <li>Use the extemporaneously prepared formulation only when the commercial product is not available</li> </ul>

## **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

## **Directions**

- 1. Withdraw 2 mL of Gentamicin sulfate 80 mg/2 mL under a laminar airflow using an aseptic technique.
- 2. Mix with 5 mL of the commercially available Gentamicin ophthalmic solution 0.3% (15 mg/5 mL).
- 3. Transfer to a sterile ophthalmic dropper bottle via a 0.22-µm filter needle.
- 4. Close the bottle.
- 5. Shake well to mix.
- 6. Label the bottle.

Formula Qty Final	Final Product Description	Storage Condition
7 mL	Clear soultion	Refrigerate
Shelf life	Container Type	Special Instructions
7 days	Plastic ophthalmic sterile dropper bottle	For ophthalmic use only

- 1. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.
- 2. McBride HA, Martinez DR, Trang JM, Lander RD, Helms HA. Stability of gentamicin sulfate and tobramycin sulfate in extemporaneously prepared ophthalmic solutions at 8 degrees C. Am J Hosp Pharm. 1991 Mar;48(3):507-9. PMID: 2028997.

prepared ophthalmic solutions at 8 degrees C. Am J Hosp Phar	m. 1991 Mar;48(3):507-9. PMID: 2028997.	
	34	

3. McBride HA, Martinez DR, Trang JM, Lander RD, Helms HA. Stability of gentamicin sulfate and tobramycin sulfate in extemporaneously

## Mitomycin-C 0.02% Ophthalmic Solution

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	0.2 mg/mL	- Must Be Prepared in a laminar
Ingredients	Quantity		flow hood  - Hazardous medication must be prepared following (USP 800)  - Caution : Anti-neoplastic agent  - The formula for four dropper bottles
Mitomycin 10 mg	1 Vial 50 mL		
Distilled water for used injection (Preservative-free)			

## **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

## **Directions**

- 1. Reconstitute 10 mg Mitomycin vial powder with 50 mL of distilled water for used injection (preservative-free) under a vertical laminar airflow hood to make 0.2 mg/mL.
- 2. From the Mitomycin-c solution vial, withdraw 12.5 mL via a 0.22-micron filter needle.
- 3. Transfer to an empty sterile bottle.
- 4. Close the dropper bottle.
- 5. Shake well to mix.
- 6. Label with chemotherapy handling, disposal precautions, and store out of direct light.

Formula Qty Final	Final Product Description	Storage Condition
12.5 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
14 days	Sterile amber dropper bottle	For ophthalmic use only and protect from light

- 1. Velpandian T, Saluja V, Ravi AK, et al. Evaluation of the stability of extemporaneously prepared ophthalmic formulation of mitomycin C. Journal of Ocular Pharmacology and Therapeutics Jun 2005;21(3):217-222.
- 2. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). Extemporaneous Ophthalmic Preparations (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4 9.

# Mitomycin-C 0.04% Ophthalmic Solution

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	0.4 mg/mL	- Hazardous medication must be
Ingredients	Quantity		prepared following (USP 800)
Mitomycin 10 mg	1 Vial		<ul><li>Caution : Anti-neoplastic agent</li><li>The formula for two dropper</li></ul>
Distilled water for used injection (Preservative-free)	25 mL		bottles

# **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

### **Directions**

- 1. Reconstitute 10 mg Mitomycin vial powder with 25 mL of distilled water for used injection (preservative-free) under a vertical laminar airflow hood to make 0.2 mg/mL.
- 2. From the Mitomycin-c solution vial, withdraw 12.5 mL via a 0.22-micron filter needle.
- 3. Transfer to an empty sterile bottle.
- 4. Close the dropper bottle.
- 5. Shake well to mix.
- 6. Label with chemotherapy handling, disposal precautions, and store out of direct light.

Formula Qty Final	Final Product Description	Storage Condition
12.5 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
14 days	Sterile amber dropper bottle (plastic or glass)	For ophthalmic use only and protect from light  Caution, Chemotherapy, Handle properly

- 1. Velpandian T, Saluja V, Ravi AK, et al. Evaluation of the stability of extemporaneously prepared ophthalmic formulation of mitomycin C. Journal of Ocular Pharmacology and Therapeutics Jun 2005;21(3):217-222.
- 2. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). *Extemporaneous Ophthalmic Preparations* (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

# Potassium Permanganate 1:8000 Solution

Route	Dosage Form	Concentration	Note
Topical	Solution	1:8000	- Other ratios can be prepared using
Ingredients	Quantity		the following calculations:
Potassium permanganate powder	0.125 g		Ex. for the (1:8000) ratio. 1/8000*100% = 0.0125%
Distilled water	1000 mL		= 0.0125 gm = 12.5 mg 12.5 mg → 100 mL ? → 1000 mL = 125 mg in 1000 mL = 0.125 g in 1000 mL

# **Equipment Needed**

Electronic balance, graduated cylinder, and amber bottle

### **Directions**

- 1. Weight the potassium permanganate powder.
- 2. Dissolve the powder with distilled water.
- 3. Transfer to a bottle.
- 4. Label with an expiry date.

Formula Qty Final	Final Product Description	Storage Condition
1000 mL	Purple solution	Room temperature
Shelf life	Container Type	Special Instructions
2 weeks	Amber bottle	For external use only, and protect from light and moisture

### **References:**

1. Farouq Shaker, N. (2012). Extemporaneous Preparations Adult and Pediatric Guide (1st ed.).

# **Salicylic Acid 10% Ointment**

Route	Dosage Form	Concentration	Note
Topical	Ointment	10 %	<ul> <li>Other concentrations of</li> </ul>
Ingredients	Quantity		salicylic acid ointment can be
Salicylic acid powder	10 g		prepared using the same procedure (3%, 6%, 20%,
White soft paraffin (Vaseline)	100 g		30%, 40%)

# **Equipment Needed**

Mortar and pestle, spatula, electronic balance, and ointment jar

# **Directions**

- 1. Measure out the salicylic acid powder.
- 2. Using mortar and pestle, levigate salicylic acid powder with liquid paraffin to form a paste.
- 3. Weigh the Vaseline, add to a paste, and mix well.
- 4. Transfer the contents into a jar.
- 5. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 g	Ointment	Room temperature
Shelf life	Container Type	Special Instructions
6 months (or 25% of the time remaining on the product's expiration date, which comes earlier)	Ointment jar	For external use only

### **References:**

1. Farouq Shaker, N. (2012). Extemporaneous Preparations Adult and Pediatric Guide (1st ed.).

# Tacrolimus Ophthalmic Solution 100 µg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	100 μg/mL	- Must be prepared in a laminar flow
Ingredients	Quantity		hood
Tacrolimus capsule (Prograf) 1000 μg	1 Capsule		- Hazardous medication must be prepared following (USP 800)
Balanced salt solution	10 mL		

# **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

### **Directions**

- 1. Aseptically add a balanced salt solution (10 mL) to a tacrolimus capsule (Prograf) 1000  $\mu$ g under a laminar air flow hood to achieve a 100  $\mu$ g/mL concentration
- 2. Withdraw the content of the solution using a 0.22-µm filter needle.
- 3. In a sterile ophthalmic dropper bottle, transfer the solution.
- 4. Close the dropper bottle.
- 5. Label.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
30 days	Plastic ophthalmic sterile dropper bottle	For ophthalmic use only  Caution Hazardous, Handle properly

- 1. Shoughy SS, Jaroudi MO, Tabbara KF. Efficacy and safety of low-dose topical tacrolimus in vernal keratoconjunctivitis. Clin Ophthalmol. 2016;10:643.
- 2. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). *Extemporaneous Ophthalmic Preparations* (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

# Vancomycin Ophthalmic Solution 25 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye Drop	25 mg/mL	- Must be prepared in a laminar
Ingredients	Quantity		flow hood
Vancomycin 500 mg	1 Vial		<ul> <li>Prepare by using an aseptic technique under a class 100 horizontal-laminar-airflow hood</li> </ul>
Distilled water used for injection, USP	10 mL		<ul> <li>When adding vancomycin to the artificial tears, aseptically remove the dropper head in the laminar</li> </ul>
Artificial Tear (Tears Naturale)	qs. 10 mL		flow hood  - Calculate any other brand for powder volume displacement

# **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

### **Directions**

- 1. Reconstitute 500 mg Vancomycin vial powder with 10 mL of distilled water used for injection, USP under a laminar air flow hood using an aseptic technique to make 50 mg/mL.
- 2. Withdraw 5 mL of vancomycin injectable solution via a 0.22-µm filter needle.
- 3. Transfer the reconstituted solution into a sterile, pyrogen- free ophthalmic dropper bottle and add 5 mL of artificial tears to make the final volume 10 mL.
- 4. Close the dropper bottle.
- 5. Shake well to mix.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
7 days	Sterile dropper bottle (plastic or glass)	For ophthalmic use only

### References:

 Montes, J. A., Johnson, D., Jorgensen, J., McElmeel, M. L., Fulcher, L. C., & Kiel, J. W. (2016). Potency and Sterility of Fortified Tobramycin, Fortified Vancomycin, and Moxifloxacin at 4, 24, and 35°C for 14 Days. *Cornea*, 35(1), 122–126. https://doi.org/10.1097/ico.000000000000676.

# Vancomycin Ophthalmic Solution 31 mg/mL

Dosage Form	Concentration	Note
Eye Drop	31 mg/mL	- Must be prepared in a laminar
Quantity		flow hood  - When adding vancomycin to the artificial tears, aseptically
1 Vial		
5 mL		remove the dropper head in the laminar flow hood
qs. 15 mL		<ul> <li>Calculate any other brand for powder volume displacement</li> </ul>
	Eye Drop Quar 1 Vi	Eye Drop 31 mg/mL  Quantity  1 Vial  5 mL

# **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

### **Directions**

- 1. Reconstitute 500 mg Vancomycin vial powder with 5 mL of distilled water used for injection, USP under a laminar air flow hood using an aseptic technique to make 100 mg/mL.
- 2. Remove the dropper from the artificial tears bottle and withdraw 4.6 mL from 15 mL bottle and discard.
- 3. Withdraw 4.6 mL of vancomycin injectable solution.
- 4. Change to a 0.22-micron filter needle.
- 5. Transfer the reconstituted solution into the remaining artificial tear bottle to make 15 mL.
- 6. Close the dropper bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
15 mL	Clear solution	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
10 days refrigerated 7 days at room temperature	Sterile dropper bottle (plastic or glass)	For ophthalmic use only

- 1. Fuhrman, L. C., Jr, & Stroman, R. T. (1998). Stability of vancomycin in an extemporaneously compounded ophthalmic solution. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists, 55*(13), 1386–1388. https://doi.org/10.1093/ajhp/55.13.1386
- 2. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). *Extemporaneous Ophthalmic Preparations* (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

# Vancomycin Ophthalmic Solution 50 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye Drop	50 mg/mL	- Must be prepared in a laminar
Ingredients	Quantity		flow hood
Vancomycin 500 mg	1 Vial		<ul> <li>When adding vancomycin to the artificial tears, aseptically</li> </ul>
Distilled water used for injection, USP	10 mL		remove the dropper head in the laminar flow hood - Calculate any other brand for powder volume displacement

# **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

### **Directions**

- 1. Reconstitute 500 mg Vancomycin vial powder with 10 mL of distilled water used for injection, USP under a laminar air flow hood using an aseptic technique to make 50 mg/mL.
- 2. Transfer the reconstituted solution into a sterile, pyrogen-free ophthalmic dropper via a 0.22-micron filter needle.
- 3. Close the dropper bottle.
- 4. Shake well to mix.
- 5. Label.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Clear solution	Refrigerate
Shelf life	Container Type	Special Instructions
7 days	Sterile dropper bottle (plastic or	For ophthalmic use only

### **References:**

1. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). *Extemporaneous Ophthalmic Preparations* (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.

# Voriconazole 1% Ophthalmic Solution 10 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	10 mg/mL	- Must be prepared in a laminar
Ingredients	Quantity		flow hood
Voriconazole injection (dry powder) 200 mg	1 Vial		<ul> <li>Hazardous medication must be prepared following (USP 800)</li> </ul>
Distilled water used for injection (preservative free)	19 mL		

# **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

### **Directions**

- 1. Add 19 mL of distilled water for injection (preservative free) to 200 mg Voriconazole vial, this result in a final concentration of 200 mg/ 20 mL = (10 mg/mL).
- 2. Withdraw 20 mL solution via a 0.22-micron filter needle and transfer it into a sterile, Pyrogen-free ophthalmic dropper bottle.
- 3. Close the dropper bottle.
- 4. Shake well to mix.
- 5. Label.

Formula Qty Final	Final Product Description	Storage Condition
20 mL	Clear solution	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions

### **References:**

1. Dupuis, Antoine & Tournier, Nicolas & Moal, Gwenaël & Venisse, Nicolas. (2008). Preparation and Stability of Voriconazole Eye Drop Solution. Antimicrobial agents and chemotherapy. 53. 798-9. 10.1128/AAC.01126-08.

# Voriconazole 2% Ophthalmic Solution 20 mg/mL

Route	Dosage Form	Concentration	Note
Topical ophthalmic	Eye drop	20 mg/mL	- Must be prepared in a laminar
Ingredients	Quantity		flow hood
Voriconazole injection (dry powder) 200 mg	1 Vial		<ul> <li>Hazardous medication must be prepared following (USP 800)</li> </ul>
Distilled water used for injection (preservative free)	9 mL		

# **Equipment Needed**

0.22-µm filter needle, and sterile dropper bottle

### **Directions**

- 1. Add 9 mL of distilled water for injection (preservative free) to 200 mg voriconazole vial, this result in a final concentration of 200 mg/ 10 mL = (20 mg/mL)
- 2. Withdraw 10 mL solution via a 0.22-micron filter needle and transfer it into a sterile, pyrogen-free ophthalmic dropper bottle.
- 3. Close the dropper bottle.
- 4. Shake well to mix.
- 5. Label.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Clear solution	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
30 days	Sterile dropper bottle (Plastic or Glass)	For ophthalmic use only, only  Caution Hazardous, Handle properly

### **References:**

1. Alghamdi, E. A. S., Qahtani, A. A. Y., Sinjab, M. M., & Alyahya, K. M. (2020). *Extemporaneous Ophthalmic Preparations* (1st ed. 2020 ed.) [Ebook]. Springer. https://doi.org/10.1007/978-3-030-27492-4\_9.



# Elixir/Solution/Suspension/Syrup

# Acetazolamide Oral Suspension 25 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	25 mg/mL	<ul> <li>Ora-Sweet SF® should not be</li> </ul>
Ingredients	Quantity		used in neonates ≤28 days
Acetazolamide 250 mg	12 Tablets		corrected age
Ora-Sweet® : Ora-Plus® or Ora-Sweet SF® : Ora-Plus® (1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and amber plastic bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduate cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with small portions of the vehicle and mix to form a uniform paste.
- 4. As you mix, add the vehicle in incremental proportions to almost 120 mL.
- 5. Transfer the mortar's content to a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of
- 7. Transfer the graduated cylinder's contents to an amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	<b>Container Type</b>	Special Instructions
60 days	Plastic amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of acetazolamide, allopurinol, azathioprine, clonazepam, and flucytosine in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(16), 1944–1949. https://doi.org/10.1093/ajhp/53.16.1944

# Acetazolamide Oral Suspension 25 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	25 mg/mL	- Cherry syrup: simple syrup (1:4)
Ingredients	Quantity		ratio
Acetazolamide 250 mg	12 Tablets		
Cherry syrup	20 mL		
Simple syrup	qs. 120 mL		

### **Equipment Needed**

Mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and plastic amber bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. Levigate with small portions of cherry syrup and mix to form a uniform paste.
- 3. As you mix, add the simple syrup in incremental proportions to almost 120 mL.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the syrup and add it to the graduated cylinder until the final volume of 120 mL.
- 6. Transfer the graduated cylinder's contents to an amber bottle.
- 7. Shake well to mix.
- 8. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of acetazolamide, allopurinol, azathioprine, clonazepam, and flucytosine in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(16), 1944–1949. https://doi.org/10.1093/ajhp/53.16.1944

# Allopurinol Oral Suspension 20 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	20 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Allopurinol 100 mg	24 Tablets		corrected age
Ora-Sweet® : Ora-Plus® or Ora-Sweet SF® : Ora-Plus® (1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduate cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with small portions of the vehicle and mix to form a uniform paste.
- 4. As you mix, add the vehicle in incremental proportions to almost 120 mL.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of
- 7. Transfer the graduated cylinder's contents to an amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of acetazolamide, allopurinol, azathioprine, clonazepam, and flucytosine in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(16), 1944–1949. https://doi.org/10.1093/ajhp/53.16.1944

# Allopurinol Oral Suspension 20 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	20 mg/mL	- Cherry syrup: simple syrup
Ingredients	Quantity		(1:4) ratio
Allopurinol 100 mg	24 Tablets		
Cherry syrup	30 mL		
Simple syrup	qs. 120 <b>mL</b>		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. Levigate with small portions of cherry syrup and mix to form a uniform paste.
- 3. As you mix, add the simple syrup in incremental proportions to almost 120 mL.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the syrup and add it to the graduated cylinder until the final volume of 120 mL.
- 6. Transfer the graduated cylinder contents to an amber plastic bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Cautain an Tana	
Sileil ille	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of acetazolamide, allopurinol, azathioprine, clonazepam, and flucytosine in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(16), 1944–1949. https://doi.org/10.1093/ajhp/53.16.1944

# Amiodarone Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	5 mg/mL	- To prepare Sodium Bicarbonate
Ingredients	Quantity		8.4%:
Amiodarone 200 mg	3 Tablets powder in 10		Mix 5 g of sodium bicarbonate powder in 100 mL distilled water
Sodium Bicarbonate	±4* mL		<ul> <li>Add sodium bicarbonate 8.4%</li> <li>to adjust the pH of the mixture</li> </ul>
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 12	0 mL	to 6-7  - * The volume listed is an estimate, more or less may be needed

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), stirring rod, counting tray, pH meter, and plastic bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet® and 60 mL of Ora-Plus® vehicle.
- 3. Use the sodium bicarbonate to adjust the pH of the mixture to 6-7.
- 4. Levigate the powder with small portions of the vehicle and mix to form a uniform paste.
- 5. As you mix, add the vehicle in incremental proportions to almost 120 mL.
- 6. Pour the mortar's contents into a graduated cylinder.
- 7. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 120 mL.
- 8. Transfer the graduated cylinder's contents to a plastic bottle.
- 9. Shake well to mix.
- 10. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
91 days refrigerated or 42 days at room temperature	Plastic prescription bottle	Shake well before use

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Jew, R., Soo-Hoo, W., Amiri, E., & Gomes, J. (2022). *Extemporaneous formulations for pediatric, geriatric and special needs patients* (4th ed., p. 9). Harvey Whitney Books DOI: 10.37573/9781585286522.

