



## MASTER FORMULATION SHEETS

By:

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Updated 2nd May 2018

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# **Acetazolamide**

## **25mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Acetazolamide 250mg</b>				12 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Solubility of Acetazolamide in water is 0.7mg/ml; Optimum pH stability is 4.0—5.0

**2. Procedure ( )**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 150ml</b>
<b>Storage</b>	Room temperature $25 \pm 2$ °C <b>Stored in the dark</b>
<b>Expiry</b>	60 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 89 -95
3. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 2 - 4

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***Allopurinol***  
***20mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Allopurinol 300 mg</b>				8 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Allopurinol is slightly soluble in water.

Allopurinol is light-sensitive

**2. Procedure ( )**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic  
**bottle 150ml.**

**Shake bottle before used.**

**Storage**

Fridge temperature  
 2 – 8 ° C

**Keep away from light**

**Expiry**

60 days

**References:**

- Am J Health Syst. Pharm, 53(16):1944-1949, 1996
- M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 96-102
- Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 9-11

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***Alprazolam***  
***1mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Alprazolam 0.5mg</b>				120 tablets		
<b>X-Temp</b>	Pharm-D			qs 60 mL		

**\* Remark:**

Alprazolam is white or off-white crystalline powder which is insoluble in water.

Alprazolam products should be stored in tight, light-resistant containers at controlled room temperatures of 20 to 25°C

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature  
20 to 25°C

**Stored in the dark**

**Expiry** 60 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Am J Health Syst Pharm 1998;55:1915-20
3. Trissel's "Stability of Compounded Formulations, 4th Ed" pg 22

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# **Aminophylline**

## **3mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Aminophylline inj 250mg/10ml</b>				12 ml		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Aminophylline has an aqueous solubility of 200mg/ml. Aminophylline exposed to air may gradually absorbed carbon dioxide and free theophylline, becoming turbid or developing crystals. Refrigeration encourages crystal formation in some injections. For 21mg/ml suspension was not stable when stored at fridge temperature, formed crystal

**2. Procedure ( )**

1.	Measure out X-temp
2.	Draw up the required amount of injection using a filter needle or filter straw and transfer to a measuring cylinder
3.	Gradually add X-temp vehicle in small amounts to the injection and mix well until a liquid is formed.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the syrup into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE plastic amber bottle 120ml

**Storage** Room temperature  
 $25 \pm 2$  °C  
 Do not keep in the fridge  
 Keep away from light

**Expiry** 91 days

**References:**

- Chong E et al. "Stability of aminophylline in extemporaneously prepared oral suspensions" J Informed Pharmacother. 2000;2:100-6
- Beverley D Glass, *Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products*. JPPS 9(3): 398-426,2006
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 31

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Disclaimer: the information on this master formulation sheet is for informational purposes for qualified health care professionals. We will not assume responsibility for any errors or omissions, and/or any consequences arising from the use of the information by any hospitals. Patient circumstances will vary and some information may have become outdated as a result of more recent developments. We have no information on using X-Temp as the vehicle though X-Temp concept was developed based on an established Oral Suspending Vehicle in USA. It would be up to the compounding professional's judgment to use X-Temp as a possible alternative.

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# **Amiodarone**

## **5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Amiodarone 200mg</b>	Cordarone*			3 tablets		
<b>Sodium bicarbonate 5%</b>				Approx 10mL**		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

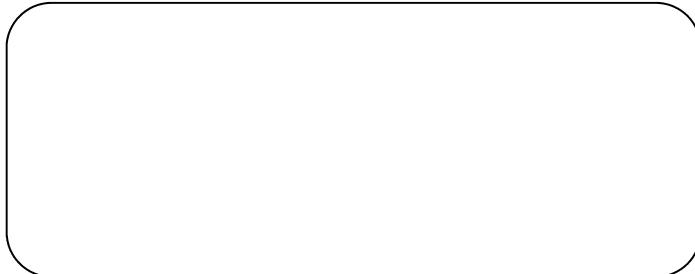
**\* Remark:**

Amiodarone HCl is a white to cream crystalline powder that has solubility in water of about 0.72mg/ml. Amiodarone has a pKa of about 6.6. It should be stored in tight containers at controlled room temperature & protected from light.

\*\* Approximately 10ml of Sodium bicarbonate 5% is needed to adjust 120ml X-Temp, depending on the brand of Amiodarone used due to different excipients in the tablet.

**2. Procedure (✓)**

1.	Measure out X-temp. Adjust the pH of X-Temp to pH 6-7 using Sodium Bicarbonate 5% solution.
2.	Soak the tablet with small amount of water to soften the tablet. Grind the tablets to fine powder in the mortar. Add small amount of X-Temp (pH adjusted) to levigate the powder to form a smooth paste
3.	Gradually add X-temp (pH adjusted) vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp (pH adjusted) vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 120ml

**Storage** a) Room temperature  
25 ± 2 °C  
b) Fridge temperature

**Expiry** a) 42 days  
b) 91 days

**References:**

1. J of Ped Pharm Prac 1999;4(4):186-189
2. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 103-109
3. Trissel's "Stability of Compounded Formulations, 4th Ed" pg 34

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# **Amiodarone**

## **40mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Amiodarone 200mg</b>	Cordarone*			20 tablets		
<b>Sodium bicarbonate 5%</b>				Approx 10mL**		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

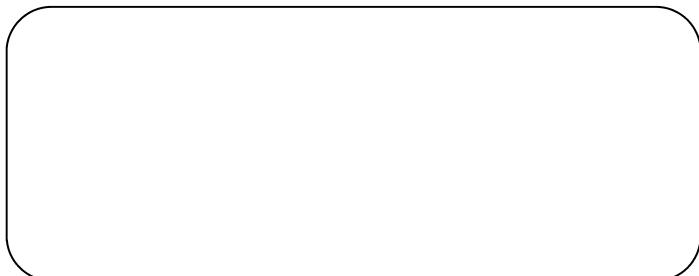
**\* Remark:**

Amiodarone HCl is a white to cream crystalline powder that has solubility in water of about 0.72mg/ml. Amiodarone has a pKa of about 6.6. It should be stored in tight containers at controlled room temperature & protected from light.

\*\* Approximately 10ml of Sodium bicarbonate 5% is needed to adjust 100ml X-Temp, depending on the brand of Amiodarone used due to different excipients in the tablet.

**2. Procedure (✓)**

1.	Measure out X-temp. Adjust the pH of X-Temp to pH 6-7 using Sodium Bicarbonate 5% solution.
2.	Soak the tablet with small amount of water to soften the tablet. Grind the tablets to fine powder in the mortar. Add small amount of X-Temp (pH adjusted) to levigate the powder to form a smooth paste
3.	Gradually add X-temp (pH adjusted) vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp (pH adjusted) vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature  
25 ± 2 °C

**Keep away from light**  
**Shake the bottle before use**

**Expiry** 28 days

**References:**

1. J of Ped Pharm Prac 1999;4(4):186-189
2. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 103-109
3. Trissel's "Stability of Compounded Formulations, 4th Ed" pg 34

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Last updated : \_\_\_\_\_

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***Amlodipine***  
***1mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Amlodipine 5mg (besylate)</b>				12 tablets		
<b>X-Temp</b>	Pharm-D			qs 60 mL		

**\* Remark:**

Amlodipine besylate is slightly soluble in water. The commercial tablet should be packaged in tight, light-resistance containers and stored at controlled room temperature.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablet in the mortar. Add 3-4 ml of water to disintegrate the tablets Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**    **HDPE amber plastic bottle 100ml**

**Storage**                  a. Fridge temperature  
                                    2 – 8 °C

b. Room temperature  
                                    25 ± 2 °C

**Expiry**                  a. 90 days  
                                    b. 60 days

**References:**

1. J American Pharm. Assoc. 1999; 39: 375-377 (Besylate)
2. **Stability of Extemporaneously Compounded Amlodipine Besylate Oral Suspensions.** CJHP 2016; 69(4)
3. Paddock Laboratories, Secundum Artem Vol 14, No 1.
4. Lawrence A. Trissel "Stability of Compounded Formulations, 4th Ed" pg 35

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Last updated : \_\_\_\_\_

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**Atenolol****2mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Atenolol 50mg</b>				4 tablets		
<b>Glycerin</b>				2 ml		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Atenolol has solubility of 26.5mg/ml at 37°C. Atenolol exhibits maximum stability at pH 4.0. Exposure of atenolol solutions to UV light resulted in drug decomposition at both physiologic & acid pH.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add glycerin to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle HDPE amber plastic  
bottle 50ml**

**Storage** Room temperature  
 $25 \pm 2^{\circ}\text{C}$   
**Keep away from light**

**Expiry** 90 days

**References:**

- Patel D et al, **Short-term stability of atenolol in oral liquid formulations.** Int J Pharm Compound. 1997;1:437-9.
- Paddock Laboratories Secundum Artem Vol 14 No 1
- Lawrence A. Trissel "Stability of Compounded Formulations, 4th Ed" pg 55

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Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

# **Azathioprine**

## **50mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Azathioprine 50mg</b>				50 tablets		
<b>X-Temp</b>	Pharm-D			qs 50 mL		

**\* Remark:**

Azathioprine is slightly soluble in water, about 0.13mg/ml

**CYTOTOXIC**– Must use designated cytotoxic equipment and prepare in segregated area. Wear protective equipment**2. Procedure ( )**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Wet the tablets with small of X-Temp before crushing the tablet to prevent exposure to medicine powder. Crush the tablets to form a smooth paste.  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal. Additional label: <b>Cytotoxic</b>  |

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 50ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$ <b>Stored in the dark</b>
<b>Expiry</b>	60 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Am J Health-Syst Pharm. 1996; 53: 1944-49
3. Paddock Laboratories, Secundum Artem Vol 5 No 4.
4. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 36-38

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**Baclofen**  
**10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Baclofen 10 mg</b>				120 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Solubility of Baclofen in water is 7.5mg/ml

**2. Procedure ( )**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**    HDPE amber plastic  
bottle 150ml

**Storage**              Room temperature  
25 ± 2 °C

**Keep away from light**

**Expiry**                60 days

**References:**

- Am J Health Syst Pharm 53 (18):2179-2184, 1996
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 39 – 40

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# **Bethanechol**

## **5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Bethanechol 10mg</b>				50 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Bethanechol Chloride occurs as hygroscopic colorless powder. It has a characteristic fishy odor. Bethanechol is reported to be very soluble in water, having an aqueous solubility of about 1.67g/ml.

Bethanechol chloride should be protected from temperatures above 40°C. The injection should be protected from freezing.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature <b>25 ± 2 °C</b>
	<b>Keep away from light</b>
<b>Expiry</b>	60 days

**References:**

- Allen LV, Erickson MA "Stability of bethanechol chloride, pyrazinamide, quinidine sulfate, rifampin and tetracycline hydrochloride in extemporaneously compounded oral liquids." Am J Health Syst Pharm. 1998;55:1804-9
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 71



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**MASTER FORMULA SHEET**

Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

**Bosentan****6.25mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Bosentan 62.5mg</b>	Tracleer			10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Tracleer 62.5mg and Tracleer 125mg are film coated tablets.

**2. Procedure (✓)**

1.	Measure out X-temp.
2.	Soak the tablet with small amount of water/glycerin to remove the film-coat. Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste.
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well.
5.	Transfer the suspension into bottle.
6.	Label and affix shrink seal.

**3. Sample label : Affix here****Special Instruction**

Packaging bottle	<b>HDPE amber plastic bottle 100ml</b>
Storage	Room temperature <b>25 ± 2 °C</b> <b>Store in the dark</b>
Expiry	30 days

**References:**

- Malik A., Gorman G., Coward L., and Arnold J.J. "**Stability of an Extemporaneously Compounded Oral suspension of Bosentan.**" Hosp Pharm 2016; 51(5):389-395.
- Tracleer PI.

Supported by:



**MASTER FORMULA SHEET**

Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

# **Captopril**

## **1.25mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Captopril 25mg</b>	Hexal AG			5 tablets		
<b>Ascorbic Acid 100mg</b>	Drug Houses of Australia (Asia) Pte			5 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**Remark:**

Captopril soluble in water &amp; ethanol ; decomposed or oxidized easily.