# Amiodarone Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	5 mg/mL	- Methylcellulose 1% solution :
Ingredients	Quantity		Simple Syrup (1 :1) ratio
Amiodarone 200 mg	3 Tablet		
Methylcellulose 1% solution	60 mL		
Simple Syrup	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), stirring rod, counting tray, and plastic bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduated cylinder, mix 60 mL of methylcellulose 1% and 60 mL of simple syrup vehicle.
- 3. Levigate the powder with small portions of the vehicle and mix to form a uniform paste.
- 4. As you mix, add the vehicle in incremental proportions to almost 120 mL.
- 5. Rinse the mortar and pestle and transfer to an appropriate sized plastic bottle.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
91 days refrigerated or 42 days at room temperature	Glass or plastic prescription bottle	Shake well before use

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Nahata M. C. (1997). Stability of amiodarone in an oral suspension stored under refrigeration and at room temperature. *The Annals of pharmacotherapy*, *31*(7-8), 851–852. https://doi.org/10.1177/106002809703100707

# Amitriptyline Oral Suspension 20 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	20 mg/mL	- Must be shaken vigorously to
Ingredients	Quantity		form a suspension
Amitriptyline 25 mg	96 Tablets		
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), stirring rod, counting tray, and plastic bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduate cylinder, mix 60 mL of Ora-sweet and 60 mL of Ora-Plus vehicle, Use mixture as vehicle.
- 3. Levigate the powder with small portions of the vehicle and mix to form a uniform paste.
- 4. As you mix, add the vehicle in incremental proportions to almost 120 mL.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume reaches 120 mL.
- 7. Transfer the graduated cylinder's contents to a plastic bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
91 days	Plastic bottle	Shake well before use

### References:

1. Nahata M. C. (2016). Long-term Stability of Zonisamide, Amitriptyline, and Glycopyrrolate in Extemporaneously Prepared Liquid-dosage Forms at Two Temperatures. *International journal of pharmaceutical compounding*, 20(2), 164–166.

# Amlodipine Oral Suspension 1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	1 mg/mL	
Ingredients	Quantity		
Amlodipine 5 mg	24 Tablets		-
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), stirring rod, counting tray, and amber plastic bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. Levigate with small portions of the chosen vehicle and mix to form a uniform paste.
- 3. As you mix, add the vehicle in incremental proportions to almost 120 mL.
- 4. Transfer the content to a calibrated bottle.
- 5. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 120 mL.
- 6. Transfer the graduated cylinder contents to an amber plastic bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
91 days refrigerated 56 days at room temperature	Plastic amber bottle	Shake well before use

- 1. Nahata, M. C., Morosco, R. S., & Hipple, T. F. (1999). Stability of amlodipine besylate in two liquid dosage forms. *Journal of the American Pharmaceutical Association (Washington, D.C. : 1996), 39*(3), 375–377. https://doi.org/10.1016/s1086-5802(16)30454-5
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

Route	Dosage Form	Concentration	Note
Oral	Suspension	1 mg/mL	- Methylcellulose 1% solution :
Ingredients	Quantity		Simple Syrup (1:1) ratio
Amlodipine 5 mg	24 Tablets		
Methylcellulose 1% Solution	60 mL		
Simple Syrup	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), stirring rod, counting tray, and amber plastic bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduated cylinder, mix 60 mL of methylcellulose 1% and 60 mL of simple syrup vehicle.
- 3. Levigate the powder with small portions of the vehicle and mix to form a uniform paste.
- 4. As you mix, add the vehicle in incremental proportions to almost 120 mL.
- 5. Transfer the content to a calibrated bottle.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 120 mL.
- 7. Transfer the graduated cylinder contents to an amber plastic bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
91 days refrigerated 56 days at room temperature	Plastic amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., Morosco, R. S., & Hipple, T. F. (1999). Stability of amlodipine besylate in two liquid dosage forms. *Journal of the American Pharmaceutical Association (Washington, D.C.: 1996), 39*(3), 375–377. <a href="https://doi.org/10.1016/s1086-5802(16)30454-5">https://doi.org/10.1016/s1086-5802(16)30454-5</a>
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

### Atenolol Oral Suspension 2 mg/mL **Route Dosage Form** Concentration **Note** Ora-Sweet SF® should not be Oral Suspension 2 mg/mL **Ingredients** Quantity used in neonates ≤28 days corrected age Atenolol 50 mg 4 Tablets Glycerin 4 mL Ora-Sweet SF® qs. 100 mL

# **Equipment Needed**

Mortar and pestle, graduated cylinder, counting tray, stirring rod, and amber bottle.

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. Levigate with small portions of glycerin and mix to form a uniform paste.
- 3. As you mix, add Ora-Sweet SF® vehicle in incremental proportions.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 100 mL.
- 6. Transfer the graduated cylinder contents to an amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
90 days	Amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Patel, D., Doshi, D. H., & Desai, A. (1997). Short-term stability of atenolol in oral liquid formulations. *International journal of pharmaceutical compounding*, 1(6), 437–439.
- 3. Jew, R. K., Soo-Hoo, W., Amiri, E., & Gomes, J. M. (2022). "Atenolol Syrup 2 mg/mL—Formulation 2\*". In *Extemporaneous Formulations*. Bethesda MD, USA: ASHP. Retrieved Apr 3, 2023, from <a href="https://doi.org/10.37573/9781585286522.016">https://doi.org/10.37573/9781585286522.016</a>.

# Azathioprine Oral Suspension 50 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	50 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Azathioprine 50 mg	120 Tablets		800) - Ora-Sweet SF® should not be
Ora-Sweet®: Ora-Plus® or Ora-Sweet SF®: Ora-Plus® (1:1)	qs. 12	0 mL	used in neonates ≤28 days corrected age

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduate cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with small portions of the vehicle and mix to form a uniform paste.
- 4. As you mix, add the vehicle in incremental proportions almost to volume.
- 5. Transfer the mortar's contents to a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduate cylinder until the final volume of 120 mL
- 7. Transfer the contents of the cylinder to an amber plastic bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions

- 1. Lam M. S. (2011). Extemporaneous compounding of oral liquid dosage formulations and alternative drug delivery methods for anticancer drugs. *Pharmacotherapy*, *31*(2), 164–192. https://doi.org/10.1592/phco.31.2.164
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of acetazolamide, allopurinol, azathioprine, clonazepam, and flucytosine in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(16), 1944–1949. <a href="https://doi.org/10.1093/ajhp/53.16.1944">https://doi.org/10.1093/ajhp/53.16.1944</a>
- 3. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

# Azathioprine Oral Suspension 50 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	50 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Azathioprine 50 mg	120 Tablets		800) - Cherry syrup: simple syrup
Cherry syrup	30 mL		(1:4) ratio
Simple syrup	qs. 120 mL		

### **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and amber plastic bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduate cylinder, mix 30 mL of Cherry syrup and 90 mL of Simple syrup vehicle.
- 3. Levigate with approximately 40 mL of the vehicle and mix to form a uniform paste.
- 4. As you mix, add the vehicle in incremental proportions almost to volume.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduate cylinder until the final volume of 120 mL
- 7. Transfer the graduated cylinder contents to an amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions

- 1. Lam M. S. (2011). Extemporaneous compounding of oral liquid dosage formulations and alternative drug delivery methods for anticancer drugs. *Pharmacotherapy*, *31*(2), 164–192. <a href="https://doi.org/10.1592/phco.31.2.164">https://doi.org/10.1592/phco.31.2.164</a>
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of acetazolamide, allopurinol, azathioprine, clonazepam, and flucytosine in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(16), 1944–1949. https://doi.org/10.1093/ajhp/53.16.1944.

# Busulfan Oral Suspension 2 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	2 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Busulfan 2 mg	100 Tablets		800)
Simple Syrup	qs. 100 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and amber bottle

# **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. Add small portions of simple syrup and mix to form a uniform paste.
- 3. As you mix, add the simple syrup in incremental proportions to almost 100 mL.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 100 mL.
- 6. Transfer the graduated cylinder contents to an amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
30 days	Amber bottle	Shake well before use and protect from light Caution Chemotherapy, Handle properly

- 1. Allen, L. V. (1990). Busulfan oral suspension. US Pharm, 15, 94-5.
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# Carvedilol Oral Suspension 1.67 mg/mL

Route	Dosage Form	Concentration	
Oral	Suspension	1.67 mg/mL	
Ingredients	Quantity		
Carvedilol 25 mg	8 Tablets		
Purified water	20 mL		
Ora-Plus®	60 mL		
Ora-Sweet®	qs. 12	qs. 120 mL	

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass amber bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a glass mortar and pestle.
- 2. Levigate with 20 mL of purified water and mix to a uniform paste.
- 3. As you mix, add Ora-Plus® in incremental proportions.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using Ora-Sweet® and pour it into a graduated cylinder.
- 6. Add Ora-Sweet® to the graduated cylinder to achieve a total volume of 120 mL.
- 7. Transfer the graduated cylinder's contents to an amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
84 days	Glass amber bottle	Shake well before use and protect from light

### References:

1. Jew, R., Soo-Hoo, W., Amiri, E., & Gomes, J. (2022). *Extemporaneous formulations for pediatric, geriatric and special needs patients* (4th ed., p. 9). Harvey Whitney Books DOI: 10.37573/9781585286522.030.

# Chlorpromazine HCl Oral Solution 100 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Solution	100 mg/mL	- The tablet cannot be selected
Ingredients	Quantity		instead of the powder due to
Chlorpromazine HCl powder	12 g		the presence of insoluble excipients which are
Ora-Sweet®	qs. 12	0 mL	undesirable for the sublingual/buccal delivery rout that can negatively affect the drug absorption process

### **Equipment Needed**

Mortar and pestle, weigh paper, stirring rod, balance, graduated cylinder, and plastic amber bottle.

### **Directions**

- 1. Weigh out chlorpromazine HCl powder and triturate to a fine powder.
- 2. Levigate the powder with small portions of Ora-Sweet®to form a uniform paste.
- 3. As you mix, add the vehicle in incremental proportions.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 120 mL.
- 6. Transfer the graduated cylinder's contents into a plastic amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Solution	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions

- 1. Jew, R., Soo-Hoo, W., Amiri, E., & Gomes, J. (2022). *Extemporaneous formulations for pediatric, geriatric and special needs patients* (4th ed., p. 9). Harvey Whitney Books DOI: 10.37573/9781585286522.037.
- 2. Prohotsky, D. L., Juba, K. M., & Zhao, F. (2014). Formulation and Stability of an Extemporaneously Compounded Oral Solution of Chlorpromazine HCl. Journal of Pain & Palliative Care Pharmacotherapy, 28(4), 367–370. https://doi.org/10.3109/15360288.2014.969874.

# Ciprofloxacin Oral Suspension 50 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	50 mg/mL	
Ingredients	Quantity		
Ciprofloxacin hydrochloride 500 mg	12 Tablets		-
Ora-Plus® : Simple Syrup (1 :1)	qs. 120 mL		

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

### **Directions**

- 1. Crush the tablets and triturate them to a fine powder with a mortar and pestle.
- 2. In a graduate cylinder, mix 60 mL of Ora-Plus® vehicle and 60 mL of Simple Syrup.
- 3. Levigate with a small amount of the vehicle to form a uniform paste.
- 4. Add the vehicle geometrically, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into the graduated cylinder to achieve the final volume of 120 mL.
- 7. Transfer the contents to an appropriate-size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions

### References:

1. Johnson, C. E., Wong, D. V., Hoppe, H. L., & Bhatt-Mehta, V. (1998). Stability of ciprofloxacin in an extemporaneous oral liquid dosage form. *International journal of pharmaceutical compounding*, *2*(4), 314–317.

# Clonidine Oral Suspension 0.1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	0.1 mg/mL	
Ingredients	Quantity		
Clonidine hydrochloride 0.1 mg	60 Tablets		-
Purified Water USP	2 mL		
Simple Syrup	qs. 60 mL		

# **Equipment Needed**

Glass mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and glass amber bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a glass mortar and pestle.
- 2. Levigate with 2 mL of purified water USP to form a uniform paste.
- 3. Add 15 mL of simple syrup to the paste, triturate well, and transfer to a graduated cylinder.
- 4. Rinse the mortar and pestle using the simple syrup and add it to the graduated cylinder until the final volume of 60 mL.
- 5. Transfer the contents into an appropriate size glass amber bottle.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
60 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
28 days	Glass amber bottle	Shake well before use and protect from light

- 1. Levinson, M. L., & Johnson, C. E. (1992). Stability of an extemporaneously compounded clonidine hydrochloride oral liquid. *American Journal of Health-System Pharmacy*, 49(1), 122–125. https://doi.org/10.1093/ajhp/49.1.122.
- 2. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

# Clopidogrel Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	5 mg/mL	
Ingredients	Quantity		
Clopidogrel 75 mg	8 Tablets		-
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, stirring rod, counting tray, graduated cylinder, and plastic amber bottle

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with a small amount of the vehicle to form a uniform paste.
- 4. Add the vehicle geometrically, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using a sufficient amount of vehicle and add it to the graduated cylinder until the final volume of 120 mL.
- 7. Transfer the contents into an appropriate size amber plastic bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Skillman, K. L., Caruthers, R. L., & Johnson, C. E. (2010). Stability of an extemporaneously prepared clopidogrel oral suspension. *American Journal of Health-System Pharmacy*, *67*(7), 559–561. https://doi.org/10.2146/ajhp090163.

# Cyclophosphamide Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Cyclophosphamide 1g injection	2 Vials		800) - Not for injection
0.9 % sodium chloride for injection	100 mL		
Ora-Plus <sup>®</sup> or simple syrup	qs. 200 mL		

# **Equipment Needed**

Sterile syringe with needle, graduated cylinder, and amber polypropylene oral syringe

### **Directions**

- 1. Reconstitute Cyclophosphamide 2 g injection vial with 100 mL of 0.9 % sodium chloride solution to achieve a solution of 20 mg /mL concentration.
- 2. Using two 60-mL syringes, withdraw the reconstituted solution.
- 3. Transfer the reconstituted solution to a graduated cylinder.
- 4. Add base solution to the graduated cylinder to achieve a total volume of 200 mL.
- 5. Transfer the graduated cylinder's contents into an appropriate amber polypropylene oral syringe.
- 6. Shake well to mix.
- 7. Label and store in a plastic bag.

Formula Qty Final	Final Product Description	Storage Condition
200 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
<ul> <li>56 days in the refrigerator</li> <li>For Ora- Plus: 3 days at room temperature</li> <li>For simple syrup: 8 days at room temperature</li> </ul>	Amber polypropylene oral syringe	Shake well before use, for oral use only, and protect from light  Caution Chemotherapy, Handle properly

### References:

1. Kennedy, R., Groepper, D., Tagen, M., Christensen, R., Navid, F., Gajjar, A., & Stewart, C. F. (2010). Stability of Cyclophosphamide in Extemporaneous Oral Suspensions. *Annals of Pharmacotherapy*, *44*(2), 295–301. https://doi.org/10.1345/aph.1m578.



# Route Dosage Form Concentration Note Oral Suspension 2 mg/mL Ingredients Quantity Dapsone 100 mg 4 Tablets Ora-Sweet®: Ora-Plus ®(1:1) qs. 200 mL

### **Equipment Needed**

Mortar and pestle, graduate cylinder counting tray, stirring rod, and plastic amber bottle.

### **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. In a graduated cylinder, mix 100 mL of Ora-Sweet® and 100 mL of Ora-Plus® vehicle.
- 3. Levigate with small portions of the vehicle and mix to a uniform Paste.
- 4. Add the vehicle in a geometric amount and mix well.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 200 mL.
- 7. Transfer the content into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
200 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions
91 days	Plastic amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Nahata, M. C., Morosco, R. S., & Trowbridge, J. M. (2000). Stability of Dapsone in Two Oral Liquid Dosage Forms. *Annals of Pharmacotherapy*, *34*(7–8), 848–850. https://doi.org/10.1345/aph.19273.

# Diltiazem Hydrochloride Oral Suspension 12 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	12 mg/mL	<ul> <li>Ora-Sweet SF® and Ora-</li> </ul>
Ingredients	Quantity		Blend SF® should not be used
Diltiazem Hydrochloride 60 mg tablet	24 Tablets		in neonates ≤28 days corrected age
Ora-Sweet® : Ora-Plus ®or Ora-Sweet SF® : Ora-Plus ®(1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduate cylinder counting tray, stirring rod, and plastic amber bottle

### **Directions**

- 1. Crush the tablets and triturate them to a fine powder.
- 2. In a graduate cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Add the vehicle in a geometric amount and mix well.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduate, until a total volume of 120 mL.
- 7. Transfer into an amber bottle of appropriate size.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber bottle	Shake well before use

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen LV, L. V., & Erickson, M. A. (1996). Stability of baclofen, captopril, diltiazem hydrochloride, dipyridamole, and flecainide acetate in extemporaneously compounded oral liquids. *American Journal of Health-System Pharmacy*, *53*(18), 2179–2184. https://doi.org/10.1093/ajhp/53.18.2179.

# Diltiazem Hydrochloride Oral Suspension 12 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	12 mg/mL	- Cherry syrup: simple syrup
Ingredients	Quantity		(1:4) ratio
Diltiazem Hydrochloride 60 mg tablet	24 Tablets		
Cherry Syrup	30 mL		
Simple Syrup	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduate cylinder counting tray, stirring rod, and plastic amber bottle

### **Directions**

- 1. Crush the tablets and triturate them to a fine powder.
- 2. In a graduated cylinder, mix 30 mL of cherry syrup and 90 mL of simple syrup vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduate, until a total volume of 120 mL.
- 7. Transfer into an amber bottle of appropriate size.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
	Plastic amber	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen LV, L. V., & Erickson, M. A. (1996). Stability of baclofen, captopril, diltiazem hydrochloride, dipyridamole, and flecainide acetate in extemporaneously compounded oral liquids. *American Journal of Health-System Pharmacy*, 53(18), 2179–2184. https://doi.org/10.1093/ajhp/53.18.2179.