**2. Procedure ( )**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**      **HDPE plastic  
bottle 100ml**

**Storage**      Room temperature  
 $25 \pm 2^{\circ}\text{C}$

**Expiry**      14 days

Supported by:

**Reference:**

Local Stability Study in Malaysia at Zone 4 climate. Conducted by Pharm-D Sdn Bhd (30/12/09—  
27/02/10)

**MASTER FORMULA SHEET**

Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

***Carbidopa/ Levodopa (Sinemet®)***  
***1.25mg carbidopa/5mg levodopa/ml***  
***Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Sinemet ® 25/100 mg</b>	MSD			5 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Levodopa turns dark when exposed to air; Oxidation of levodopa in alkaline solution leads to formation of inactive compound such as melanin

**2. Procedure ( )**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Fridge temperature 2 – 8 ° C <b>Keep away from light</b>
<b>Expiry</b>	28 days

**References:**

1. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 158-165
2. Paddock Laboratories, Secundum Artem Vol 14 No 3
3. Sick Kids Pharmacy Formulation Sheet (updated April 2007)

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**MASTER FORMULA SHEET**

Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

**Carvedilol****1.67mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:

**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Carvedilol 25mg</b>				8 tablets		
<b>Sterile Water</b>				20 mL		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**Remark:**

Carvedilol is a white to off-white crystalline powder. It is practically insoluble in water.

**2. Procedure ( )**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Crush the tablets to fine powder in the mortar.<br>Levigate with sterile water for irrigation to form a smooth paste   |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic  
**bottle 120ml**

**Storage** Room temperature  
25 ± 2 °C  
Stored in the dark

**Expiry** 84 days

Supported by:

**Reference:**

- Rita K. Jew, Winson Soo-Hoo & Sarah C. Erush "Extemporaneous Formulations for Pediatric, Geriatric & Special Needs Patient, 2nd Ed" pg 19
- Lawrence A. Trissel "Stability of Compounded Formulations, 4th Ed" pg 103

## MASTER FORMULA SHEET

*Last updated :*

*Updated by* : Date

*Hospital* :

***Chloral Hydrate***  
***40mg/ml Oral Suspension***

Batch No.:      Batch Size:      Date Prepared:      EXP date:      Prepared by:      Final Checked by:

## 1. Raw Materials Quality Control

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Chloral Hydrate</b>				4000mg or 4g		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Chloral hydrate occurs as transparent colorless or white crystals and has an aromatic penetrating, slightly acrid odor and a caustic bitter taste.

Chloral hydrate is very soluble in water. A 10% chloral hydrate solution in water has a pH of 3.5 to 5.5.

## **2. Procedure ( )**

- |  |    |  |
|--|----|--|
|  | 1. | Measure out X-temp   |
|  | 2. | Measure the require amount of powder.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
|  | 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
|  | 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
|  | 5. | Transfer the suspension into bottle  |
|  | 6. | Label and affix shrink seal  |

### **3. Sample label : Affix here**



### **Special Instruction**

<b>Storage</b>	Room temperature $30 \pm 2^\circ\text{C}$ ; 75% RH Keep away from light. Should not be freeze.
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**Expiry** 6 months

Supported by:

#### **Reference:**

Local Stability Study in Malaysia at Zone 4 climate. Conducted by Pharm-D Sdn Bhd (28/12/2015 — 05/07/2016)



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**MASTER FORMULA SHEET**

Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

# ***Chloroquine Phosphate 15mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Chloroquine Phosphate 250mg</b>				6 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Chloroquine Phosphate is freely soluble in water &amp; has the aqueous solubility of 250mg/ml.

Chloroquine Phosphate is sensitive to light, discoloring upon exposure to light.

**2. Procedure ( )**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$ <b>Keep away from light</b>
<b>Expiry</b>	60 days

**Reference:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 79-81

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**MASTER FORMULA SHEET**

Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

**Clobazam****1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Clobazam 10mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

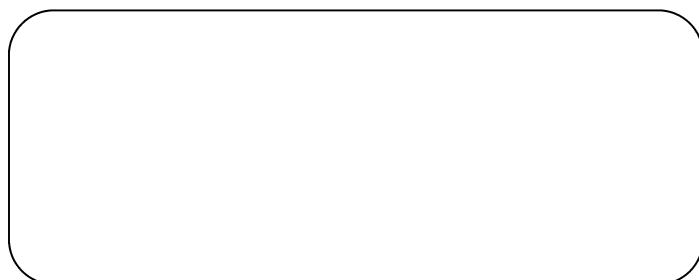
**\* Remark:**

Clobazam is white to almost white crystalline powder.

Clobazam is slightly soluble in water, with solubility 188mg/L. It is sparingly soluble in ethanol and freely soluble in methylene chloride.

**2. Procedure ( )**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**    HDPE amber plastic  
bottle 120ml

**Storage**              Room temperature  
25 ± 2 °C

**Expiry**                24 weeks (168 days)

**References:**

1. Lwin EMP, Ellis D, Song Y, et al. Stability Studies of Extemporaneously Compounded Clobazam Oral Suspension. *Annals of Pharmacotherapy* 2016, 50 (2):155-6.
2. IWK Health Centre Formulation Sheet
3. National Center for Biotechnology Information. PubChem Compound Database; CID=2789, <https://pubchem.ncbi.nlm.nih.gov/compound/2789> .

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Last updated : \_\_\_\_\_

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# **Clonazepam**

## **0.1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Clonazepam 2mg*</b>				5 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Clonazepam oral drops formulation is commercially available

Clonazepam practically insoluble in water, &lt;0.1mg/ml in water at 25°C; degradation occurs principally via hydrolysis.

Clonazepam solution exhibit loss due to sorption to PVC containers

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction****Packaging bottle**   **Amber glass bottle 100ml****Avoid PVC containers****Shake well before use****Storage**

Room temperature

25 ± 2 °C

**Keep away from light****Expiry**

60 days

**References:**

1. Am J Health Syst Pharm, 53(16):1944-1949,1996
2. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
3. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 138 - 143

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# **Clonidine Hydrochloride**

## **0.01mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Clonidine HCl 100mcg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Clonidine HCl is a white, odorless, crystalline powder with a bitter taste. It has an aqueous solubility of 77mg/ml.

**2. Procedure (v)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	91 days

**References:**

- Mary H H Ensom, Diane Décarie, **Stability of Extemporaneously Compounded Clonidine in Glass and Plastic Bottles and Plastic Syringes.** CJHP 2014; 67 (4)
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 146

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# **Clonidine Hydrochloride**

## **0.1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Clonidine HCl 200mcg</b>				50 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Clonidine HCl is a white, odorless, crystalline powder with a bitter taste. It has an aqueous solubility of 77mg/ml.

**2. Procedure ( )**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Fridge temperature 2 - 8 °C <b>Keep away from light</b>
<b>Expiry</b>	28 days

**References:**

- Levinson M.L et al "Stability of an extemporaneously compounded clonidine hydrochloride oral liquid" Am J Hosp Pharm, 49(1):122-125, 1992
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 144
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 146

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Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

# **Clopidogrel**

## **5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Clopidogrel 75mg</b>				8 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Clopidogrel Bisulfate is a white to off-white powder. It is freely soluble in water.

The preparation was palatable, with a slightly gritty consistency & a slightly bitter after taste; the bitterness intensified slightly between 28 and 60 days but remained fairly mild.

**2. Procedure ( )**

1.	Measure out X-temp
2.	Grind the tablet to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>Amber plastic bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	60 days

**References:**

1. Skillman KL, Caruthers RL, Johnson CE "Stability of an extemporaneously prepared Clopidogrel Oral Suspension" Am J Health Syst Pharm 2010;67(7):559-561
2. Secundum Artem Vol 16 No 3

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**MASTER FOMULA SHEET**

Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

**Clozapine**  
**20mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Clozapine 100mg (Clozaril)</b>	Novartis			20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Clozapine has poor solubility in water

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE plastic  
**bottle 100ml**  
**Shake bottle before  
used.**

**Storage** Room temperature  
 $25 \pm 2^{\circ}\text{C}$

**Expiry** 28 days

**References:**

- Can J Hosp Pharm 2005; 58: 279 - 84
- Paddock Laboratories, Secundum Artem Vol 16 No 1
- M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 150-157

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**MASTER FORMULA SHEET**

Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

**Dapsone****2mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Dapsone 25mg</b>				8 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Dapsone is a white to yellowish-white crystalline powder with bitter taste; very slightly soluble in water. Dapsone may discolor if exposed to light. No chemical change associated with the discoloration has been detected.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Fridge temperature  
2 – 8 °C

**Keep away from light**

**Expiry** 91 days

**References:**

- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
- Nahata et al, **Stability of Dapsone in two oral liquid dosage form**. Ann Pharmacother, 2000;34:848-50
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 172

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Last updated : \_\_\_\_\_

Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

# **Dexamethasone**

## **0.5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Dexamethasone (Sod Phosphate) injection 4mg/ml</b>	Sabex Inc			12.5 mL		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Dexamethasone is white crystalline powder.

1mg Dexamethasone (solubility is 0.1mg/ml) = 1.1mg Dexamethasone acetate (insoluble in water); 1mg Dexamethasone = 1.3mg Dexamethasone Soda Phosphate (solubility 500mg/ml). Dexamethasone Soda phosphate is very hygroscopic crystalline powder.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Draw up the required amount of injection using a filter needle or filter straw and transfer to a measuring cylinder
3.	Gradually add X-temp vehicle in small amounts to the injection and mix well until a liquid is formed.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the syrup into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature

25 ± 2 °C

**Keep away from light**

**Expiry** 91 days

**References:**

- Wen-Lin Chow et al **Stability of dexamethasone in extemporaneously prepared oral suspensions.** Can J Hosp Pharm 2001;54:96-101
- M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 171—177
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 176—179

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Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

# **Dexamethasone**

## **1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Dexamethasone 4mg</b>	Pharmascience			25 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Dexamethasone is white crystalline powder.

1mg Dexamethasone (solubility is 0.1mg/ml) = 1.1mg Dexamethasone acetate (insoluble in water); 1mg Dexamethasone = 1.3mg Dexamethasone Sodium Phosphate (solubility 500mg/ml). Dexamethasone Sodium phosphate is very hygroscopic crystalline powder.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Draw up the required amount of injection using a filter needle or filter straw and transfer to a measuring cylinder
3.	Gradually add X-temp vehicle in small amounts to the injection and mix well until a liquid is formed.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the syrup into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature  
25 ± 2 °C

**Keep away from light**

**Expiry** 91 days

**References:**

- Mary H H Ensom et al **Dexamethasone 1mg/ml Suspension Prepared from Crushed Tablets: Stability in Glass and Plastic Bottles and Plastic Syringes.** CJHP 2016; 69 (1).
- Wen-Lin Chow et al **Stability of dexamethasone in extemporaneously prepared oral suspensions.** Can J Hosp Pharm 2001;54:96-101
- M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 171—177
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 176—179

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**Diazoxide**  
**10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Diazoxide 100mg*</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Diazoxide is practically insoluble in water.

Diazoxide solution darkens when expose to light.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Draw up the required amount of injection using a filter needle or filter straw and transfer to a measuring cylinder
3.	Gradually add X-temp vehicle in small amounts to the injection and mix well until a liquid is formed.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the syrup into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction****Packaging bottle** HDPE amber plastic  
**bottle 100ml****Storage** Room temperature  
 $25 \pm 2^{\circ}\text{C}$ **Keep away from light**  
**Do not freeze****Expiry** 90 days**References:**

1. Friciu M et al **Stability of Diazoxide in Extemporaneously Compounded Oral Suspensions.** PLoS One 2016.
2. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 178—181

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**Diltiazem**  
**12mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Diltiazem 60mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 50 mL		

**\* Remark:**

Diltiazem HCl is freely soluble in water. Decomposition occurred at higher pH (7-8)

Optimum pH ~ 5. Choice of sugars as excipients influences the drug stability

**2. Procedure ( )**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Crush the tablets to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

Packaging bottle	<b>HDPE amber plastic bottle 50ml</b>
Storage	Room temperature <b>25 ± 2 °C</b> <b>Keep away from light</b>
Expiry	60 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Ann Pharmacother 2000; 34:848 - 50
3. Paddock Laboratories, Secundum Artem Vol 6 No 1
4. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 127 - 129

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# **Dipyridamole**

## **10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Dipyridamole 25mg</b>				40 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Dipyridamole is soluble in dilute acid solution

**2. Procedure ( )**

1.	Measure out X-temp
2.	Wet the tablets with small amount of diluent & leave for a few minutes. Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature <b>25 ± 2 °C</b> <b>Stored in the dark</b>
<b>Expiry</b>	60 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Am J Health Syst Pharm 1996; 53:2179 - 84
3. Paddock Laboratories, Secundum Artem Vol 6 No 1
4. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 132 - 133

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**Dolasetron****10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Dolasetron mesylate 50mg</b>				20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Dolasetron mesylate is a white powder &amp; is freely soluble in water.