# **Enalapril Oral Suspension 1 mg/mL**

Route	Dosage Form	Concentration	Note
Oral	Suspension	1 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Enalapril maleate 10 mg	12 Tablets		corrected age
Ora-Sweet®: Ora-Plus® Ora-Sweet SF®: Ora-Plus®(1:1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

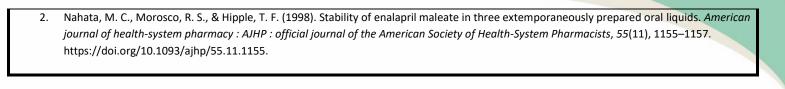
### **Directions**

- 1. Crush the tablets and triturate them to a fine powder.
- 2. In a graduate cylinder, mix 60 mL of Ora-Plus® vehicle and 60 mL of Ora-Sweet® or Ora-Sweet® SF.
- 3. Levigate with a small amount of the vehicle to form a uniform paste.
- 4. Add the vehicle geometrically, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve the final volume of 120 mL.
- 7. Transfer the contents to an appropriate size amber bottle.
- 8. Shake well.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
Ora-Sweet® : Ora-Plus® :91 days Ora-Sweet® : Ora-Plus®SF : 60 days	Plastic amber bottle	Shake well before use and protect from light

### **References:**

1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1998). Stability of alprazolam, chloroquine phosphate, cisapride, enalapril maleate, and hydralazine hydrochloride in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 55(18), 1915–1920. <a href="https://doi.org/10.1093/ajhp/55.18.1915">https://doi.org/10.1093/ajhp/55.18.1915</a>



# **Enalapril Oral Suspension 1 mg/mL**

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	1 mg/mL	- Cherry syrup: simple syrup
Ingredients	Quantity		(1:4) ratio
Enalapril maleate 10 mg	12 Tablets		
Cherry syrup	30 mL		
Simple syrup	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and amber plastic bottle

### **Directions**

- 1. Crush the tablets and triturate them to a fine powder.
- 2. In a graduate cylinder, mix 30 mL of cherry syrup and 90 mL of simple syrup vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the simple syrup and pour it into the graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer contents to an appropriate size amber bottle.
- 8. Shake well.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber bottle	Shake well before use and protect from light

### **References:**

1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1998). Stability of alprazolam, chloroquine phosphate, cisapride, enalapril maleate, and hydralazine hydrochloride in extemporaneously compounded oral liquids. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 55(18), 1915–1920. https://doi.org/10.1093/ajhp/55.18.1915.

# Ethambutol Oral Suspension 100 mg/mL

Route	Dosage Form   Concentration		Note
Oral	Suspension	100 mg/mL	- Ora-Sweet SF® and Ora-
Ingredients	Quantity		Blend SF® should not be used
Ethambutol 400 mg tablet	30 Tablets		in neonates ≤28 days corrected age
Ora-Sweet SF® : Ora-Plus ®(1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduate cylinder, stirring rod, counting tray, and amber bottle

## **Directions**

- 1. Crush the tablets and triturate them to a fine powder.
- 2. Levigate with Ora-Plus® to a uniform paste, mixing well after each addition.
- 3. Pour the mortar's contents into a graduated cylinder.
- 4. Rinse the mortar and pestle using Ora-Sweet SF® and add it to a graduated cylinder until a final volume of 120 mL.
- 5. Transfer into an appropriate size amber bottle.
- 6. Shake well to mix.
- 7. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
	1	\

## **References:**

 Loyd V. Allen, Jr., PhDProfessor EmeritusCollege of Pharmacy, University of OklahomaOklahoma City. (2017, July 19). Ethambutol Hydrochloride Compounded Oral Suspension USP (100 mg/mL). U.S. Pharmacist. Retrieved June 7, 2022, from https://www.uspharmacist.com/article/ethambutol-hydrochloride-compounded-oral-suspension-usp-100-mg-ml.

# Flucytosine Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg/mL	- Ora-Sweet SF® and Ora-
Ingredients	Quantity		Blend SF® should not be used
Flucytosine 500 mg	2 Capsules		in neonates ≤28 days corrected age
Ora-Sweet®: Ora-Plus ®or Ora-Sweet SF ®: Ora-Plus ®(1:1)	qs. 100 mL		

# **Equipment Needed**

Mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and plastic amber bottle

## **Directions**

- 1. Empty capsule contents in a mortar and triturate into fine powder.
- 2. In a graduate cylinder, mix 50 mL of Ora-Sweet® or Ora-Sweet SF® and 50 mL of Ora-Plus® vehicle.
- 3. Levigate with a small portion of the base solution to form a uniform paste.
- 4. Geometrically add the base solution, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the base solution and pour it into a graduated cylinder.
- 7. Add the base solution to the graduated cylinder to achieve a total volume of 100 mL.
- 8. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 9. Shake well to mix.
- 10. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of acetazolamide, allopurinol, azathioprine, clonazepam, and flucytosine in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(16), 1944–1949. https://doi.org/10.1093/ajhp/53.16.1944.

# Flucytosine Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg/mL	- Cherry syrup: simple syrup
Ingredients	Quantity		(1:4) ratio
Flucytosine 500 mg	2 Capsules		
Cherry Syrup	25 mL		
Simple Syrup	qs. 100 mL		

# **Equipment Needed**

Mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and plastic amber bottle

## **Directions**

- 1. Empty the capsule contents in a mortar, and triturate it into a fine powder.
- 2. In a graduated cylinder, mix 25 mL of cherry syrup and 80 mL of simple syrup vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the simple syrup, and pour it into the graduated cylinder.
- 7. Add the base solution to the graduated cylinder to achieve a total volume of 100 mL.
- 8. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 9. Shake well to mix.
- 10. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of acetazolamide, allopurinol, azathioprine, clonazepam, and flucytosine in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(16), 1944–1949. https://doi.org/10.1093/ajhp/53.16.1944.

# Flucytosine Oral Suspension 50 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	50 mg/mL	- Ora-Sweet SF® and Ora-
Ingredients	Quantity		Blend SF® should not be used
Flucytosine 500 mg capsule	6 Capsules		in neonates ≤28 days corrected age
Ora-Sweet SF ®: Ora-Plus ®(1 :1)	qs. 60 mL		

# **Equipment Needed**

Mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and plastic amber bottle

## **Directions**

- 1. Empty the capsule contents in a mortar, and triturate it into a fine powder.
- 2. In a graduate cylinder, mix 30 mL of Ora-Plus with 30 mL of Ora-Sweet SF.
- 3. Add approximately 15 mL of vehicle mixture to the powder, triturate well, and transfer the contents to a graduated cylinder.
- 4. Rinse the mortar with about 15 mL of the vehicle mixture and transfer the contents to a graduated cylinder.
- 5. Transfer the contents to an appropriate-sized amber bottle.
- 6. Repeat step 4 as necessary with enough vehicle mixture to bring the final volume to 60 mL.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
60 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
90 days	Plastic amber bottle	Shake well before use and protect from light

## **References:**

1. VandenBussche, H. L., Johnson, C. E., Yun, J., & Patel, S. A. (2002). Stability of flucytosine 50 mg/mL in extemporaneous oral liquid formulations. *American Journal of Health-System Pharmacy*, *59*(19), 1853–1855. https://doi.org/10.1093/ajhp/59.19.1853.

# Folic acid 1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	1 mg/mL	
Ingredients	Quantity		
Folic acid 5 mg	20 Tablets		-
Simple Syrup	qs. 100 mL		

# **Equipment Needed**

Mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and amber plastic bottle

### **Directions**

- 1. Crush folic acid tablets in mortar and triturate to a fine powder.
- 2. Levigate with small portions of simple syrup and mix to form a uniform paste.
- 3. As you mix, add the vehicle in incremental proportions to almost 100 mL.
- 4. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 100 mL.
- 5. Transfer the graduated cylinder's contents to an amber bottle.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate (Preferred) or room temperature
Shelf life	Container Type	Special Instructions
60 Days	Plastic amber	Shake well before use and protect from light

## **References:**

1. The Stability of Folic Acid Suspension. (2015). *International Journal of Scientific and Research Publications*, *5*(8). https://www.ijsrp.org/research-paper-0815/ijsrp-p4461.pdf.

# Glycopyrrolate Oral Solution 0.1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Solution	0.1 mg/mL	
Ingredients	Quantity		
Glycopyrrolate 200 mcg/mL injection	50 mL		-
Ora-Sweet® : Ora-Plus® (1 :1)	qs. 100 mL		

# **Equipment Needed**

Sterile syringe with needle, glass stirring rod, graduated cylinder, and plastic amber bottle

## **Directions**

- 1. Withdraw the content of glycopyrrolate from the ampule with an appropriate-size filter needle and pour it into a graduated cylinder.
- 2. In a graduated cylinder, add the mixture of 25 mL of Ora-Plus® and 25 mL of Ora-Sweet® vehicle while mixing.
- 3. Transfer the contents to an appropriate-sized amber bottle.
- 4. Shake well to mix.
- 5. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Solution	Refrigerate
Shelf life	Container Type	Special Instructions
35 days	Plastic amber bottle	Shake well before use and refrigerate

#### **References:**

1. Landry, C., Forest, J. M., & Hildgen, P. (2005). Stability and subjective taste acceptability of four glycopyrrolate solutions for oral administration. *International journal of pharmaceutical compounding*, *9*(5), 396–398.

# Hydralazine Hydrochloride Oral Suspension 4 mg/mL Route Dosage Form Concentration Note Oral Suspension 4 mg/mL - Ora-Sweet SF® and Ora-Blend SF® should not be used in neonates ≤28 days

16 Tablets

qs. 100 mL

corrected age

# **Equipment Needed**

25 mg

Ora-Sweet ®: Ora-Plus ®or

Ora-Sweet SF \*: Ora-Plus \*(1:1)

Mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 50 mL of Ora-Sweet® or Ora-Sweet SF® and 50 mL of Ora-Plus® vehicle.
- 3. Levigate with a small portion of the vehicle to form a viscous but smooth and uniform paste.
- 4. Continue to add the vehicle geometrically, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into the graduated cylinder.
- 7. Add the base solution to the graduated cylinder to achieve a total volume of 100 mL.
- 8. Transfer the graduated cylinder's contents into an appropriate size amber bottle
- 9. Shake well to mix.
- 10. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
Ora-sweet®: Ora plus®: 1 day Ora-sweet SF®: Ora plus® :2 days	Plastic amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1998). Stability of alprazolam, chloroquine phosphate, cisapride, enalapril maleate, and hydralazine hydrochloride in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 55(18), 1915–1920. https://doi.org/10.1093/ajhp/55.18.1915.

# Hydroxyurea Oral Solution 100 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note	
Oral	Solution	100 mg/mL	- Hazardous medication must	
Ingredients	Quantity		be prepared following (USP	
Hydroxyurea 500 mg capsules	24 Capsules		800)	
Sterile water	60 mL			
Flavored syrup, not colored (Syrpalta)	qs. 120 mL			

## **Equipment Needed**

Beaker, magnetic stirrer, filter paper, graduated cylinder, counting tray, and plastic amber bottle

## **Directions**

- 1. Empty the capsule contents into a beaker.
- 2. Dissolve the contents of the capsules into room-temperature sterile water with vigorous stirring for several hours using a magnetic stirrer.
- 3. Filter the solution in order to remove insoluble excipients.
- 4. Mix this solution in geometric proportion with small quantities of Syrpalta, with a constant stirring.
- 5. Pour the beaker's contents into a graduated cylinder.
- 6. Add Syrpalta to the graduated cylinder to achieve a total volume of 120 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Solution	Room temperature
Shelf life	Container Type	Special Instructions
90 days	Plastic amber bottle	Shake well before use, do not refrigerate, and protect from light  Caution Hazardous, Handle properly

### References:

1. Heeney, M. M., Whorton, M. R., Howard, T. A., Johnson, C. A., & Ware, R. E. (2004). Chemical and functional analysis of hydroxyurea oral solutions. *Journal of pediatric hematology/oncology*, 26(3), 179–184. https://doi.org/10.1097/00043426-200403000-00007.

# Indomethacin Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	5 mg/mL	
Ingredients	Quantity		
Indomethacin 25 mg	20 Capsules		-
Ora-Sweet®	qs. 100 mL		

# **Equipment Needed**

Mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and amber bottle

## **Directions**

- 1. Empty the contents of the capsules into the mortar.
- 2. Levigate with small portions of Ora-Sweet®and mix to form a uniform paste.
- 3. Add more Ora sweet to the paste until a liquid is formed.
- 4. Transfer the mortar's content to a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of
- 6. Transfer the graduated cylinder's contents to an amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition	
100 mL	Suspension	Refrigerate	
Shelf life	Container Type	Special Instructions	
60 Days	Amber bottle	Shake well before use and protect from light	

## References:

1. INDOMETHACIN ORAL SUSPENSION 5 MG/ML. IWK Health Centre. (1988). Retrieved February 28, 2023, from https://www.iwk.nshealth.ca/sites/default/files/compounding-formulas/indomethacin1.pdf?m=1.

# Labetalol Hydrochloride Oral Suspension 40 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	40 mg/mL	- Ora-Sweet SF® and Ora-
Ingredients	Quantity		Blend SF® should not be used
Labetalol Hydrochloride 100 mg	48 Tablets		in neonates ≤28 days corrected age
Ora-Sweet®: Ora-Plus® or Ora-Sweet SF®: Ora-Plus® (1:1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, glass stirring rod, graduated cylinder, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with a small amount of the base solution to form a uniform paste.
- 4. Geometrically add the base solution, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle with the base solution and pour it into a graduated cylinder to achieve a total volume of 120 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition	
120 mL	Suspension	Refrigerate or room temperature	
Shelf life	Container Type	Special Instructions	
60 days	Plastic amber bottle	Shake well before use and protect from light	

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of labetalol hydrochloride, metoprolol tartrate, verapamil hydrochloride, and spironolactone with hydrochlorothiazide in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(19), 2304–2309. <a href="https://doi.org/10.1093/ajhp/53.19.2304">https://doi.org/10.1093/ajhp/53.19.2304</a>.
- 3. Jew, R. K., Soo-Hoo, W., Amiri, E., Gomes, J., & American Society of Health-System Pharmacists. (2022). *Extemporaneous Formulations for Pediatric, Geriatric and Special Needs Patients* (4th ed.). American Society of Health-System Pharmacists. https://doi.org/10.37573/9781585286522.087.

# Labetalol Oral Suspension 40 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	40 mg/mL	- Cherry syrup: simple syrup
Ingredients	Quantity		(1:4) ratio
Labetalol 100 mg	48 Tablets		
Cherry syrup	30 mL		
Simple syrup	qs. 120 mL		

## **Equipment Needed**

Mortar and pestle, glass stirring rod, graduated cylinder, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 30 mL of cherry syrup and 90 mL of simple syrup vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using simple syrup and pour it into a graduated cylinder to achieve a total volume of 120 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company
- 2. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of labetalol hydrochloride, metoprolol tartrate, verapamil hydrochloride, and spironolactone with hydrochlorothiazide in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, *53*(19), 2304–2309. https://doi.org/10.1093/ajhp/53.19.2304.
- 3. Jew, R. K., Soo-Hoo, W., Amiri, E., Gomes, J., & American Society of Health-System Pharmacists. (2022). *Extemporaneous Formulations for Pediatric, Geriatric and Special Needs Patients* (4th ed.). American Society of Health-System Pharmacists. https://doi.org/10.37573/9781585286522.087.

## Lamotrigine Oral Suspension 1 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	1 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Lamotrigine 100 mg	1 Tablet		corrected age
Ora-Sweet®: Ora-Plus® or Ora-Sweet SF®: Ora-Plus® (1:1)	qs. 100 mL		

# **Equipment Needed**

Mortar and pestle, glass stirring rod, graduated cylinder, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablet in a mortar and triturate it into a fine powder.
- 2. In a graduate cylinder, mix 50 mL of Ora-Sweet® or Ora-Sweet SF® and 50 mL of Ora-Plus® vehicle.
- 3. Levigate with a small amount of the vehicle to form a uniform paste.
- 4. Continue adding the vehicle geometrically, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a total volume of 100 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition	
100 mL	Suspension	Refrigerate or room temperature	
Shelf life	Container Type	Special Instructions	

- 1. Nahata, M. C., Morosco, R. S., & Hipple, T. F. (1999). Stability of lamotrigine in two extemporaneously prepared oral suspensions at 4 and 25 degrees C. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 56(3), 240–242. https://doi.org/10.1093/ajhp/56.3.240
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# Levodopa/Carbidopa Oral Suspension 5 mg/mL and 1.25 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	Levodopa 5 mg/mL and Carbidopa 1.25 mg/mL	<ul> <li>Use the extemporaneously prepared formulation only when the commercial</li> </ul>
Ingredients	Quantity		product is not available
Levodopa 100 mg/Carbidopa 25 mg	6 Tablets		
Ora-Sweet® : Ora-Plus® (1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Plus® vehicle and 60 mL of Ora-Sweet®.
- 3. Levigate with a small amount of the vehicle to form a uniform paste.
- 4. Add the vehicle geometrically, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the contents to an appropriate-sized amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions

## **References:**

1. Nahata, M. C., Morosco, R. S., & Leguire, L. E. (2000). Development of two stable oral suspensions of levodopa-carbidopa for children with amblyopia. *Journal of pediatric ophthalmology and strabismus*, *37*(6), 333–337. https://doi.org/10.3928/0191-3913-20001101-06.

# Levofloxacin Oral Suspension 50 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	50 mg/mL	- Use the extemporaneously
Ingredients	Quantity		prepared formulation only
Levofloxacin 500 mg	12 Tablets		when the commercial product is not available
Ora-Plus®: Strawberry syrup (1: 1)	qs. 120 mL		

## **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Plus® vehicle and 60 mL of Strawberry syrup.
- 3. Levigate with a small amount of the mixture to form a uniform and smooth paste.
- 4. Add the mixture geometrically, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the contents to an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions
57 days	Plastic amber bottle	Shake well before use and protect from light

## **References:**

1. VandenBussche, H. L., Johnson, C. E., Fontana, E. M., & Meram, J. M. (1999). Stability of levofloxacin in an extemporaneously compounded oral liquid. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, *56*(22), 2316–2318. https://doi.org/10.1093/ajhp/56.22.2316.

# Levothyroxine 25 mcg/mL

Route	Dosage Form	Concentration
Route	Dosage Form	Concentiation
Oral	Suspension	25 mcg/mL
Ingredients	Quantity	
Levothyroxine 100 mcg	25 Tablets	
Glycerol	40 mL	
Purified water	q.s. 100 mL	

# **Equipment Needed**

Mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and plastic amber bottle

## **Directions**

- 1. Crush the tablets to a fine powder with a mortar and pestle.
- 2. Levigate with glycerol and mix to form a uniform paste.
- 3. Transfer the mortar's content to a graduated cylinder.
- 4. Rinse the mortar and pestle using purified water and add it to the graduated cylinder until the final volume of 100 mL.
- 5. Transfer the graduated cylinder's contents to a plastic amber bottle.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
8 Days	Plastic amber	Shake well before use and protect from light

- 1. Boulton, D. W., Fawcett, J. P., & Woods, D. J. (1996). Stability of an extemporaneously compounded levothyroxine sodium oral liquid. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, *53*(10), 1157–1161. https://doi.org/10.1093/ajhp/53.10.1157.
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# Lisinopril Oral Suspension 1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	1 mg/mL	
Ingredients	Quantity		
Lisinopril 10 mg	10 Tablets		-
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 100 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), stirring rod, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets and triturate to a fine powder in a mortar and pestle.
- 2. In a graduated cylinder, mix 50 mL of Ora-Sweet® and 50 mL of Ora-Plus® vehicle.
- 3. With a small amount of the mixture, levigate the powder to form a smooth paste.
- 4. Continue adding the vehicle geometrically, mixing after each addition to near the final volume.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 100 mL.
- 7. Transfer the graduated cylinder's contents into a plastic amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions
91 Days	Plastic amber bottle	Shake well before use and protect from light

## **References:**

1. Nahata MC, Morosco RS. Stability of lisinopril in two liquid dosage forms. Ann Pharmacother. 2004;38(3):396-399. doi:10.1345/aph.1D415.

# Losartan Oral Suspension 2.5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	2.5 mg/mL	<ul> <li>Ora-Sweet SF® should not be</li> </ul>
Ingredients	Quantity		used in neonates ≤28 days
Losartan 50 mg	10 Tablets		corrected age
Purified Water	10 mL		
Ora-Sweet SF® : Ora-Plus® (1 :1)	qs. 200 mL		

# **Equipment Needed**

Graduated cylinder, glass stirring rod, counting tray, and plastic amber bottle

## **Directions**

- 1. Place the tablets into a plastic amber bottle.
- 2. Add purified water and shake for at least 2 minutes.
- 3. Allow the concentrate to stand for one hour, then shake it for one minute to disperse the tablets.
- 4. In a graduate cylinder, mix 100 mL of Ora-Sweet SF® and 100 mL of Ora-Plus® vehicle.
- 5. Add 190 mL of the vehicle to the bottle and shake for 1 minute to disperse the ingredients.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition
200 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
28 days	Plastic amber bottle	Shake well before use and refrigerate

## **References:**

1. Product Information: COZAAR® oral tablets. Accessdata.fda.gov. (2022). Retrieved 7 June 2022, from https://www.accessdata.fda.gov/drugsatfda\_docs/label/2013/020386s058lbl.pdf.

Mercaptopurine Oral Suspension 50 mg/mL				
Route	Dosage Form	Concentration	Note	
Oral	Suspension	50 mg/mL	- Hazardous medication must be	
Ingredients	Quantity		prepared following (USP 800)	
Mercaptopurine 50 mg	100 Tablets		<ul> <li>Adding ascorbic acid at a concentration of 0.1% w/v (100</li> </ul>	
Sterile water for irrigation	17 mL		mg tablet) to the standard	
Simple syrup	33 mL		formulation increases the shelf life of the suspension to 11	
Cherry syrup	qs. 100 mL		weeks at room temperature	

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass amber bottle

## **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. Levigate with sterile water for irrigation to form a uniform paste.
- 3. Geometrically add simple syrup, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using cherry syrup and pour it into the graduated cylinder to achieve a final volume of 100 mL.
- 6. Transfer the contents to an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
35 days	Glass amber bottle	Shake well, do not refrigerate and protect from light Caution Chemotherapy, Handle properly

## References:

1. Aliabadi, H. M., Romanick, M., Desai, S., & Lavasanifar, A. (2008). Effect of buffer and antioxidant on stability of a mercaptopurine suspension. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 65(5), 441–447. https://doi.org/10.2146/ajhp070325.

#### Methotrexate Oral Solution 2 mg/mL Route **Dosage Form** Concentration Note Oral Solution 2 mg/mL Hazardous medication must **Ingredients** Quantity be prepared in compliance with (USP 800) Methotrexate 500 mg/ 20 mL 2.4 mL Ora-Sweet® 7.5 mL

0.6 g

qs. 30 mL

# **Equipment Needed**

Sodium bicarbonate powder

Sterile water for injection

Mortar and pestle, graduate cylinder, 5-mL syringe, stirring rod, biological safety cabinet (BSC), and glass amber type I bottle

## **Directions**

- 1. Add sodium bicarbonate powder to a mortar.
- 2. Levigate with 7.5 mL of Ora-Sweet to form a paste.
- 3. Withdraw 2.4 mL of methotrexate injection using a 5-mL syringe.
- 4. Transfer syringe 's content to the mortar.
- 5. Geometrically add the vehicle, mixing well after each addition.
- 6. Transfer the mortar's contents to a graduated cylinder.
- 7. Rinse the mortar and pestle with the vehicle and pour into a graduated cylinder to achieve a total volume of 30 mL.
- 8. Transfer the graduated cylinder 's contents of the graduated cylinder into an appropriately sized amber bottle.
- 9. Shake well to mix.
- 10. Label.

Formula Qty Final	Final Product Description	Storage Condition
30 mL	Solution	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
120 days	Glass amber type I bottle	Shake well before use Caution Hazardous, Handle properly

# References:

1. Vrignaud, S., Briot, T., Launay, A., Kempf, M., & Lagarce, F. (2015). Design and stability study of a paediatric oral solution of methotrexate 2mg/ml. *International Journal of Pharmaceutics*, 487(1–2), 270–273. https://doi.org/10.1016/j.ijpharm.2015.04.016.

# Methyldopa Oral Syrup 50 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Syrup	50 mg/mL	
Ingredients	Quantity		
Methyldopa 250 mg	10 Tablets		-
Simple Syrup	qs. 50 mL		

## **Equipment Needed**

Glass mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and amber glass bottle

### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. Levigate with a small portion of the vehicle to form a uniform paste.
- 3. Geometrically add the vehicle, mixing well after each addition.
- 4. Transfer to a graduate cylinder.
- 5. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a total volume of 50 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
50 mL	Syrup	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Newton, D. W., Rogers, A. G., Becker, C. H., & Torosian, G. (1975). Extemporaneous preparation of methyldopa in two syrup vehicles. *American journal of hospital pharmacy*, *32*(8), 817–821.

# Metolazone Oral Suspension 1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	1 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Metolazone 2.5 mg	48 Tablets		corrected age
Ora-Sweet® : Ora-Plus® or Ora-Sweet SF® : Ora-Plus® (1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a total volume of 120 mL.
- 7. Transfer the contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
	Plastic amber	

- 1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of ketoconazole, metolazone, metronidazole, procainamide hydrochloride, and spironolactone in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(17), 2073–2078. <a href="https://doi.org/10.1093/ajhp/53.17.2073">https://doi.org/10.1093/ajhp/53.17.2073</a>.
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company

# Metolazone Oral Suspension 1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	1 mg/mL	- Cherry syrup: simple syrup
Ingredients	Quantity		(1:4) ratio
Metolazone 2.5 mg	48 Tablets		
Cherry syrup	30 mL		
Simple syrup	qs. 120 mL		

## **Equipment Needed**

Mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 30 mL of cherry syrup and 90 mL of simple syrup vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Geometrically add simple syrup, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the simple syrup and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
	,,	5 <b>P</b> 5 5 5 5 5 5

- 1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of ketoconazole, metolazone, metronidazole, procainamide hydrochloride, and spironolactone in extemporaneously compounded oral liquids. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 53(17), 2073–2078. https://doi.org/10.1093/ajhp/53.17.2073.
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# Metoprolol Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Metoprolol tartrate 50 mg	24 Tablets		corrected age
Ora-Sweet® : Ora-Plus®or Ora-Sweet SF® : Ora-Plus® (1 :1)	qs. 120 mL		

## **Equipment Needed**

Mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber	Shake well before use and protect from light

#### References:

1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of labetalol hydrochloride, metoprolol tartrate, verapamil hydrochloride, and spironolactone with hydrochlorothiazide in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, *53*(19), 2304–2309. https://doi.org/10.1093/ajhp/53.19.2304.

# Metoprolol Oral Suspension 10 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	10 mg/mL	- Cherry syrup: simple syrup
Ingredients	Quantity		(1:4) ratio
Metoprolol tartrate 50 mg	24 Tablets		
Cherry syrup	30 mL		
Simple syrup	qs. 120 mL		

## **Equipment Needed**

Mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 30 mL of cherry syrup and 90 mL of simple syrup vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber bottle	Shake well before use and protect from light

### References:

1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of labetalol hydrochloride, metoprolol tartrate, verapamil hydrochloride, and spironolactone with hydrochlorothiazide in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(19), 2304–2309. <a href="https://doi.org/10.1093/ajhp/53.19.2304">https://doi.org/10.1093/ajhp/53.19.2304</a>.

# Moxifloxacin Oral Suspension 20 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	20 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Moxifloxacin 400 mg tablets	6 Tablets		corrected age
Ora-Sweet®: Ora-Plus® or Ora-Sweet SF® : Ora-Plus® (1 :1)	qs. 120 mL		

## **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, glass stirring rod, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 60 mL of ora-Sweet® or ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with a small portion of the vehicle to form a uniform paste.
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
90 days	Plastic amber bottle	Shake well before use and protect from light

#### **References:**

1. Hutchinson, D. J., Johnson, C. E., & Klein, K. C. (2009). Stability of extemporaneously prepared moxifloxacin oral suspensions. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists, 66*(7), 665–667. <a href="https://doi.org/10.2146/ajhp080152">https://doi.org/10.2146/ajhp080152</a>.

# Mycophenolate Mofetil Oral Suspension 50 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	50 mg/mL	- Hazardous medication must be
Ingredients	Quantity		prepared following (USP 800)
Mycophenolate Mofetil 250 mg	24 Capsules		- Ora-Plus : Cherry syrup (1:4) ratio
Ora-Plus®	30 mL		
Cherry syrup	qs. 120 mL		

## **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and amber bottle

## **Directions**

- 1. Empty the capsule contents into a mortar.
- 2. Levigate with a small amount of ora-Plus to form a uniform paste.
- 3. Add Cherry syrup in geometric proportions until the suspension is pourable.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using cherry syrup and pour it into the graduated cylinder to achieve a final volume of 120 mL.
- 6. Transfer the contents to an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
Refrigerate: 50 days Room temperature: 28 days	Amber bottle	Shake well before use and protect from light  Caution Hazardous, Handle properly

- 1. Venkataramanan, R., McCombs, J. R., Zuckerman, S., McGhee, B., Pisupati, J., & Dice, J. E. (1998). Stability of mycophenolate mofetil as an extemporaneous suspension. *The Annals of pharmacotherapy*, *32*(7-8), 755–757. <a href="https://doi.org/10.1345/aph.17213">https://doi.org/10.1345/aph.17213</a>.
- 2. Jew, R., Soo-Hoo, W., Amiri, E., & Gomes, J. (2022). Extemporaneous formulations for pediatric, geriatric and special needs patients (4th ed.). Harvey Whitney Books DOI: 10.37573/9781585286522.163.

# Mycophenolate Mofetil Oral Syrup 100 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Syrup	100 mg/mL	- Hazardous medication must be
Ingredients	Quantity		prepared following (USP 800)
Mycophenolate Mofetil 250 mg	80 Capsules		
Sterile water for irrigation	Small amount		
Cherry syrup	qs. 200 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Empty the capsule contents into a mortar.
- 2. Levigate with a small amount of the sterile water to form a uniform paste.
- 3. Add Cherry syrup geometrically, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using cherry syrup and pour it into the graduated cylinder to achieve a final volume of 200 mL.
- 6. Transfer the contents to an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
200 mL	Syrup	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions
121 days	Plastic amber bottle	Shake well before use and protect from light  Caution Hazardous and Handle properly

- 1. Anaizi, N. H., Swenson, C. F., & Dentinger, P. J. (1998). Stability of mycophenolate mofetil in an extemporaneously compounded oral liquid. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 55(9), 926–929. https://doi.org/10.1093/ajhp/55.9.926.
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# Omeprazole Oral Solution 2 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Solution	2 mg/mL	
Ingredients	Quantity		
Omeprazole delayed release 10 mg	24 Capsules		-
Sodium Bicarbonate Injection 8.4%	qs. 120 mL		

# **Equipment Needed**

Flask, graduated cylinder, counting tray, magnetic stirrer, and plastic amber oral syringe or bottle

### **Directions**

- 1. Empty the capsule contents in a flask.
- 2. Measure 120 mL of sodium bicarbonate 8.4% in a graduated cylinder and pour it into the flask.
- 3. Stir the mixture with a magnetic stirrer for 30 minutes.
- 4. Transfer the graduated cylinder's contents into an appropriate size plastic amber oral syringe.
- 5. Shake well to mix.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Solution	Refrigerate (preferred) or room temperature
Shelf life	Container Type	Special Instructions
<ul> <li>Plastic amber oral syringe:</li> <li>14 days at room</li> <li>temperature</li> <li>45 refrigerated</li> <li>Amber glass vial:</li> <li>14 days at room</li> <li>temperature</li> <li>30 days refrigerated</li> </ul>	Plastic amber oral syringe Or glass vial	Shake well before use, for oral use only and protect from light

## References:

1. Quercia, R. A., Fan, C., Liu, X., & Chow, M. S. (1997). Stability of omeprazole in an extemporaneously prepared oral liquid. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 54(16), 1833–1836. <a href="https://doi.org/10.1093/ajhp/54.16.1833">https://doi.org/10.1093/ajhp/54.16.1833</a>.

. DiGiacinto, J. L., Olsen, K. M., Bergman, K. L., & Hoie, E. B. (2000). Stability of suspension formulations of lansoprazole and of	
stored in amber-colored plastic oral syringes. <i>The Annals of pharmacotherapy, 34</i> (5), 600–605. https://doi.org/10.1345/api	h.19086.

# Oseltamivir Oral Suspension 6 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	6 mg/mL	
Ingredients	Quantity		- Ora-Sweet SF® should not be
Oseltamivir 75 mg	8 Capsules		used in neonates ≤28 days corrected age
Sterile Water for irrigation	7 mL		
Ora-sweet SF® Or Cherry syrup® Or Simple syrup®	qs. 100 mL		

# **Equipment Needed**

Glass or plastic amber bottle, and funnel

## **Directions**

- 1. Add an amount of water into a plastic or glass amber bottle.
- 2. Empty the capsules and pour the contents into the bottle. (Weighing paper may also be used to hold capsule contents to transfer it into the bottle).
- 3. Gently shake the suspension to ensure adequate powder wetting for at least 2 minutes.
- 4. Add the vehicle geometrically, shaking after each addition.
- 5. Use a child-resistant cap to close the bottle, and shake for 30 seconds to ensure the suspension is completely dissolved.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
<ul><li> 35 days refrigerated</li><li> 5 days at room temperature</li></ul>	Glass or plastic bottle	Shake well before use

## **References:**

1. PrTAMIFLU® PRODUCT MONOGRAPH. Rochecanada.com. (2020). Retrieved 12 June 2022, from https://www.rochecanada.com/PMs/Tamiflu/Tamiflu\_PM\_E.pdf.

# Oseltamivir Oral Syrup 15 mg/mL

		-	
Route	Dosage Form	Concentration	Note
Oral	Syrup	15 mg/mL	<ul> <li>Ora-Sweet SF® should not be</li> </ul>
Ingredients	Quantity		used in neonates ≤28 days
Oseltamivir 75 mg	12 Capsules		corrected age
Ora-sweet SF or cherry syrup	qs. 60 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass or plastic amber bottle

## **Directions**

- 1. Empty the capsule contents into a mortar and triturate it to a fine powder.
- 2. Levigate with a small amount of the vehicle to form a uniform paste.
- 3. Geometrically add the vehicle, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 60 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
60 mL	Syrup	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
Ora sweet SF:  -35 days (refrigerated or at room temperature (25 C)) -13 days at (30 C)  Cherry syrup:  -35 days refrigerated, 5 days at room temperature (25 C) - Not stable at (30 C)	Glass or plastic amber bottle	Shake well before use and protect from light

# **References:**

1. Winiarski, A. P., Infeld, M. H., Tscherne, R., Bachynsky, M., Rucki, R., & Nagano-Mate, K. (2007). Preparation and stability of extemporaneous oral liquid formulations of oseltamivir using commercially available capsules. *Journal of the American Pharmacists Association : JAPhA*, 47(6), 747–755. https://doi.org/10.1331/JAPhA.2007.06125.

# Propylthiouracil Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	5 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Propylthiouracil 50 mg tablet	20 Tablets		800)
Ora-Sweet® : Ora-Plus® (1 :1)	qs. 200 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder in a mortar and pestle.
- 2. In a graduated cylinder, mix 100 mL of Ora-Sweet® and 100 mL of Ora-Plus® vehicle.
- 3. Levigate with a small amount of the base solution to form a uniform paste.
- 4. Geometrically add the base solution, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the base solution and pour it into a graduated cylinder to achieve a final volume of 200 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
200 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
<ul> <li>70 days at room</li> <li>temperature.</li> <li>91 days refrigerated.</li> </ul>	Plastic amber bottle	Shake well before use and protect from light  Caution Hazardous Medication

- 1. Nahata, M. C., Morosco, R. S., & Trowbridge, J. M. (2000). Stability of propylthiouracil in extemporaneously prepared oral suspensions at 4 and 25 degrees C. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, *57*(12), 1141–1143.
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# Propylthiouracil Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	5 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Propylthiouracil 50 mg	20 Tablets		800)
methylcellulose 1%: simple syrup (1:1)	qs. 200 mL		

## **Equipment Needed**

Mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 100 mL of methylcellulose 1% and 100 mL of simple syrup.
- 3. Levigate with a small amount of the base solution to form a uniform paste.
- 4. Geometrically add the base solution, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the base solution and pour into a graduated cylinder to achieve a final volume of 200 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
200 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
- 70 days at room		

- 1. Nahata, M. C., Morosco, R. S., & Trowbridge, J. M. (2000). Stability of propylthiouracil in extemporaneously prepared oral suspensions at 4 and 25 degrees C. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, *57*(12), 1141–1143.
- 2. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

# Pyrazinamide Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg/mL	<ul> <li>Ora-Sweet SF® should not be</li> </ul>
Ingredients	Quantity		used in neonates ≤28 days
Pyrazinamide 500 mg	3 Tablets		corrected age
Ora-Sweet®: Ora-Plus® or Ora-Sweet SF®: Ora-Plus® (1:1)	qs. 150 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and plastic amber bottle

## **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 75 mL of Ora-Sweet® or Ora-Sweet SF® and 75 mL of Ora-Plus® vehicle.
- 3. Levigate with a small amount of the vehicle to form a uniform paste.
- 4. Geometrically add the base solution, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 150 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
150 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- Allen, L., & Erickson, M. (1998). Stability of bethanechol chloride, pyrazinamide, quinidine sulfate, rifampin, and tetracycline hydrochloride in extemporaneously compounded oral liquids. *American Journal Of Health-System Pharmacy*, 55(17), 1804-1809. https://doi.org/10.1093/ajhp/55.17.1804.