Dolasetron mesylate should be stored at controlled room temperature &amp; protected from sunlight.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	90 days

**References:**

- Johnson CE, Wagner DS, Bussard WE "Stability of dolasetron in two oral liquid vehicles" Am J Health-Syst Pharm. 2003;60:2242—44
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 33
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 203

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# **Domperidone**

## **1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Domperidone 10mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Domperidone is practically insoluble in water.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Wet the tablets with small amount of X-Temp & leave for a few minutes. Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2$ °C
<b>Expiry</b>	91 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. International Journal of Pharmaceutical Compounding 2006; 10(1): 61
3. Sick Kids Pharmacy Formulation Sheet, (updated Feb 008)

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***Domperidone***  
***5mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Domperidone 10mg</b>	Ranbaxy			50 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Domperidone is practically insoluble in water.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Wet the tablets with small amount of X-Temp & leave for a few minutes. Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	91 days

**References:**

1. Lingertat-Walsh K, Sales P et al **Stability of Extemporaneously Compounded Domperidone 5mg/ml Suspension.** Department of Pharmacy, The Hospital for Sick Children, Toronto and Sunnybrook Health Sciences Center, Toronto.
2. Lawrence A. Trissel "Stability of Compounded Formulations, 4th Ed" pg 204

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# **Domperidone**

## **10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Domperidone 10mg</b>				100 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Domperidone is practically insoluble in water.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Wet the tablets with small amount of X-Temp & leave for a few minutes. Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	91 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
2. International Journal of Pharmaceutical Compounding 2006; 10(1): 61

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***Enalapril***  
***1mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Enalapril 20mg (maleate)</b>				5 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

An aqueous solubility of enalapril maleate around 25mg/ml at room temperature

**2. Procedure (✓)**

1. Measure out X-temp
2. Crush the tablets to fine powder in the mortar.  
Add small amount of X-Temp to levigate the powder to form a smooth paste
3. Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4. Make up the final volume in the graduated using more X-temp vehicle. Stir well
5. Transfer the suspension into bottle
6. Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature <b>25 ± 2 °C</b> <b>Stored in the dark</b>
<b>Expiry</b>	90 days

**References:**

1. Friciu M et al **Stability of Extemporaneously Prepared Enalapril Maleate Suspensions in Glass Bottles and Plastic Syringes.** CJHP 2016; 69 (6)
2. Am J Health Syst Pharm 1998; 55:1915 - 20
3. Paddock Laboratories, Secundum Artem Vol 6 No 2
4. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
5. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 138 - 140

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# **Ethambutol**

## **100mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Ethambutol 400mg</b>				25 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Ethambutol is a white crystalline powder. It is freely soluble in water with solubility of 1mg/ml. A 2% aqueous solution of Ethambutol HCl has a pH of 3.7—4.0.

**2. Procedure (✓)**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Grind the tablet to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste   |
| 3. | Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature

25 ± 2 °C

**Keep away from light**

**Expiry** 28 days

Supported by:

**References:**

- M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 194—199
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 224



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***Flecainide acetate***  
***20mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

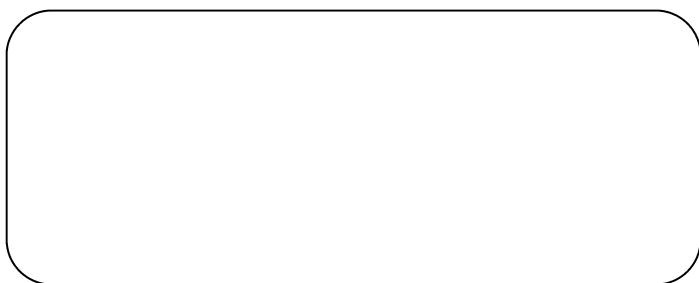
Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Flecainide Acetate 100mg</b>				20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Flecainide acetate is a white hygroscopic crystalline powder & has an aqueous solubility of 48.4mg/ml.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	60 days

**References:**

- Am J Health-Syst Pharm. 1996;53:2179—84
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 37
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 236

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# ***Flucytosine***

## ***10mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Flucytosine 250mg</b>				4 capsules		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Flucytosine is a white odorless crystalline powder & is sparingly soluble in water, having an aqueous solubility of about 1.5g in 100ml.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Carefully empty the capsules content into the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	60 days

**References:**

- Am J Health-Syst Pharm. 1996;53:1944—99
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 39
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 239

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# ***Flucytosine***

## ***50mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Flucytosine 250mg</b>				20 capsules		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Flucytosine is a white odorless crystalline powder & is sparingly soluble in water, having an aqueous solubility of about 1.5g in 100ml.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Carefully empty the capsules content into the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	90 days

**References:**

1. Vandebussche H et al. "Stability of flucytosine 50mg/ml in extemporaneous oral liquid formulation" Am J Health-Syst Pharm. 2002;59:1853–55
2. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
3. Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 40
4. Trissel's "Stability of Compounded Formulations, 4th Ed" pg 239

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**Folic Acid**  
**1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Folic Acid 5mg</b>	Pharmaniaga			20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**Remark:**

Folic acid is very slightly soluble in water; Sensitive to heat & light.

**2. Procedure ( )**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**      **HDPE plastic  
bottle 100ml**

**Storage**      Room temperature  
25 ± 2 °C

**Expiry**      60 days

Supported by:

**Reference:**

Local Stability Study in Malaysia at Zone 4 climate. Conducted by Pharm-D Sdn Bhd (22/12/09—25/02/10)

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Hospital : \_\_\_\_\_

# **Gabapentin**

## **100mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Gabapentin 300mg</b>				20 capsules		
<b>X-Temp</b>	Pharm-D			qs 60 mL		

**\* Remark:**

Gabapentin is freely soluble in water.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Carefully empty the capsules content into the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$ (Do Not keep in the fridge)
<b>Expiry</b>	90 days

**References:**

1. Friciu M et al **Stability of Gabapentin in Extemporaneously Compounded Oral Suspensions.** *PLoS One* 2017
2. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** *JPPS* 9(3): 398-426,2006
3. Pediatr Neurol 1999 Mar; 20(3): 195-7

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# **Granisetron Hydrochloride**

## **0.05mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Granisetron 1mg</b>				6 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Granisetron HCl is a white to off-white solid.