### Pyrazinamide Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg/mL	- Cherry syrup: Simple syrup
Ingredients	Quantity		(1:4) ratio
Pyrazinamide 500 mg tablet	3 Tablets		
Cherry Syrup	37.5 mL		
Simple Syrup	qs. 150 mL		

### **Equipment Needed**

Mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. Levigate the powder with cherry syrup to form a uniform paste.
- 3. Geometrically add the vehicle, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar using the simple syrup and pour it into a graduated cylinder to achieve a final volume of 150 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
150 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L., & Erickson, M. (1998). Stability of bethanechol chloride, pyrazinamide, quinidine sulfate, rifampin, and tetracycline hydrochloride in extemporaneously compounded oral liquids. *American Journal Of Health-System Pharmacy*, *55*(17), 1804-1809. https://doi.org/10.1093/ajhp/55.17.1804.

#### Pyrazinamide Oral Suspension 100 mg/mL Route **Dosage Form** Concentration **Note** Oral Safety note: there are two Suspension 100 mg/mL concentrations for **Ingredients** Quantity pyrazinamide preparation Pyrazinamide 500 mg tablets 24 Tablet 10 mg/mL and 100 mg/mL Simple Syrup qs. 120 mL

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic or glass amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. Levigate the powder with a small portion of the vehicle to obtain a uniform paste.
- 3. Geometrically add the vehicle, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar using the simple syrup and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic or glass amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Nahata, M. C., Morosco, R. S., & Peritore, S. P. (1995). Stability of pyrazinamide in two suspensions. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, *52*(14), 1558–1560. https://doi.org/10.1093/ajhp/52.14.1558.

### Quinidine Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg /mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Quinidine Sulfate 200 mg	6 Tablets		corrected age
Ora-Sweet® : Ora-Plus® or Ora-Sweet SF® : Ora-Plus® (1 :1)	qs. 120 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. Levigate the powder with a small portion of the vehicle to form a uniform paste.
- 3. Geometrically add the vehicle, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.
- Allen, L., & Erickson, M. (1998). Stability of bethanechol chloride, pyrazinamide, quinidine sulfate, rifampin, and tetracycline hydrochloride in extemporaneously compounded oral liquids. *American Journal Of Health-System Pharmacy*, 55(17), 1804-1809. https://doi.org/10.1093/ajhp/55.17.1804.

### Quinidine Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg/mL	- Cherry syrup: Simple syrup
Ingredients	Quantity		(1:4) ratio
Quinidine Sulfate 200 mg	6 Tablets		
Cherry syrup	30 mL		
Simple syrup	qs. 120 mL		

### **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 30 mL of cherry syrup and 90 mL of simple syrup vehicle.
- 3. Levigate the powder with a small portion of the vehicle to form a uniform paste.
- 4. Almost to volume, add the vehicle in geometric proportions, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle with the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L., & Erickson, M. (1998). Stability of bethanechol chloride, pyrazinamide, quinidine sulfate, rifampin, and tetracycline hydrochloride in extemporaneously compounded oral liquids. *American Journal Of Health-System Pharmacy*, *55*(17), 1804-1809. https://doi.org/10.1093/ajhp/55.17.1804.

### Rifabutin Oral Suspension 20 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	20 mg/mL	- The suspension may tend to
Ingredients	Quantity		retain bubbles after being
Rifabutin 150 mg	8 Capsules		shaken that may not settle back
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 60 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Empty the content of the capsules into a mortar and triturate to a fine powder.
- 2. In a graduated cylinder, mix 30 mL of Ora-Sweet® and 30 mL of Ora-Plus® vehicle.
- 3. Levigate the powder with a small portion of the vehicle to form a uniform paste.
- 4. Almost to volume, add the vehicle in geometric proportions, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 60 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
60 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container True	Charial Instructions
Shen me	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Haslam, J. L., Egodage, K. L., Chen, Y., Rajewski, R. A., & Stella, V. (1999). Stability of rifabutin in two extemporaneously compounded oral liquids. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 56(4), 333–336. https://doi.org/10.1093/ajhp/56.4.333.

### Rifabutin Oral Suspension 20 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	20 mg/mL	
Ingredients	Quantity		
Rifabutin 150 mg	8 Capsules		-
Cherry Syrup	qs. 60 mL		

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Empty the content of the capsules in a glass mortar and triturate to a fine powder.
- 2. Levigate the powder with cherry syrup to form a uniform paste.
- 3. Almost to volume, add the vehicle in geometric proportions, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 60 mL.
- 6. Transfer into appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
60 mL	Suspension	Refrigerate (preferable) or room temperature
Chalf life		
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Haslam, J. L., Egodage, K. L., Chen, Y., Rajewski, R. A., & Stella, V. (1999). Stability of rifabutin in two extemporaneously compounded oral liquids. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 56(4), 333–336. https://doi.org/10.1093/ajhp/56.4.333.

### Sildenafil Citrate Oral Suspension 2.5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	2.5 mg/mL	
Ingredients	Quantity		
Sildenafil 20 mg tablet	15 Tablets		-
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 120 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate the powder with a small portion of the mixture to form a smooth paste.
- 4. Almost to volume, add the vehicle in geometric proportions, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions

#### **References:**

1. Nahata, M., Morosco, R., & Brady, M. (2006). Extemporaneous sildenafil citrate oral suspensions for the treatment of pulmonary hypertension in children. *American Journal Of Health-System Pharmacy*, *63*(3), 254-257. https://doi.org/10.2146/ajhp050208.

### Sildenafil Citrate Oral Suspension 2.5 mg/mL

Route	Dosage Form	Concentration	Note	
Oral	Suspension	2.5 mg/mL	- Methylcellulose 1% solution :	
Ingredients	Quantity		Simple Syrup (1 :1) ratio	
Sildenafil 20 mg	15 Tablets			
Simple syrup	60 mL			
Methylcellulose 1% (1 :1)	qs. 120 mL			

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 60 mL of simple syrup and 60 mL of methylcellulose 1% vehicle.
- 3. Levigate the powder with a small amount of the vehicle to form a smooth paste.
- 4. Almost to volume, add the vehicle in geometric proportions, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
	7,00	

#### References:

1. Nahata, M., Morosco, R., & Brady, M. (2006). Extemporaneous sildenafil citrate oral suspensions for the treatment of pulmonary hypertension in children. *American Journal Of Health-System Pharmacy*, *63*(3), 254-257. https://doi.org/10.2146/ajhp050208.

### Sotalol Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	5 mg/mL	<ul> <li>The strength used in the study</li> </ul>
Ingredients	Quantity		is 120 mg from the drug but the
Sotalol hydrochloride 80 mg	8 Tablets		available strength in the formulary is 80 mg, so the
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 128 mL		volume was changed accordingly

### **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets and triturate them to a fine powder in a mortar.
- 2. In a graduated cylinder, mix 64 mL of Ora-Sweet® and 64 mL of Ora-Plus® vehicle.
- 3. Levigate the powder with a small amount of the vehicle to a uniform paste
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Transfer the contents to a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into the graduated cylinder to achieve a final volume of 128 mL.
- 7. Transfer into appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
128 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
91 days	Plastic amber bottle	Shake well before use and protect from light

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Nahata, M. C., & Morosco, R. S. (2003). Stability of sotalol in two liquid formulations at two temperatures. *The Annals of pharmacotherapy*, *37*(4), 506–509. https://doi.org/10.1345/aph.1C333.

### Sotalol Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note	
Oral	Suspension	5 mg/mL	- The strength used in the study	
Ingredients	Quantity		is 120 mg from the drug but the	
Sotalol hydrochloride 80 mg	8 Tablets		available strength in the formulary is 80 mg, so the	
Methylcellulose 1%	14.2 mL		volume was changed	
Simple Syrup NF (1 :9)	qs. 128 mL		accordingly	

### **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets and triturate them to a fine powder in a mortar.
- 2. Add Methylcellulose 1% and levigate to a uniform paste.
- 3. Add the simple syrup in geometric proportions and mix well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 128 mL.
- 6. Transfer into appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
128 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Nahata, M. C., & Morosco, R. S. (2003). Stability of sotalol in two liquid formulations at two temperatures. *The Annals of pharmacotherapy*, *37*(4), 506–509. https://doi.org/10.1345/aph.1C333.

### Sucralfate Oral Suspension 200 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	200 mg/mL	<ul> <li>Used for the treatment of</li> </ul>
Ingredients	Quantity		ulcerations, erosions, and
Sucralfate 1 g	20 Tablets		infections of the esophagus
Nystatin 2 million units	20 mL		
Methylcellulose 1% solution	q.s. 100 mL		

### **Equipment Needed**

Glass mortar and pestle, glass stirring rod, counting tray, graduated cylinder, and amber bottle

#### **Directions**

- 1. Triturate the tablets to a fine powder with a mortar and pestle.
- 2. Levigate the powder with nystatin and small portions of methylcellulose 1% solution to form a smooth paste.
- 3. As you mix, add the vehicle in incremental proportions to almost 100 mL.
- 4. Transfer the mortar's content to a graduated cylinder.
- 5. Rinse the mortar and pestle using methylcellulose 1% solution and add it to the graduated cylinder until the final volume of 100 mL.
- 6. Transfer the graduated cylinder's contents to an amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions

#### References:

Loyd V. Allen, Jr., PhD Professor Emeritus College of Pharmacy, University of Oklahoma Oklahoma City. (2017, January 19). Sucralfate 200 mg/mL and Nystatin 20,000 U/mL Oral Suspension. U.S. Pharmacist. Retrieved February 27, 2023, from https://www.uspharmacist.com/article/sucralfate-200-mg-ml-and-nystatin-20000-u-ml-oral-suspension

### Sulfasalazine Oral Suspension 100 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	100 mg/mL	
Ingredients	Quantity		
Sulfasalazine 500 mg	20 Tablets		-
Ora-Sweet® : Ora-Plus ® (1 :1)	qs. 100 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and amber bottle

### **Directions**

- 1. Count the tablets and place them in a mortar.
- 2. In a graduated cylinder, mix 50 mL of Ora-Sweet® and 50 mL of Ora-Plus® vehicle.
- 3. Cover them with a minimal amount of mixture.
- 4. Allow to soften for 20 30 minutes.
- 5. Levigate softened tablets to form a smooth paste.
- 6. Continue adding the vehicle geometrically, mixing after each addition to near the final volume.
- 7. Pour the mortar's contents into a graduated cylinder.
- 8. Rinse the mortar using the vehicle and pour it into a graduate to achieve a final volume of 100 mL.
- 9. Transfer the suspension to an amber bottle of the appropriate size.
- 10. Shake well to mix.
- 11. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions

# References:

1. Walsh, K. L., Walker, S. E., Law, S., Abesamis, M., & Sales, P. (2006). Stability of Sulfasalazine Oral Suspension. *The Canadian Journal of Hospital Pharmacy*, *59*(4). https://doi.org/10.4212/cjhp.v59i4.256.

### Sumatriptan Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	5 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Sumatriptan 100 mg	9 Tablets		corrected age
Ora-Plus	40 mL		
Ora-Sweet® or Ora-Sweet SF®	qs. 180 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. Add 40 mL of Ora-Plus® to the powder, 5 mL each time mixing after each addition to form a uniform paste.
- 3. Pour the mixture into an appropriate size glass amber bottle.
- 4. Rinse the mortar and pestle using 10 mL of Ora-Plus and pour into the bottle (repeat this step 5 times with 10 mL).
- 5. Complete with Ora-sweet or Ora-sweet SF to achieve a final volume of 180 mL.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
180 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
21 days	Glass amber bottle	Shake well before use

#### References:

1. Fish, D., Beall, H., Goodwin, S., & Fox, J. (1997). Stability of sumatriptan succinate in extemporaneously prepared oral liquids. *American Journal Of Health-System Pharmacy*, *54*(14), 1619-1622. https://doi.org/10.1093/ajhp/54.14.1619.

### Sunitinib malate Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Sunitinib malate 50 mg	24 Capsules		800)
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 120 mL		

### **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Empty the contents of the capsules into a mortar and triturate them to a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet® and 60 mL of Ora-Plus® vehicle.
- 3. With a small amount of the mixture, levigate the powder to form a smooth paste.
- 4. Add the mixture to the paste gradually, mixing after each addition to near the final volume.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar using the mixture, and pour it into a graduate to achieve a volume of 120 mL.
- 7. Transfer the suspension to an amber bottle of the appropriate size.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber bottle	Shake well before use  Caution Chemotherapy and Handle properly

#### References:

1. Navid, F., Christensen, R., Minkin, P., Stewart, C. F., Furman, W. L., & Baker, S. (2008). Stability of sunitinib in oral suspension. *The Annals of pharmacotherapy*, 42(7), 962–966. https://doi.org/10.1345/aph.1K654.

### Tacrolimus Oral Suspension 0.5 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	0.5 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Tacrolimus 5 mg	6 Capsules		800)
Ora-Plus®: Simple syrup (1:1)	qs. 60 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and amber bottle

#### **Directions**

- 1. Empty the contents of the capsules into a mortar and triturate them to a fine powder.
- 2. In a graduated cylinder, mix 30 mL of Ora-Sweet® and 30 mL of simple syrup vehicle.
- 3. With a small amount of the mixture, levigate the powder to form a smooth paste.
- 4. Add the mixture to the paste gradually, mixing after each addition to near the final volume.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar using a small amount of the mixture and transfer the contents to the graduated cylinder to achieve a final volume of 60 mL.
- 7. Transfer the suspension to an amber bottle of the appropriate size.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
60 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
56 days	Glass or plastic amber bottle	Shake well before use  Caution Hazardous Medication

#### References:

1. Jacobson, P. A., Johnson, C. E., West, N. J., & Foster, J. A. (1997). Stability of tacrolimus in an extemporaneously compounded oral liquid. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, *54*(2), 178–180. https://doi.org/10.1093/ajhp/54.2.178.

#### Tacrolimus Oral Suspension 1 mg/mL **Dosage Form** Concentration Route **Note** Hazardous medication must Oral Suspension 1 mg/mL **Ingredients** be prepared following (USP Quantity 800) Tacrolimus 5 mg 24 Capsules Ora-Sweet ®: Ora-Plus ® (1:1) qs. 120 mL

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and amber plastic bottle

#### **Directions**

- 1. Empty the contents of the capsules into a mortar and triturate them to a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet® and 60 mL of Ora-Plus® vehicle.
- 3. With a small amount of the base solution, levigate the powder to form a smooth paste.
- 4. Add the remaining amount of base solution to the paste gradually and mix between each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar using a small amount of the mixture in the graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the graduated cylinder's contents into an amber bottle of appropriate size.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
120 days	Plastic amber bottle	Shake well before use  Caution Hazardous Medication

### References:

1. Elefante, A., Muindi, J., West, K., Dunford, L., Abel, S., Paplham, P., Brown, K., Hahn, T., Padmanabhan, S., Battiwalla, M., & McCarthy, P. L. (2006). Long-term stability of a patient-convenient 1 mg/ml suspension of tacrolimus for accurate maintenance of stable therapeutic levels. *Bone marrow transplantation*, *37*(8), 781–784. https://doi.org/10.1038/sj.bmt.1705320.

### Tadalafil Oral Suspension 5 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	5 mg/mL	
Ingredients	Quantity		
Tadalafil 5 mg	60 Tablet		-
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 60 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 30 mL of Ora-Sweet® and 30 mL of Ora-Plus® vehicle.
- 3. Levigate the powder with the mixture in geometric proportions and mix to form a smooth suspension.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar with the mixture, and pour it into a graduate to achieve a final volume of 60 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
60 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
91 days	Plastic amber bottle	Shake well before use

#### References:

1. Pettit, R., Johnson, C., & Caruthers, R. (2012). Stability of an extemporaneously prepared tadalafil suspension. *American Journal Of Health-System Pharmacy*, *69*(7), 592-594. https://doi.org/10.2146/ajhp110034.

### Terbinafine Hydrochloride Oral Suspension 25 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	25 mg/mL	
Ingredients	Quantity		
Terbinafine 250 mg tablet	12 Tablets		-
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 120 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet® and 60 mL of Ora-Plus® vehicle.
- 3. With a small amount of the mixture, levigate the powder to form a smooth paste.
- 4. Add the mixture to the paste gradually, mixing after each addition to near the final volume.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar using the mixture and pour it into a graduate to achieve a final volume of 120 mL.
- 7. Transfer the suspension to an appropriate-sized amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
42 days	Plastic amber bottle	Shake well before use

- 1. Abdel-Rahman, S. M., & Nahata, M. C. (1999). Stability of terbinafine hydrochloride in an extemporaneously prepared oral suspension at 25 and 4 degrees C. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 56(3), 243–245. https://doi.org/10.1093/ajhp/56.3.243.
- 2. Jew, R., Soo-Hoo, W., Amiri, E., & Gomes, J. (2022). *Extemporaneous formulations for pediatric, geriatric and special needs patients* (4th ed.). Harvey Whitney Books DOI: 10.37573/9781585286522.163.

### Thalidomide Oral Suspension 20 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	20 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Thalidomide 100 mg	12 Capsules		800)
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 60 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and amber plastic bottle

#### **Directions**

- 1. Empty the contents of the capsules into a glass mortar and triturate them to a fine powder.
- 2. In a graduated cylinder, mix 30 mL of Ora-Sweet® and 30 mL of Ora-Plus® vehicle.
- 3. With a small amount of the mixture, levigate the powder to form a smooth paste.
- 4. Add the mixture to the paste gradually, mixing after each addition to near the final volume.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the mixture and pour it into a graduated cylinder to achieve the final volume of 60 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
60 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
35 days	Plastic amber bottle	Shake well before use  Caution Hazardous, Handle properly

- 1. Kraft, S., Johnson, C. E., & Tyler, R. P. (2012). Stability of an extemporaneously prepared thalidomide suspension. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists, 69*(1), 56–58. <a href="https://doi.org/10.2146/aihp110105">https://doi.org/10.2146/aihp110105</a>.
- Loyd V. Allen, Jr., PhD Professor Emeritus College of Pharmacy, University of Oklahoma Oklahoma City, Oklahoma. (2012, February 17). Thalidomide 20 mg/mL Oral Suspension. US Pharmacist. Retrieved June 7, 2022, from https://www.uspharmacist.com/article/thalidomide-20-mgml-oral-suspension.

#### Topiramate Oral Suspension 6 mg/mL Concentration Note Route **Dosage Form** Oral Suspension 6 mg/mL Hazardous medication must **Ingredients** Quantity be prepared in compliance with (USP 800) Topiramate 100 mg 6 Tablets Ora-Sweet®: Ora-Plus®(1:1) qs. 100 mL

### **Equipment Needed**

Mortar and pestle, graduate cylinder, stirring rod, counting tray, and plastic amber bottle

### **Directions**

- 1. Crush tablets in a mortar and triturate into a fine powder.
- 2. In a graduated cylinder, mix 50 mL of Ora-Sweet® and 50 mL of Ora-Plus®.
- 3. With a small amount of the mixture, levigate the powder to form a smooth paste.
- 4. Continue adding the vehicle geometrically, mixing after each addition to near the final volume.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle with the vehicle and pour into graduate cylinder to achieve the final volume of 100 mL.
- 7. Transfer the suspension to an appropriate-size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
90 days	Plastic bottle	Shake well before use,  Caution Hazardous, Handle properly

#### References:

1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

### Valacyclovir Oral Suspension 50 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	50 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Valacyclovir 500 mg	18 Tablets		corrected age
Ora-Plus	40 mL		
Ora-Sweet ® or Ora-Sweet SF®	qs. 180 mL		

### **Equipment Needed**

Porcelain mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass amber bottle

#### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. Levigate the powder with Ora-Plus to form a uniform paste.
- 3. Add Ora-Plus to the paste gradually and mix after each addition
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar using 10 mL of Ora-Sweet ® or Ora-Sweet SF® and transfer the contents to an amber bottle.
- 6. Repeat step 4 as often as necessary to bring the final volume to 180 mL.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
180 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
21 days	Glass amber bottle	Shake well before use and protect from light

#### References:

1. Fish, D. N., Vidaurri, V. A., & Deeter, R. G. (1999). Stability of valacyclovir hydrochloride in extemporaneously prepared oral liquids. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, *56*(19), 1957–1960. https://doi.org/10.1093/ajhp/56.19.1957.

### Valganciclovir Oral Suspension 60 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	60 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Valganciclovir 450 mg	16 Tablets		800)
Ora-Sweet® : Ora-Plus® (1 :1)	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass amber bottle

#### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with a small amount of the mixture to form a paste.
- 4. Geometrically add the mixture, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the mixture and pour it into a graduated cylinder to achieve a total volume of 120 mL.
- 7. Transfer the contents into an appropriate size amber glass bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
35 days	Glass amber bottle	Shake well before use and protect from light  Caution Hazardous, Handle properly

- 1. Henkin, C. C., Griener, J. C., & Ten Eick, A. P. (2003). Stability of valganciclovir in extemporaneously compounded liquid formulations. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System*
- 2. Jew, R., Soo-Hoo, W., Amiri, E., & Gomes, J. (2022). *Extemporaneous formulations for pediatric, geriatric and special needs patients* (4th ed.. Harvey Whitney Books DOI: 10.37573/9781585286522.308.

### Valsartan Oral Suspension 4 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	4 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days
Valsartan 80 mg	8 Tablets		corrected age
Ora-Plus®	80 mL		
Ora-Sweet SF®	qs. 160 mL		

### **Equipment Needed**

Graduated cylinder, counting tray, and glass amber bottle

### **Directions**

- 1. Add 80 mL of Ora-Plus® vehicle to an amber glass bottle that contains the tablets and shake for at least two minutes.
- 2. Allow the suspension to stand at least for one hour.
- 3. Shake the suspension for at least an additional minute after the standing time.
- 4. Add 80 mL of Ora-Sweet SF® to the bottle and shake the suspension for at least 10 seconds to disperse the ingredients.
- 5. Shake well to mix.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition
160 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
- 30 days at room temperature		Shake the bottle for 10 seconds before dispensing each

#### **References:**

1. *Diovan prescribing information*. Accessdata.fda.gov. (2011). Retrieved 7 June 2022, from https://www.accessdata.fda.gov/drugsatfda\_docs/label/2011/021283s033lbl.pdf.

### Vancomycin Oral Syrup 25 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Syrup	25 mg/mL	
Ingredients	Quantity		
Vancomycin 500 mg	20 Vials for injection		-
Sterile Water for injection	100 mL		
Ora-Sweet®: distilled water (1:1)	qs. 400 mL		

### **Equipment Needed**

Syringe, graduated cylinder, and plastic amber bottles

### **Directions**

- 1. Reconstitute each vial with 5 mL of sterile water for injection.
- 2. Shake well and make sure all vancomycin powder is dissolved.
- 3. Withdraw all vials contents.
- 4. Pour into an appropriate-sized graduated cylinder, then add the vehicle to a final volume of 400 mL.
- 5. Transfer into an appropriate-sized amber bottle.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
400 mL	Syrup	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
<ul><li>75 days refrigerated</li><li>26 days at room</li><li>temperature</li></ul>	Plastic amber bottles	shake well before use and protect from light

- 1. Ensom, M. H., Decarie, D., & Lakhani, A. (2010). Stability of Vancomycin 25 mg/mL in Ora-Sweet and Water in Unit-Dose Cups and Plastic Bottles at 4°C and 25°C. *The Canadian journal of hospital pharmacy*, *63*(5), 366–372. <a href="https://doi.org/10.4212/cjhp.v63i5.948">https://doi.org/10.4212/cjhp.v63i5.948</a>.
- 2. Jew, R., Soo-Hoo, W., Amiri, E., & Gomes, J. (2022). *Extemporaneous formulations for pediatric, geriatric and special needs patients* (4th ed.). Harvey Whitney Books DOI: 10.37573/9781585286522.163.

#### Verapamil Oral Suspension 50 mg/mL **Dosage Form** Concentration Route Note Oral Suspension 50 mg/mL Ora-Sweet SF® should not be **Ingredients** Quantity used in neonates ≤28 days corrected age Verapamil 80 mg tablet 75 Tablets Ora-Sweet®: Ora-Plus® or Ora-Sweet SF®: Ora-Plus® qs. 120 mL (1:1)

### **Equipment Needed**

Mortar and pestle, glass stirring rod, graduated cylinder, counting tray, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate with a small amount of the vehicle to form a uniform paste.
- 4. Geometrically add the mixture, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the mixture and pour it into a graduated cylinder to achieve a total volume of 120 mL.
- 7. Transfer the contents to an appropriate-sized amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions

#### References:

1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of labetalol hydrochloride, metoprolol tartrate, verapamil hydrochloride, and spironolactone with hydrochlorothiazide in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(19), 2304–2309. https://doi.org/10.1093/ajhp/53.19.2304.

### Verapamil Oral Suspension 50 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	50 mg/mL	- Cherry syrup: Simple syrup
Ingredients	Quantity		(1:4) ratio
Verapamil 80 mg	75 Tablets		
Cherry Syrup	30 mL		
Simple Syrup	qs. 120 mL		

### **Equipment Needed**

Mortar and pestle, glass stirring rod, graduated cylinder, counting tray, and plastic amber bottle

### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. Levigate with a small amount of the cherry syrup to form a uniform paste.
- 3. Geometrically add the simple syrup, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using simple syrup and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 6. Transfer the contents into an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
60 days	Plastic amber bottle	Shake well and protect from light

### References:

1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of labetalol hydrochloride, metoprolol tartrate, verapamil hydrochloride, and spironolactone with hydrochlorothiazide in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(19), 2304–2309. https://doi.org/10.1093/ajhp/53.19.2304.



# **Commercially Available Products**

### Baclofen Oral Suspension 10 mg/mL

	_			
Route	Dosage Form	Concentration	Note	
Oral	Suspension	10 mg/mL	- Ora-Sweet SF® should not be	
Ingredients	Quantity		used in neonates ≤28 days	
Baclofen 10 mg	120 Tablets		corrected age - Use the extemporaneously	
Ora-Sweet®: Ora-Plus® or Ora-Sweet SF®: Ora-Plus® (1:1)	qs. 120 mL		prepared formulation only when the commercial product is not available	

### **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets to a fine powder in a mortar and pestle.
- 2. Levigate with small portions of the vehicle and mix well to form a viscous, smooth, and uniform paste.
- 3. Continue adding the vehicle in geometric portions, mixing well.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and add it to the graduated cylinder until the final volume of 120 ml.
- 6. Transfer the graduated cylinder contents to a plastic amber bottle.
- 7. Shake well to mix.
- 8. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
		·

- 1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of baclofen, captopril, diltiazem hydrochloride, dipyridamole, and flecainide acetate in extemporaneously compounded oral liquids. *American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists*, 53(18), 2179–2184. <a href="https://doi.org/10.1093/ajhp/53.18.2179">https://doi.org/10.1093/ajhp/53.18.2179</a>
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

### Baclofen Oral Suspension 5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	5 mg/mL	
Ingredients	Quantity		- Use the extemporaneously
Baclofen 10 mg	30 Tablets		prepared formulation only when the commercial product
Glycerin	3 mL		is not available
Simple Syrup	qs. 60 mL		

### **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass amber bottle

#### **Directions**

- 1. Crush the tablets to a fine powder with a glass mortar and pestle.
- 2. Levigate with small portions of glycerin and mix to form a uniform paste.
- 3. As you mix, add 15 mL of simple syrup to the paste.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using about 15 mL of simple syrup and transfer the contents into the graduated cylinder.
- 6. Repeat the last step as necessary to achieve the final volume of 60 mL.
- 7. Transfer the graduated cylinder's contents to a glass amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
60 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
35 days	Glass amber bottle	Shake well before use and protect from light

- 1. Johnson, C. E., & Hart, S. M. (1993). Stability of an extemporaneously compounded baclofen oral liquid. *American journal of hospital pharmacy*, *50*(11), 2353–2355.
- 2. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

	Captopril Oral Solution 1 mg/mL			
Route	Dosage Form	Concentration	Note	
Oral	Solution	1 mg/mL	- Use the extemporaneously	
Ingredients	Quantity		prepared formulation only	

Captopril 25 mg

4 Tablets

when the commercial product is not available

Ascorbic acid 500 mg

1 Tablets

qs. 100 mL

### **Equipment Needed**

Distilled water

Graduated cylinder, counting tray, stirring rod, and glass bottle

### **Directions**

- 1. In a graduated cylinder, allow the tablets to dissolve in 50 mL of distilled water.
- 2. Add the content of one ascorbic acid 500 mg tablet and allow it to dissolve.
- 3. Add a quantity of distilled water sufficient to make 100 mL.
- 4. Transfer the content to a glass bottle.
- 5. Shake well to mix.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Solution	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
<ul><li>56 days refrigerated</li><li>28 days at room</li><li>temperature</li></ul>	Glass bottle	Shake well before use

### **References:**

1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

# Captopril Oral Solution 1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Solution	1 mg/mL	- Use the extemporaneously
Ingredients	Quantity		prepared formulation only
Captopril 25 mg	4 Tablets		when the commercial product is not available
Ascorbic acid 500 mg	1 Injection		
Distilled water	qs. 100 mL		

### **Equipment Needed**

Graduated cylinder(s), counting tray, stirring rod, and glass bottle

### **Directions**

- 1. In a graduated cylinder, allow the tablets to dissolve while adding distilled water gradually.
- 2. Add sodium ascorbate to the graduated cylinder.
- 3. Add a quantity of distilled water to achieve a total volume of 100 mL.
- 4. Transfer the contents to an appropriate size glass bottle.
- 5. Shake well to mix.
- 6. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Solution	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
<ul><li>56 days refrigerated</li><li>14 days at room</li><li>temperature</li></ul>	Glass bottle	Shake well before use

#### **References:**

1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

# Carbamazepine Oral Suspension 40 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	40 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Carbamazepine 200 mg	24 Tablets		800) - Use the extemporaneously
Simple syrup	qs. 120 mL		prepared formulation only when the commercial product is not available Refrigerate unit dose syringe

### **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass amber bottle

### **Directions**

- 1. Crush the tablets in a mortar and triturate them to a fine powder.
- 2. Levigate the powder with a small amount of the vehicle to form a uniform paste.
- 3. Add the vehicle geometrically, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 6. Transfer the contents to an appropriate-sized amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
90 days	Glass amber bottle or oral syringe	Shake well before use, for oral use only, and protect from light  Caution Hazardous, Handle properly

#### References:

1. Burckart, G. J., Hammond, R. W., & Akers, M. J. (1981). Stability of extemporaneous suspensions of carbamazepine. *American journal of hospital pharmacy*, *38*(12), 1929–1931.

### Chloroquine Phosphate Oral Suspension 15 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	15 mg/mL	- Chloroquine Phosphate 15 mg/
Ingredients	Quan	itity	mL= Chloroquine base 9 mg/mL
Chloroquine Phosphate 500 mg	Ora-Plus® or		<ul> <li>Chloroquine Phosphate 500 mg</li> <li>Chloroquine base 300 mg</li> <li>Ora-Sweet SF® should not be used in neonates ≤28 days</li> </ul>
Ora-Sweet® : Ora-Plus® or Ora-Sweet SF® : Ora-Plus® (1 :1)			corrected age  - Use the extemporaneously prepared formulation only when the commercial product is not available

### **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 50 mL of Ora-Sweet® or Ora-Sweet SF® and 50 mL of Ora-Plus® vehicle.
- 3. Levigate with small portions of the base solution to form a uniform paste.
- 4. Mix while adding the base solution in incremental proportions to almost 100 mL.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the base solution and add it to the graduated cylinder to achieve a final volume of 100 mL.
- 7. Transfer the graduated cylinder's contents to a plastic amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition	
100 mL	Suspension	Refrigerate or at room temperature	
Shelf life	Container Type	Special Instructions	
60 days	Plastic amber bottle	Shake well before use and protect from light	

- Allen, L. V., & Erickson, M. A. (1998). Stability of alprazolam, chloroquine phosphate, cisapride, enalapril maleate, and hydralazine hydrochloride in extemporaneously compounded oral liquids. *American Journal of Health-System Pharmacy*, 55(18), 1915–1920. https://doi.org/10.1093/ajhp/55.18.1915
- 2. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

# Chloroquine Phosphate Oral Suspension 15 mg/mL

Route	Dosage Form	Concentration	Note		
Oral	Suspension	15 mg/mL	<ul> <li>Chloroquine Phosphate 15</li> </ul>		
Ingredients	Quantity		mg / mL= Chloroquine base 9 mg/mL - Chloroquine Phosphate 500 mg = Chloroquine base 300		
Chloroquine Phosphate 500 mg	3 Tablets				
Cherry syrup	25 mL				
Simple syrup	qs. 10	0 mL	mg  - Use the extemporaneously prepared formulation only when the commercial product is not available  - Cherry syrup: simple syrup (1:4) ratio		

### **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. Levigate with small portions of cherry syrup to form a uniform paste.
- 3. Mix while adding the Simple syrup in incremental proportions.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the simple syrup and add it to the graduated cylinder to achieve a final volume of 100 mL.
- 6. Transfer the graduated cylinder's contents to a plastic amber bottle.
- 7. Shake well to mix.
- 8. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition	
100 mL	Suspension	Refrigerate or at room temperature	
Shelf life	Container Type	Special Instructions	

- Allen, L. V., & Erickson, M. A. (1998). Stability of alprazolam, chloroquine phosphate, cisapride, enalapril maleate, and hydralazine hydrochloride in extemporaneously compounded oral liquids. *American Journal of Health-System Pharmacy*, 55(18), 1915–1920. https://doi.org/10.1093/ajhp/55.18.1915
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# Dexamethasone Oral Suspension 0.5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	0.5 mg/mL	
Ingredients	Quantity		
Dexamethasone phosphate 4 mg/mL injection	2.5 mL		-Use the extemporaneously prepared formulation only when the
Ora-Sweet ®: Ora-Plus ®(1:1)	qs. 20 mL		commercial product is not available

# **Equipment Needed**

Filter needle, syringe, graduated cylinder, stirring rod, and plastic amber bottle.

# **Directions**

- 1. Withdraw 2.5 mL from the dexamethasone ampules using a 5 mL syringe and filter needle.
- 2. Transfer to a graduated cylinder.
- 3. Qs with the vehicle to a final volume of 20 mL.
- 4. Stir well.
- 5. Transfer the graduated cylinder's contents into an amber bottle of appropriate size.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
20 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions

#### **References:**

1. Chou, J. W.-L., Decarie, D., J. Dumont, R., & H.H. Ensom, M. (2001). Stability of Dexamethasone in Extemporaneously Prepared Oral Suspensions. *The Canadian Journal of Hospital Pharmacy*, *54*(2). https://doi.org/10.4212/cjhp.v54i2.634.

# Dexamethasone Oral Suspension 1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	1 mg/mL	
Ingredients	Quantity		
Dexamethasone phosphate 4 mg/mL injection	5 mL		- Use the extemporaneously prepared formulation only when the
Ora-Sweet ®: Ora-Plus ®(1:1)	qs. 20 mL		commercial product is not available

# **Equipment Needed**

Filter needle, syringe, graduated cylinder, stirring rod, and plastic amber bottle.

# **Directions**

- 1. Withdraw 5 mL from the dexamethasone ampules using a 5 mL syringe and filter needle.
- 2. Transfer to a graduated cylinder.
- 3. Qs with the vehicle to a final volume of 20 mL.
- 4. Stir well.
- 5. Transfer the graduated cylinder's contents into an amber bottle of appropriate size.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
20 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions

### **References:**

1. Chou, J. W.-L., Decarie, D., J. Dumont, R., & H.H. Ensom, M. (2001). Stability of Dexamethasone in Extemporaneously Prepared Oral Suspensions. *The Canadian Journal of Hospital Pharmacy*, *54*(2). https://doi.org/10.4212/cjhp.v54i2.634.