Granisetron HCl is soluble in water &amp; ethanol. Granisetron HCl 1.12mg is equal to Granisetron 1mg.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	90 days

**References:**

- Am J Health-Syst Pharm. 1998;55:2511—2513
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 138
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 264

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***Hydrochlorothiazide  
5mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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## 1. Raw Materials Quality Control

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Hydrochlorothiazide 25mg</b>				20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Hydrochlorothiazide is a white, odorless crystalline powder. It has a slightly bitter taste.

It is also slightly soluble in water.

## **2. Procedure (✓)**

- |  |    |  |
|--|----|--|
|  | 1. | Measure out X-temp   |
|  | 2. | Grind the tablets to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
|  | 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
|  | 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
|  | 5. | Transfer the suspension into bottle  |
|  | 6. | Label and affix shrink seal  |

### **3. Sample label : Affix here**



#### **Special Instruction**

**Packaging bottle** HDPE plastic amber bottle

**Storage** Room temperature  
 $30 \pm 2$  °C; 75% RH

**Expiry** 120 days

### References:

1. Local Stability Study in Malaysia at Zone 4 climate. Conducted by Pharm-D Sdn Bhd (09/10/2017— 09/02/2018) Supported by:  
2. M. Jackson & A. Lowey “Handbook of Extemporaneous Preparation” pg 315-328  
3. Lawrence A. Trissel “Stability of Compounded Formulations, 4th Ed” pg 276





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# **Hydrocortisone**

## **1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Hydrocortisone 10mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Hydrocortisone is a white, odorless, bitter-tasting crystalline powder. It is very slightly soluble in water, having an aqueous solubility of about 0.28mg/ml.

The pH range of maximum stability of hydrocortisone is 3.5 to 4.5.

**2. Procedure (✓)**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Grind the tablets to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE plastic amber bottle 120ml

**Storage** Room temperature  
25 ± 2 °C

**Keep away from light**

**Expiry** 91 days

**References:**

- Chong G. et al "Stability of hydrocortisone in extemporaneously compounded suspension" J Inform Pharmacother. 2003;13:100-110
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 277
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 43

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# **Hydrocortisone**

## **2mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Hydrocortisone 10mg</b>				20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Hydrocortisone is a white, odorless, bitter-tasting crystalline powder. It is very slightly soluble in water, having an aqueous solubility of about 0.28mg/ml.

The pH range of maximum stability of hydrocortisone is 3.5 to 4.5.

**2. Procedure (✓)**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Grind the tablets to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE plastic amber bottle 120ml

**Storage** Room temperature  
25 ± 2 °C

**Keep away from light**

**Expiry** 91 days

**References:**

- Chong G. et al "Stability of hydrocortisone in extemporaneously compounded suspension" J Inform Pharmacother. 2003;13:100-110
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 277
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 44

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# **Hydroxychloroquine Sulfate**

## **25mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

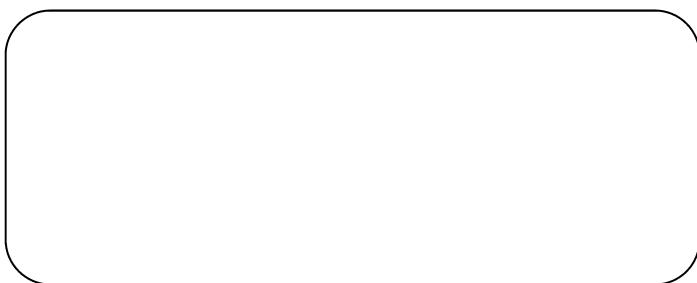
Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Hydroxychloroquine 200mg</b>				15 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Hydroxychloroquine sulfate is a white to almost white odorless crystalline powder having a bitter taste. Hydroxychloroquine sulfate 100mg is approximately equivalent to 77mg of the base. It has a solubility of about 200mg/ml in water.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	90 days

**References:**

- McHenry A.R et al **Stability of Extemporaneously Prepared Hydroxychloroquine Sulfate 25mg/ml Suspensions in Plastic Bottles and Syringes.** IJPC 2017; 21 (3)
- Lawrence A. Trissel "Stability of Compounded Formulations, 4th Ed" pg 284

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**Isoniazid**  
**10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Isoniazid 100mg</b>	Pharmaniaga			10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Isoniazid is an odorless white crystalline powder. It is soluble in water to about 125 to 140mg/ml at 25 °C. A 1% aqueous solution has a pH of 5.5 to 6.5. A 10% aqueous solution has a pH between 6.0 –7.5.

**2. Procedure ( )**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $30 \pm 2$ °C; 75% RH <b>Keep away from light</b>
<b>Expiry</b>	90 days

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**Reference:**

Local Stability Study in Malaysia at Zone 4 climate. Conducted by Pharm-D Sdn Bhd (04/01/2016—01/04/2016)

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# **Itraconazole**

## **20mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Itraconazole 200mg</b>				10 capsules		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Itraconazole is a white or nearly white powder which is practically insoluble in water.

Itraconazole capsules should be kept away from light & moisture.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Carefully empty the capsules content into the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature  
25 ± 2 °C

**Keep away from light**  
**Do not freeze**

**Expiry** 56 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Abdel-Rahman SM, Nahata, **Stability of Itraconazole in an extemporaneous suspension**. J Paed Pharm Pract. 1998;3:115-8
3. Trissel's "Stability of Compounded Formulations, 4th Ed" pg 311-312

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# **Ketoconazole**

## **20mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Ketoconazole 200mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

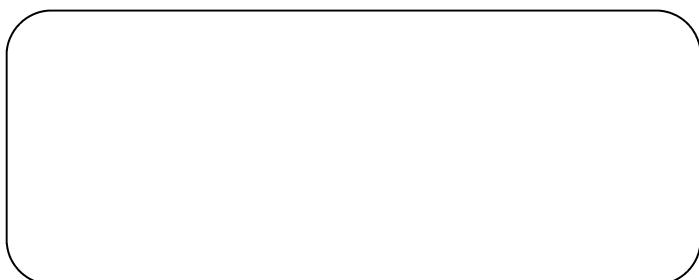
**\* Remark:**

Ketoconazole is a white to slightly beige, odorless crystalline powder.