<b>Famotidine Oral Suspe</b>	nsion 8 mg	:/mL
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Route	Dosage Form	Concentration	Note
Oral	Suspension	8 mg/mL	- Use the extemporaneously
Ingredients	Quantity		prepared formulation only
Famotidine 40 mg	24 Tablets		when the commercial
Sterile water for irrigation	Small amount		product is not available
Ora-Sweet® : Ora-Plus® (1 :1)	qs. 120 mL		

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. Levigate with a small amount of sterile water for irrigation to form a uniform paste.
- 3. In a graduated cylinder, mix 60 mL of Ora-Plus® vehicle and 60 mL of Ora-Sweet®.
- 4. Add the vehicle geometrically, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the contents to an appropriate-sized amber bottle.
- 8. Shake well.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
95 days	Plastic amber bottle	Shake well before use and protect from light

### **References:**

1. Dentinger, P. J., Swenson, C. F., & Anaizi, N. H. (2000). Stability of famotidine in an extemporaneously compounded oral liquid. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, *57*(14), 1340–1342. https://doi.org/10.1093/ajhp/57.14.1340.

# Fluconazole Oral Solution 1 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Solution	1 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared in compliance
Fluconazole 50 mg	2 Tablet		with (USP 800) - Use extemporaneously
Deionized water	qs. 10	0 mL	prepared formulation only when commercial product is unavailable

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, borosilicate glass vial with teflon septa

#### **Directions**

- 1. Crush tablets in a mortar and triturate into a fine powder.
- 2. Levigate with a small amount of vehicle to form a uniform paste.
- 3. Add the vehicle geometrically, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle with vehicle and pour into the graduated cylinder to achieve the final volume of 100 mL.
- 6. Transfer contents to a borosilicate glass vial with teflon septa.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Solution	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions
15 days	Borosilicate glass vial with Teflon septa	Shake well before use, Caution Hazardous, Handle properly

#### References:

1. Yamreudeewong, W., Lopez-Anaya, A., & Rappaport, H. (1993). Stability of fluconazole in an extemporaneously prepared oral liquid. *American journal of hospital pharmacy*, *50*(11), 2366–2367.

# Levetiracetam Oral Suspension 50 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	50 mg/mL	- Use the extemporaneously
Ingredients	Quantity		prepared formulation only
Levetiracetam 500 mg	10 Tablets		when the commercial product is not available
Ora-Sweet® : Ora-Plus® (1 :1)	qs. 100 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets and triturate them to a fine powder in a mortar and pestle.
- 2. In a graduated cylinder, mix 50 mL of Ora-Plus® vehicle and 50 mL of Ora-Sweet®.
- 3. Levigate with a small amount of the vehicle to form a uniform paste.
- 4. Add the vehicle geometrically, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 100 mL.
- 7. Transfer the contents to an appropriate-sized amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions
91 days	Plastic amber bottle	Shake well before use and protect from light

- 1. Ensom, M. H., Decarie, D., & Rudolph, S. (2011). Stability of levetiracetam in extemporaneously compounded suspensions. *The Canadian journal of hospital pharmacy*, 64(3), 207–211. https://doi.org/10.4212/cjhp.v64i3.1024.
- 2. Ensom, M. H., & Décarie, D. (2015). Stability of Extemporaneously Compounded Levetiracetam in Glass and Plastic Bottles and Plastic Syringes. *The Canadian journal of hospital pharmacy, 68*(4), 346–348. https://doi.org/10.4212/cjhp.v68i4.1480.

# Metronidazole Oral Suspension 10 mg/mL

Route	<b>Dosage Form</b>	Concentration	Note
Oral	Suspension	10 mg/mL	
Ingredients	Quantity		
Metronidazole 250 mg	5 Tablets		- Use the extemporaneously prepared formulation only when the
Ora-Sweet®: Ora-Plus® (1:1) or Ora-Plus® alone	qs. 125 mL		commercial product is not available

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder, glass stirring rod, counting tray, and glass amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them to a fine powder.
- 2. In a graduate cylinder, mix 62.5 mL of Ora-Sweet® and 62.5 mL of Ora-Plus® vehicle (or 125 mL of Ora-Plus® alone).
- 3. Levigate with a small portion of the vehicle to form a viscous but smooth and uniform paste.
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar using the vehicle and pour it into a graduated cylinder to achieve a final volume of 125 mL.
- 7. Transfer the contents into an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
125 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
90 days	Glass amber bottle	Shake well before use and protect from light

#### **References:**

1. Mathew, M., Gupta, V. D., & Bethea, C. (1994). Stability of metronidazole in solutions and suspensions. *Journal of Clinical Pharmacy and Therapeutics*, *19*(1), 27–29. https://doi.org/10.1111/j.1365-2710.1994.tb00804.

# Ondansetron Hydrochloride Oral Suspension 0.8 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	0.8 mg /mL	- Use the extemporaneously
Ingredients	Quantity		prepared formulation only when the commercial product is not available
Ondansetron Hydrochloride 8 mg	12 Tablets		
Ora-Plus®	60 mL		- Ora-Sweet SF® should not be
Ora-sweet® or Ora-sweet SF®	qs. 120 mL		used in neonates ≤28 days corrected age

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic or glass amber vial

# **Directions**

- 1. Crush the tablets in a mortar and triturate them into a fine powder.
- 2. Geometrically add Ora-Plus, mixing well after each addition.
- 3. Pour the mortar's contents into a graduated cylinder.
- 4. Rinse the mortar and pestle using Ora-sweet® or Ora-sweet SF® and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 5. Transfer the contents to an appropriate-sized amber vial.
- 6. Shake well.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
42 days	Plastic or glass amber vial	Shake well before use and protect from light

#### **References:**

1. Williams, C. L., Sanders, P. L., Laizure, S. C., Stevens, R. C., Fox, J. L., & Hak, L. J. (1994). Stability of ondansetron hydrochloride in syrups compounded from tablets. *American Journal of Health-System Pharmacy*, *51*(6), 806–809. https://doi.org/10.1093/ajhp/51.6.806.

# Rifampicin Oral Suspension 10 mg/mL

Route	Dosage Form	Concentration	Note
Route	Dosage Form	Concentration	Note
Oral	Suspension	10 mg/mL	<ul> <li>Use the extemporaneously</li> </ul>
Ingredients	Quantity		prepared formulation only when the commercial product is not available
Rifampicin 300 mg	4 Capsules		
Simple Syrup	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic bottle

#### **Directions**

- 1. Empty the contents of the capsules into a mortar and triturate them to a fine powder.
- 2. Levigate the powder with simple syrup to form a uniform paste
- 3. Add the vehicle in geometric proportions and mix well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 6. Transfer into appropriate size plastic bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
42 days	Plastic bottle	Shake well before use

#### **References:**

1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

#### Rifampicin Oral Suspension 10 mg/mL Route **Dosage Form** Concentration **Note** Oral Suspension 10 mg/mL Use the extemporaneously **Ingredients** Quantity prepared formulation only when the commercial Rifampicin 600 mg 2 Injection vials product is not available Sterile water for injection 20 mL Simple Syrup qs. 120 mL

# **Equipment Needed**

Graduated cylinder(s), plastic bottle, 2x10mL syringes, and 8x12G needles

#### **Directions**

- 1. With 10 mL of the sterile water for injection, reconstitute each vial's powder.
- 2. Then, withdraw the vial's contents into a syringe.
- 3. Pour the mortar's contents into a graduated cylinder.
- 4. Add the vehicle to the graduated cylinder to achieve a total volume of 120 mL.
- 5. Transfer the graduated cylinder's contents into an appropriate-sized bottle.
- 6. Shake well to mix.
- 7. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., Morosco, R. S., & Hipple, T. F. (1994). Effect of Preparation Method and Storage on Rifampin Concentration in Suspensions. *Annals of Pharmacotherapy*, 28(2), 182–185. <a href="https://doi.org/10.1177/106002809402800204">https://doi.org/10.1177/106002809402800204</a>
- 2. Jew, R. K., Soo-Hoo, W., Amiri, E., Gomes, J., & American Society of Health-System Pharmacists. (2022). *Extemporaneous Formulations for Pediatric, Geriatric and Special Needs Patients* (4th ed.). American Society of Health-System Pharmacists. https://doi.org/10.37573/9781585286522.145.
- 3. Nahata MC, Morosco RS, Hipple TF. Stability of rifampin in two suspensions at room tempera- ture. *J Clin Pharm Ther.* 1994;19(4):263-265.

# Rifampicin Oral Suspension 25 mg/mL

Route	Dosage Form	Concentration	Note	
Oral	Suspension	25 mg/mL	<ul> <li>Ora-Sweet SF® should not be</li> </ul>	
Ingredients	Quantity		used in neonates ≤28 days	
Rifampicin 300 mg Capsules	10 Capsules		corrected age - Use the extemporaneously	
Ora-Sweet®: Ora-Plus® or Ora-Sweet SF®: Ora-Plus® (1:1)	qs. 12	0 mL	prepared formulation only when the commercial product is not available	

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Empty the contents of the capsules into a mortar and triturate them to a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate the powder with the vehicle to form a uniform paste
- 4. Geometrically add the vehicle, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 8. Shake well to mix
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or room temperature
Shelf life	Container Type	Special Instructions
	Plastic amber	

- 1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.
- Allen, L., & Erickson, M. (1998). Stability of bethanechol chloride, pyrazinamide, quinidine sulfate, rifampin, and tetracycline hydrochloride in extemporaneously compounded oral liquids. *American Journal Of Health-System Pharmacy*, 55(17), 1804-1809. https://doi.org/10.1093/ajhp/55.17.1804.

3. Nahata, M. C., Morosco, R. S., & Hipple, T. F. (1994). Effect of Preparation Method and Storage on Rifampin Concentration in Suspensions. *Annals of Pharmacotherapy*, 28(2), 182–185. https://doi.org/10.1177/106002809402800204.

Route	Dosage Form	Concentration	Note
Oral	Suspension	25 mg/mL	- Use the extemporaneously
Ingredients	Quantity		prepared formulation only when the commercial
Rifampicin 300 mg	10 Capsules		
cherry syrup	30 mL		product is not available - Cherry syrup: simple syrup
simple syrup	qs. 120 mL		(1:4) ratio

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

# **Directions**

- 1. Empty the contents of the capsules into a mortar and triturate them to a fine powder.
- 2. Levigate the powder with cherry syrup to form a uniform paste.
- 3. Geometrically add the vehicle, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 7. Shake well to mix
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate or at room temperature
Shelf life	Container Type	Special Instructions

- 1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
- 2. Allen, L., & Erickson, M. (1998). Stability of bethanechol chloride, pyrazinamide, quinidine sulfate, rifampin, and tetracycline hydrochloride in extemporaneously compounded oral liquids. *American Journal Of Health-System Pharmacy*, *55*(17), 1804-1809. <a href="https://doi.org/10.1093/ajhp/55.17.1804">https://doi.org/10.1093/ajhp/55.17.1804</a>.
- 3. Nahata, M. C., Morosco, R. S., & Hipple, T. F. (1994). Effect of Preparation Method and Storage on Rifampin Concentration in Suspensions. *Annals of Pharmacotherapy*, 28(2), 182–185. https://doi.org/10.1177/106002809402800204.

# Spironolactone Oral Suspension 2.5 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	2.5 mg/mL	- Hazardous medication must
Ingredients	Quantity		<ul> <li>be prepared following (USP 800)</li> <li>Formulation is applicable for the concentrations of 5</li> </ul>
Spironolactone 25 mg	12 Tablets		
Purified Water (USP)	6 mL		
Cherry Syrup	qs. 120 mL		mg/mL and 10 mg/mL  - Use the extemporaneously prepared formulation only when the commercial product is not available

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. Levigate with a small amount of purified water USP to form a paste.
- 3. Geometrically add cherry syrup, mixing well after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the base solution and pour it into a graduated cylinder to achieve a total volume of 120 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size glass amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
28 days	Glass amber bottle	Shake well before use and protect from light  Caution Hazardous Medication

#### References:

1. Mathur, L. K., & Wickman, A. (1989). Stability of extemporaneously compounded spironolactone suspensions. *American journal of hospital pharmacy*, *46*(10), 2040–2042.

# Spironolactone Oral Suspension 25 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	25 mg/mL	- Hazardous medication must be
Ingredients	Quantity		<ul> <li>prepared following (USP 800)</li> <li>Ora-Sweet SF® should not be used in neonates ≤28 days corrected age</li> </ul>
Spironolactone 25 mg	120 Tablets		
Ora-Sweet® : Ora-Plus® or Ora-Sweet SF® : Ora-Plus® (1 :1)	qs. 120 mL		corrected age

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. In a graduate cylinder, mix 60 mL of Ora-Sweet® or Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. Levigate the powder with a small amount of the base solution to form a paste.
- 4. Geometrically add the base solution, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the base solution and pour it into the graduate to achieve a final volume of 120 mL.
- 7. Transfer the suspension to an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
	Plastic amber	Shake well before use and protect from light

- 1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of ketoconazole, metolazone, metronidazole, procainamide hydrochloride, and spironolactone in extemporaneously compounded oral liquids. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 53(17), 2073–2078. https://doi.org/10.1093/ajhp/53.17.2073.
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# Spironolactone Oral Suspension 25 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	25 mg/mL	- Hazardous medication must be
Ingredients	Quantity		prepared following (USP 800)
Spironolactone 25 mg	120 Tablets		- Cherry syrup: Simple syrup (1:4) ratio
Cherry syrup	30 mL		1400
Simple syrup	qs. 120 mL		

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and plastic amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them to a fine powder.
- 2. In a graduate cylinder, mix 30 mL of cherry syrup and 90 mL of simple syrup vehicle.
- 3. Levigate the powder with a small amount of the base solution to form a paste.
- 4. Geometrically add the base solution, mixing well after each addition.
- 5. Pour the mortar's contents into a graduated cylinder.
- 6. Rinse the mortar and pestle using the base solution and pour it into the graduate to achieve a final volume of 120 mL.
- 7. Transfer the suspension to an appropriate size amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions

- 1. Allen, L. V., Jr, & Erickson, M. A., 3rd (1996). Stability of ketoconazole, metolazone, metronidazole, procainamide hydrochloride, and spironolactone in extemporaneously compounded oral liquids. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, 53(17), 2073–2078. https://doi.org/10.1093/ajhp/53.17.2073.
- 2. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

Route	Dosage Form	Concentration	Note
Oral	Suspension	50 mg/mL	- Ora-Sweet SF® should not be
Ingredients	Quantity		used in neonates ≤28 days corrected age Use the extemporaneously
Ursodiol 250 mg	24 Tablets		
Ora-Sweet SF® : Ora-Plus® (1:1)	qs. 120 mL		prepared formulation only when the commercial product is not available

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and amber plastic bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. In a graduated cylinder, mix 60 mL of Ora-Sweet SF® and 60 mL of Ora-Plus® vehicle.
- 3. With a small amount of the vehicle, levigate the powder to form a uniform paste.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Suspension	Refrigerate (preferable) or room temperature
Shelf life	Container Type	Special Instructions
90 days	Plastic amber bottle	Shake well before use

#### **References:**

1. Johnson, C. E., & Streetman, D. D. (2002). Stability of oral suspensions of ursodiol made from tablets. *American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists*, *59*(4), 361–363. https://doi.org/10.1093/ajhp/59.4.361.

# Ursodiol Oral Suspension 60 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	60 mg/mL	
Ingredients	Quantity		- Use the extemporaneously prepared formulation only when the
Ursodiol 250 mg	24 Tablets		
Glycerin	8 mL		commercial product is not available
Simple Syrup	qs. 100 mL		

# **Equipment Needed**

Glass mortar and pestle, graduated cylinder(s), counting tray, stirring rod, and glass amber bottle

#### **Directions**

- 1. Crush the tablets in a glass mortar and triturate them into a fine powder.
- 2. Levigate the powder with a small amount of glycerin to form a uniform paste.
- 3. Add the syrup to the paste gradually and mix after each addition.
- 4. Pour the mortar's contents into a graduated cylinder.
- 5. Rinse the mortar with the syrup and transfer the contents to an amber bottle.
- 6. Repeat step 5 as often as necessary to bring the final volume to 100 mL.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
35 days	Glass amber bottle	Shake well before use and protect from light

- Johnson, C. E., & Nesbitt, J. (1995). Stability of ursodiol in an extemporaneously compounded oral liquid. American journal of health-system pharmacy: AJHP: official journal of the American Society of Health-System Pharmacists, 52(16), 1798–1800. https://doi.org/10.1093/ajhp/52.16.1798.
- 2. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# Voriconazole Oral Suspension 40 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	40 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared in compliance
Voriconazole 200 mg	20 Tablets		with (USP 800) - Use the extemporaneously
Ora-Sweet® : Ora-Plus ®(1 :1)	qs. 100 mL		prepared formulation only when the commercial product is not available

# **Equipment Needed**

Mortar and pestle, graduated cylinder(s), stirring rod, counting tray, and plastic bottle

#### **Directions**

- 1. Crush the tablets and triturate to a fine powder in a mortar and pestle.
- 2. In a graduated cylinder, mix 50 mL of Ora-Sweet® and 50 mL of Ora-Plus® vehicle.
- 3. Levigate powder with a small amount of vehicle to form a paste.
- 4. Continue adding the vehicle geometrically, mixing after each addition to near the final volume.
- 5. Transfer the mortar's contents to a graduated cylinder.
- 6. Rinse the mortar and pestle with the vehicle and pour into graduated cylinder to achieve the total volume.
- 7. Transfer contents of the graduated cylinder into a plastic amber bottle.
- 8. Shake well to mix.
- 9. Label.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Refrigerate (preferable) or at room temperature
Shelf life	Container Type	Special Instructions
30 Days	Plastic amber bottle	Shake well before use

- 1. Nguyen KQ, Hawkins MG, Taylor IT, et al. Stability and uniformity of extemporaneous preparations of voriconazole in two liquid suspension vehicles at two storage temperature. Am J Vet Res. 2009;70:908-914.
- 2. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.