Ketoconazole is practically insoluble in water.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	60 days

**References:**

- Am J Health-Syst Pharm. 1996;53:2073—2078
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 62
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 373

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**Labetalol**  
**10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Labetalol 100mg</b>				12 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Labetalol HCl has an aqueous stability of about 20mg/ml. Optimum pH 4.0 - 5.0

**2. Procedure ( )**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 150ml</b>
<b>Storage</b>	Room temperature <b>25 ± 2 °C</b> <b>Stored in the dark</b>
<b>Expiry</b>	60 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Am J Health Syst Pharm 1996; 53:2304-9
3. Paddock Laboratories, Secundum Artem Vol 6 No 1
4. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 209-211

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# **Lamotrigine**

## **1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Lamotrigine 100mg</b>				1 tablet		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Lamotrigine is white to pale cream powder that is very slightly soluble in water, having solubility of 0.17mg/ml at 25° C. Lamotrigine tablets should be stored between 15 and 25° C in a dry place & protected from light

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablet to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature  
25 ± 2 °C

**Keep away from light**

**Expiry** 91 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Nahata et al, **Stability of lamotrigine in two extemporaneously prepared oral suspensions at 4 and 25oC**. Am J Health Syst Pharm 1999;56:240-242
3. Trissel's "Stability of Compounded Formulations, 4th Ed" pg 321-322

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***Levetiracetam***  
***50mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Levetiracetam 500mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:****2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	95 days

**References:**

- Mary H H Ensom, Diane Décarie **Stability of Extemporaneously Compounded Levetiracetam in Glass and Plastic Bottles and Plastic Syringes.** CJHP 2015; 68 (4).
- Ensom MHH, Decarie D, Rudolph S. **Stability of Levetiracetam in extemporaneously compounded suspensions.** CJHP 2011; 64(3):207-11.

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# **Lisinopril**

## **1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Lisinopril 10mg</b>				12 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Lisinopril is a white to off-white odorless crystalline powdr. Lisinopril 2.72mg as the dehydrate is approximately equivalent to lisinopril anhydrous 2.5mg.

Lisinopril hasan aquoues solubility of 97mg/ml

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	91 days

**References:**

- Ann Pharmacother. 2004;38:396—399
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 55
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 336

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Hospital : \_\_\_\_\_

**Lorazepam****200mcg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Lorazepam 1mg</b>				10 tablet		
<b>X-Temp</b>	Pharm-D			qs 50 mL		

**\* Remark:**

Lorazepam is a white odorless crystalline powder. Lorazepam is practically insoluble in water, with a reported solubility of 0.08mg/ml

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablet to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** Amber Glass bottle  
**100ml**

**Storage** Fridge temperature  
2 – 8 ° C

**Keep away from light**

**Expiry** 7 days

**References:**

- M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 255—263
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 342

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# **Melatonin**

## **2mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Melatonin 10mg</b>				50 tablets		
<b>X-Temp</b>	Pharm-D			qs 250 mL		

**\* Remark:****2. Procedure ( )**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Grind the tablets to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction****Packaging bottle Plastic amber bottle**

**Storage** Room temperature  
 $25 \pm 2^{\circ}\text{C}$

**Expiry** 90 days

Supported by:

**Reference:**

Friciu M et al. **Evaluation of stability of melatonin in extemporaneously compounded oral suspensions.** *Journal of Pharmacy Practice and Research*, 2016;46: 28-33

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**Metolazone****1mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Metolazone 10mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

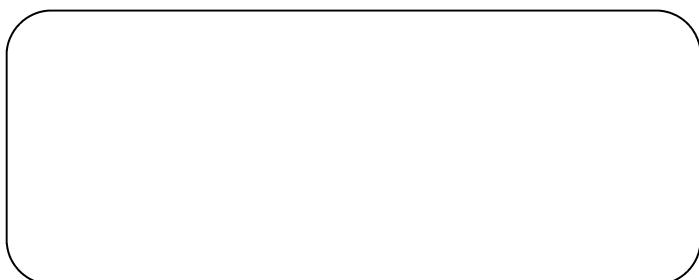
**\* Remark:**

Metolazone is a quinazoline diuretic, is a white powder.

Metolazone is practically insoluble in water

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	60 days

**References:**

- Am J Health-Syst Pharm. 1996;53:2073—2078
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 48
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 374

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**Metoprolol****10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Metoprolol tartarate 50mg (Lopresor)</b>	Novartis			24 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Metoprolol tartarate is very soluble in the water

**2. Procedure ( )**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 150ml</b>
<b>Storage</b>	Room temperature $25 \pm 2$ °C <b>Keep away from light</b>
<b>Expiry</b>	60 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Am J Health Syst Pharm 1996; 53:2304-9
3. Paddock Laboratories, Secundum Artem Vol 6 No 1
4. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 248-9

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Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

# **Metronidazole**

## **50mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Metronidazole powder</b>				6 gram		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Metronidazole is an odorless white to yellow crystalline powder, it has very bitter taste. Metronidazole is slightly soluble in water, having an aqueous solubility at 20°C of about 10mg/ml. Metronidazole are stable in air but may darken upon exposure to light.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Measure the require amount of powder. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction****Packaging bottle** HDPE amber plastic bottle 120ml**Storage** Room temperature

25 ± 2 °C

**Keep away from light****Expiry** 60 days**References:**

- Allen LV, Erickson MA, **Stability of ketoconazole, metolazone, metronidazole, procainamide hydrochloride, and spironolactone in extemporaneously compounded oral liquids.** Am J Health Syst Pharm. 1996;53:2073-8
- Secundum Artem Vol 5 No 4
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 376-380

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Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

# **Metronidazole**

## **10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Metronidazole 200mg</b>				6 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Metronidazole is an odorless white to yellow crystalline powder, it has very bitter taste. Metronidazole is slightly soluble in water, having an aqueous solubility at 20°C of about 10mg/ml. Metronidazole are stable in air but may darken upon exposure to light.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablet to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 120ml

**Storage** Room temperature  
25 ± 2 °C

**Keep away from light**

**Expiry** 90 days

**References:**

- Mathew M, Gupta VD, Bethea C, **Stability of metronidazole in solutions and suspensions**  
J Clin Pharm Ther. 1994;19:27-9
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 376-380