Zidovudine Oral Syrup 10 mg/mL			
Route	Dosage Form	Concentration	Note
Oral	Syrup	10 mg/mL	- Hazardous medication must
Ingredients	Quantity		be prepared following (USP
Zidovudine 100 mg	12 Capsule		800) - Use the extemporaneously
Simple syrup	qs. 120 mL		prepared formulation only when the commercial product is not available

# **Equipment Needed**

Containment ventilated enclosure (CVE) or biological safety cabinet (BSC), mortar and pestle, graduated cylinder, and glass amber vial

#### **Directions**

- 1. Empty the contents of the capsules into a mortar and triturate them to a fine powder.
- 2. Levigate the powder with a small amount of the vehicle to form a uniform paste.
- 3. Add the vehicle in increasing amounts and mix well.
- 4. Transfer the mortar's contents into a graduated cylinder
- 5. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 120 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate size amber vial.
- 7. Shake well to mix.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Syrup	Room temperature
Shelf life	Container Type	Special Instructions
90 days	Glass amber vial	Shake well before use, protect from light, and for oral use only  Caution Hazardous, Handle properly

- Jew, R. K., Soo-Hoo, W., Amiri, E., Gomes, J., & American Society of Health-System Pharmacists. (2022). Extemporaneous Formulations for Pediatric, Geriatric and Special Needs Patients (4th ed.). American Society of Health-System Pharmacists. https://doi.org/ 10.37573/9781585286522.312.
- 2. Radwan, M. A. (1994). Stability Indicating Hplc Assay of Zidovudine in Extemporaneous Syrup. *Analytical Letters*, *27*(6), 1159–1164. https://doi.org/10.1080/00032719408000286.



# **Electrolyte Preparations**

# Potassium Chloride Oral Solution 1 mEq/mL

Route	Dosage Form	Concentration	Note
Oral	Solution	1 mEq/mL	<ul> <li>Use the extemporaneously</li> </ul>
Ingredients	Quantity		prepared formulation only when
Potassium chloride injection 14.9%	25 mL		the commercial product is not available, or a more diluted syrup is desired
Ora-Sweet SF®	qs. 50 mL		

# **Equipment Needed**

Metered flask, syringe or graduated cylinder, and glass amber bottle.

### **Directions**

- 1. Withdraw 25 mL of potassium chloride 14.9% and add it into a graduated cylinder.
- 2. Add Ora-Sweet SF to 50 mL in a graduated cylinder to achieve the total volume indicated.
- 3. Transfer the graduated cylinder's contents into an appropriate-sized amber bottle.
- 4. Label.

Formula Qty Final	Final Product Description	Storage Condition
50 mL	Solution	Refrigerate
Shelf life	Container Type	Special Instructions
28 days	Glass amber bottle	Shake well before use and protect from light

- 1. Tannous, E., Tal, Y., & Amarny, K. (2016). A Simplified Extemporaneously Prepared Potassium Chloride Oral Solution. International journal of pharmaceutical compounding, 20(5), 438–439.
- 2. Jew, R., Soo-Hoo, W., Amiri, E., & Gomes, J. (2022). *Extemporaneous formulations for pediatric, geriatric and special needs patients* (4th ed.). Harvey Whitney Books DOI: 10.37573/9781585286522.282.

# Sodium benzoate Oral Suspension 250 mg/mL

Route	Dosage Form	Concentration	Note
Oral	Suspension	250 mg/mL	Hardler Lander
Ingredients	Quantity		<ul> <li>Use the extemporaneously prepared formulation only when</li> </ul>
Sodium benzoate powder	25 g		the commercial product is not
Sterile water for irrigation	50 mL		available
Ora-Sweet®	qs. 100 mL		

# **Equipment Needed**

Weigh paper, balance, beaker, stirring rod, graduated cylinder, and plastic amber bottle

#### **Directions**

- 1. Weigh the sodium benzoate powder and place it in a beaker.
- 2. Rinse the final container and all glassware with sterile water.
- 3. Add the sterile water for irrigation and stir well until the powder dissolves.
- 4. Filter the solution and place it into a graduated cylinder.
- 5. Add Ora-sweet to give a final volume of 100 mL.
- 6. Transfer the graduated cylinder's contents into an appropriate-sized amber bottle.
- 7. Shake well to mix.
- 8. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
100 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
90 days	Plastic amber bottle	Shake well before use and protect from light

- 1. Atkins, J. R., Lull, M. E., Decker, A. S., & Hutchinson, D. J. (2018). Stability of Extemporaneously Prepared Sodium Benzoate Oral Suspension. International journal of pharmaceutical compounding, 22(4), 326–328.
- 2. Jew, R., Soo-Hoo, W., Amiri, E., & Gomes, J. (2022). Extemporaneous formulations for pediatric, geriatric and special needs patients (4th ed.). Harvey Whitney Books DOI: 10.37573/9781585286522.148.

# Sodium bicarbonate Oral Solution 1 mEq/mL (8.4%)

Route	Dosage Form	Concentration	Note
Noute	Dosage Form		Note
Oral	Colution	1 mEq/mL	
Oral	Solution	(8.4%)	
Ingredients	Quantity		
Sodium bicarbonate powder	84 g		-
Purified water	qs. 1000 mL		

# **Equipment Needed**

Weigh paper, balance, beaker, stirring rod, graduated cylinder, and glass amber bottle.

# **Directions**

- 1. Weigh the sodium bicarbonate powder and place it in a beaker.
- 2. Add purified water and stir well until the powder dissolves.
- 3. Transfer into an amber glass bottle of appropriate size immediately.
- 4. Shake well.
- 5. Label and store the bottle away from direct light.

Formula Qty Final	Final Product Description	Storage Condition
1000 mL	Solution	Room temperature
Shelf life	Container Type	Special Instructions
30 days	Glass amber bottle	Shake well before use and protect from light

# **References:**

1. Nahata, M. C., & Pai, V. B. (2014). *Pediatric Drug Formulations* (6th Edition, Revised ed.). Harvey Whitney Books company.



# **Miscellaneous Preparations**

# **Hydrogen Peroxide 3% Mouthwash**

Route	Dosage Form	Concentration	Note
Topical	Solution	3%	
Ingredients	Quantity		
Hydrogen Peroxide 6% solution	60 mL		-
Distilled water	qs. 120 mL		

# **Equipment Needed**

Graduated cylinder(s), stirring rod, and amber bottle

# **Directions**

- 1. Add distilled water to Hydrogen Peroxide 6% to achieve a 3% Hydrogen Peroxide mouthwash solution.
- 2. Shake well
- 3. Transfer graduated cylinder's contents into an appropriate size amber bottle.
- 4. Label.

Formula Qty Final	Final Product Description	Storage Condition
120 mL	Solution	Refrigerate
Shelf life	Container Type	Special Instructions
	,,	•

#### **References:**

1. Farouq Shaker, N. (2012). Extemporaneous Preparations Adult and Pediatric Guide (1st ed., p. 173)

# **Magic Mouthwash (stomatitis)**

Route	Dosage Form	Concentration	Note
Topical	Suspension	-	
Ingredients	Quantity		
Lidocaine 2% Viscous	30 mL		
Miconazole Oral Gel	30 gm		_
Antacid Suspension	60 mL		
Chlorpheniramine 2mg/5mL Syrup	60 mL		
Distilled Water	120 mL		

# **Equipment Needed**

Graduate beaker, graduated cylinder(s), stirring rod, and amber bottle

# **Directions**

- 1. Mix all the ingredients in a graduated beaker.
- 2. Shake well.
- 3. Transfer the contents into an appropriate size amber bottle.
- 4. Label.

Formula Qty Final	Final Product Description	Storage Condition
300 mL	Suspension	Refrigerate
Shelf life	Container Type	Special Instructions
14 days	Amber bottle	Shake well before use and protect from light

# **References:**

1. Farouq Shaker, N. (2012). Extemporaneous Preparations Adult and Pediatric Guide (1st ed., p. 177).

# **Methylcellulose Oral Suspension 1%**

Route	Dosage Form	Concentration	Note
Oral	Suspension	1%	- Make sure the mixture is
Ingredients	Quantity		sufficiently heated, so powders are
Methylcellulose powder	10 g		completely dissolved.
Methylparaben powder	200 mg		
Propylparaben powder	100 mg		
Purified Water, USP	qs. 1000 mL		

# **Equipment Needed**

Balance, beaker, hot plate with magnetic stirrer, and a prescription bottle

#### **Directions**

- 1. Weigh the Methylcellulose, Methylparaben and Propylparaben powder.
- 2. In a beaker, heat 200 mL of purified water to boiling.
- 3. Add the Methylparaben, Propylparaben and mix well.
- 4. Add the Methylcellulose powder and stir for 2-3 minutes.
- 5. Allow to stand for 15 minutes, then remove it from heat.
- 6. Qs. with cold purified water and mix well with a magnetic stirrer.
- 7. Keep mixing until a clear, homogenous solution results, and pour into an amber bottle of appropriate size.
- 8. Label.

Formula Qty Final	Final Product Description	Storage Condition
1000 mL	Suspension	Room temperature
Shelf life	Container Type	Special Instructions
6 months (experience)	Prescription bottle	Shake well before use and protect from light

#### **References:**

1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.

# **Simple Syrup BP**

Route	Dosage Form	Concentration	Note
Oral	Syrup	66.7% w/w	- One or more suitable
Ingredients	Quantity		antimicrobial preservatives may
Sugar (sucrose)	667 gm		be added
Sodium Benzoate powder	1 gm		<ul> <li>Use the extemporaneously prepared formulation only</li> </ul>
Distilled water	qs. 1000 mL		when the commercial product is not available

# **Equipment Needed**

Balance, hot plate, beaker, stirring rod, and glass amber bottle

# **Directions**

- 1. Weigh the sugar and Sodium Benzoate powder and place them in a beaker.
- 2. Add distilled water while mixing and boil on a hot plate.
- 3. Dissolve with heating until a clear syrup solution is gained and allow to cool.
- 4. Pour the contents into a glass amber bottle of appropriate size.

Formula Qty Final	Final Product Description	Storage Condition	
1000 mL	Clear syrup	Room temperature	
Shelf life	Container Type	Special Instructions	
6 Months	Glass amber bottle	Shake well before use and protect from light	

# **References:**

1. Farouq Shaker, N. (2012). Extemporaneous Preparations Adult and Pediatric Guide (1st ed., p. 237).

# Tranexamic Acid Mouthwash 50 mg/mL Route Dosage Form Concentration Note Topical Solution 50 mg/mL Ingredients Quantity Tranexamic acid 100 mg/mL injection 5 mL Sterile Water qs. 10 mL

# **Equipment Needed**

Graduated cylinder, and needle, and glass amber bottle

# **Directions**

- 1. Dilute 5 mL of the tranexamic acid with 5 mL of the sterile water.
- 2. Keep in a glass amber bottle.
- 3. Shake well to mix.
- 4. Label.

Formula Qty Final	Final Product Description	Storage Condition
10 mL	Mouthwash solution	Refrigerate
Shelf life	Container Type	Special Instructions
5 Days	Glass amber bottle	Protect from light

- 1. Lam M. S. (2011). Extemporaneous compounding of oral liquid dosage formulations and alternative drug delivery methods for anticancer drugs. Pharmacotherapy, 31(2), 164–192. <a href="https://doi.org/10.1592/phco.31.2.164">https://doi.org/10.1592/phco.31.2.164</a>
- 2. Tranexamic Acid (Professional Patient Advice). (n.d.). Drugs.com. <a href="https://www.drugs.com/ppa/tranexamic-acid.html">https://www.drugs.com/ppa/tranexamic-acid.html</a>
- 3. Jackson, M. (2010) Handbook of Extemporaneous Preparation: A Guide to Pharmaceutical Compounding. London: Pharmaceutical Press.

#### **Universal Vehicle** Route **Dosage Form** Concentration Note Other names of universal Methyl Cellulose 1% 700 mL / vehicle: Oral Solution Simple Syrup Suspending Vehicle. 300 mL M. S Vehicle. **Ingredients** Quantity Used in some preparations as alternative of Ora-Plus®: Methylcellulose 1% Solution 700 mL Ora-Sweet® Simple Syrup qs. 1000 mL

# **Equipment Needed**

Graduated cylinder, stirring rod, and amber bottle

# **Directions**

- 1. Add 700 mL of Methylcellulose 1% to 300 mL of the simple syrup in a graduated cylinder.
- 2. Allow simple mixing to obtain the final solution.

Formula Qty Final	Final Product Description	Storage Condition	
1000 mL	Solution	Room temperature	
Shelf life	Container Type	Special Instructions	
6 Months	Amber bottle	Shake well before use and protect from light	

# **References:**

1. ABDULRAHMAN, M. (2003). THE ART OF PHARMACEUTICAL COMPOUNDING (2nd ed., p. 167). PHARM COMPOUNDING INC.



# **Mawared Equipment Codes:**

#	Equipment	Code
1.	5-micron filter needle	189110007
2.	Alcohol swabs Bactericidal Wipes, Saturated with A 70% W Solution of IsopropylL Alcohol BP for the Disinfection of Hard Surfaces, SIZE 130MMX185MM (PACKING: 100 WIPES CAN)	135280416
3.	Amber Glass Bottles: 60 mL, 100 mL	128220170
4.	Amber Oral Syringes	128220173
5.	Amber Plastic Bottles: 16 OZ	12822072
6.	Amber polypropylene oral syringe 20mL	133060882
7.	Amber polypropylene oral syringe 3mL	133060951
8.	Amber polypropylene oral syringe 60mL	133060884
9.	Balance External calibration	128220194
10.	Beaker, laboratory, 100 mL, Pyrex	785030218
11.	Beaker, laboratory, 250 mL, Pyrex	785030219
12.	Beaker, laboratory, 50 mL, Pyrex	785030217
13.	Beaker, laboratory, 500 mL, Pyrex	785070154
14.	Chemo Spill Kits	128220183
15.	Filter needle	189110007
16.	Flint Glass Mortar and Pestle Set: 8 Oz	128220190
17.	Glass Beaker 50ml,100mL, 250mL, 500mL, 1000mL	128220195
18.	Glass Funnel	128220199
19.	Glass Graduated Cylinder 50mL, 250mL, 500mL, 1000 mL	128220197

20.	Glass Stirring Rod	128220198
21.	Hot and Magnetic Stirrer	128220200
22.	Mortar Scraper	128220191
23.	Oral Medication Syringes 1 mL: Clean, single-use polypropylene syringes with separate ribbed tip caps; polypropylene barrel and plunger rod, latexfree plunger tip; dual graduations in milliliters; oral feeding luer tip, clear or amber tint.	133060623
24.	Plastic Vial with Push and Turn Type Safe Fitted Caps Wide Mouth, Amber Color, Polystyrene Material, Capacity: 60mL	137200439
25.	Plastic Vial with Push and Turn Type Safe Fitted Caps Wide Mouth, Amber Color, Polystyrene Material, Capacity: 120mL	137200438
26.	Plastic Vial with Push and Turn Type Safe Fitted Caps Wide Mouth, Amber Color, Polystyrene Material, Size: 165mL	137200435
27.	Plastic Vial with Push and Turn Type Safe Fitted Caps Wide Mouth, Amber Color, Polystyrene Material, Size: 20mL	137200437
28.	Plastic Vial with Push And Turn Type Safe Fitted Caps Wide Mouth, Amber Color, Polystyrene Material, Size: 45mL, 12 Dram,	137200434
29.	Plastic Vial With Push And Turn Type Safe Fitted Caps Wide Mouth, Amber Color, Polystyrene Material , Size : 30ML	137200436
30.	Plastic Zipper Bag (Zip Lock):  5X7 cm –6X8 cm  7X10 cm –10X15 cm  17X12 cm –17X24 cm  20X30 cm –30X38 cm	128220182
31.	Porcelain Mortar and Pestle Set: 3 Oz 11 Oz	128220189
32.	Protect from Light Bags: *Amber Bags* 4*3 29*20	128220174
33.	Sterile dropper bottle	137440050
34.	Wash Bottle	128220202
35.	Wash Bottle	128220202
36.	Wire Drying Rack	128220203

# **Glossary:**

#### • Component:

Any ingredient used in the compounding of a drug preparation, including any ingredients or added substance that are used in its preparation

#### Pharmacy Generated Product (PGP):

A product that is prepared, packaged, and labeled in a pharmacy and can be sold by the pharmacy without a prescription.

# • Compounder:

A compounder is a pharmacist/ pharmacy technician or a physician who is engaged in the act of compounding pursuant to a prescription order by a licensed prescriber.

#### • Preparation:

A term used to describe compounded formulations. It is a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug.

#### Official Substance:

Includes an active drug entity, a dietary supplement, or a pharmaceutical ingredient or a component of a finished device.

#### Active Ingredient:

Usually refers to chemicals, substances, or other components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or other animals or for use as dietary supplements.

#### • Active Pharmaceutical Ingredient (API):

Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

#### Added Substances:

Ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms inactive ingredients, excipients, and pharmaceutical ingredients.

## • Compounding Sterile Preparations (CSPs) include:

- Preparations are prepared according to the manufacturer's labeled instructions and other manipulations when manufacturing sterile products that expose the original contents to potential contamination.
- Preparations containing nonsterile ingredients or employing nonsterile components and devices that must be sterilized before administration.
- Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the above two characteristics, and which include, but are not limited to, baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injection, irrigations, metered sprays, and ophthalmic and otic preparations.

# • Beyond-Use Date (BUD):

The date after which a compounded preparation shall not be used; determined from the date the preparation is compounded.

#### Hazardous Drug:

- Any drug identified by at least one of the following six characteristics:
- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Geno toxicity
- New drugs that mimic existing hazardous drugs in structure or toxicity [for examples see current National Institute for Occupational Safety and Health (NIOSH) publications].

#### • Stability:

The extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.

#### Vehicle:

A component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.

#### • Elixir:

A clear, sweetened, alcohol-containing solution that is used mainly for drugs that are insoluble in water alone. It is usually not as sweet and less viscous than a syrup. The alcohol content of elixirs makes it a less desirable vehicle or base solution for preparing extemporaneous formulations in pediatric patients. Levigating agent

#### A levigating agent:

Is used to moisten and soften a tablet to facilitate the preparation of a liquid, especially when a large number of tablets is required, or the tablets are extremely difficult to crush. Preferably, the vehicle or base solution used for the product is used as the levigating agent.

#### Simple syrup:

A sucrose solution that is made with purified water alone. One or more suitable antimicrobial preservatives may be added to extend its stability.

#### Solution:

A liquid containing medication that is dissolved in water or other liquids.

#### Suspending agent:

A substance that is added to fluids to prevent agglomeration of the dispersed particles and to increase the viscosity of the liquid. This allows for slow settling of the drug particles to ensure uniform distribution and accurate measurement of the dose.

#### • Suspension:

A suspension is a dispersion containing fine insoluble particles suspended in a liquid medium.

# • Syrup:

A syrup is a concentrated solution of sugar, such as sucrose in water or other aqueous liquid used as a vehicle or base solution to mask the taste of drugs. The high concentration of sugar in syrups provides preservative property as well.