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**Morphine****10mg/5ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Morphine HCl Trihydrate</b>	Fagron GmbH, Germany			200 mg		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Morphine soluble in water; Stable in pH around 4.8

Solution turn darker when exposed to light (oxidation)

**2. Procedure ( )**

1.	Measure out X-temp
2.	Measure the require amount of powder. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction****Packaging bottle** HDPE plastic  
**bottle 100ml****Storage** Room temperature  
 $30 \pm 2$  °C; 75% RH  
**Should not be freeze****Expiry** 12 months

Supported by:

**Reference:**

Local Stability Study in Malaysia at Zone 4 climate. Conducted by Pharm-D Sdn Bhd in collaboration with Pusat Perubatan Universiti Kebangsaan Malaysia, PPUKM (01/12/12—02/12/13)

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# **Mycophenolate Mofetil 50mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Mycophenolate Mofetil 250mg</b>				20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

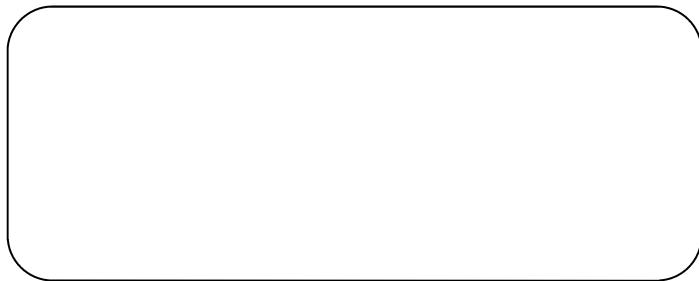
**\* Remark:**

This drug has been characterized as a potential **TERATOGEN**

Mycophenolate mofetil has an aqueous solubility of 43mcg/ml at pH 7.4. Aqueous solubility increases as the pH becomes more acidic; solubility increases to 4.27mg/ml at pH 3.6.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	91 days

**References:**

1. Mary H H Ensom, Diane Décarie **Stability of Mycophenolate Mofetil in a 1:1 Mixture of Ora-Sweet and Ora-Plus** CJHP 2002; 55 (1).
2. Venkataraman R et al **Stability of Mycophenolate Mofetil as an extemporaneous suspension.** Ann Pharmacother 1998; 32:755-7

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# **Mycophenolate Mofetil**

## **100mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Mycophenolate Mofetil 250mg</b>				40 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

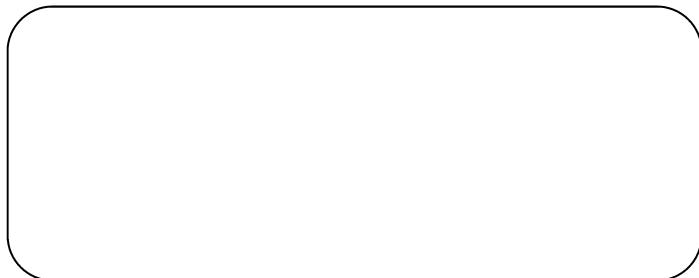
**\* Remark:**

This drug has been characterized as a potential **TERATOGEN**

Mycophenolate mofetil has an aqueous solubility of 43mcg/ml at pH 7.4. Aqueous solubility increases as the pH becomes more acidic; solubility increases to 4.27mg/ml at pH 3.6.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	91 days

**References:**

1. Mary H H Ensom, Diane Décarie **Stability of Mycophenolate Mofetil in a 1:1 Mixture of Ora-Sweet and Ora-Plus** CJHP 2002; 55 (1).
2. Anaizi NH et al **Stability of mycophenolate mofetil in an extemporaneously compounded oral liquid.** Am J Health Syst Pharm 1998; 55:926-9

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**Naproxen****25mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Naproxen 250mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Naproxen acid is practically insoluble in water at low pH but is freely soluble at high pH.

The milky, pale yellow suspensions were easily re-suspended.

**2. Procedure (v)**

1.	Measure out X-temp.
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste.
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well.
5.	Transfer the suspension into bottle.
6.	Label and affix shrink seal.

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	91 days

**References:**

- Mary H H Ensom, Diane Décarie, Karen Lingertat-Walsh "Stability of Extemporaneously Compounded Naproxen 25 mg/mL Suspension in Glass and Plastic Bottles and Plastic Syringes." The Canadian Journal of Hospital Pharmacy (CJHP) 2015, 68(6):489-491.
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 402.

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# **Naratriptan Hydrochloride**

## **0.5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Naratriptan 2.5mg</b>				24 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

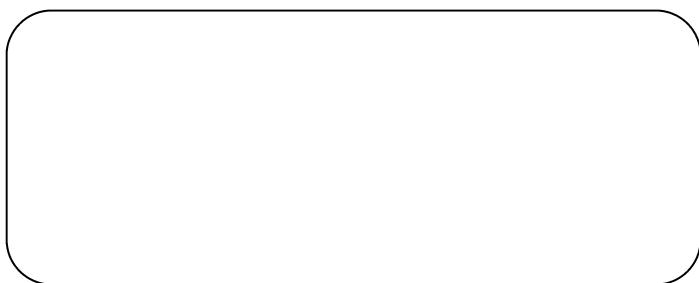
**\* Remark:**

Naratriptan HCl is a white to pale yellow crystalline powder.

Naraptriptan HCl is readily soluble in water.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Fridge temperature 2 - 8 °C
<b>Expiry</b>	90 days

**References:**

- Int J Pharm Compound 2000;4:69—71
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 69
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 403

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***Nifedipine***  
***4mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Nifedipine 10 mg</b>	Novopharm			25 capsules		
<b>X-Temp</b>	Pharm-D			qs 60 mL		

**\* Remark:**

Nifedipine is practically insoluble in water; light-sensitive

Nifedipine liquid-filled capsules should be packed in tight, light-resistant containers & stored between 15 and 25°C. The extended-release tablets may be stored in room temperature.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Carefully empty the liquid-filled capsules into the mortar, using needle & syringe, 2-hole method. With care and two repetitions per capsule, about 95% of the liquid will be removed. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature

25 ± 2 °C

**Store in the dark**

**Expiry** 91 days

Supported by:

**References:**

- Secundum Artem Vol 14 No 4
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 406—409

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Updated by : \_\_\_\_\_

Hospital : \_\_\_\_\_

# **Nitrofurantoin**

## **10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Nitrofurantoin 50mg</b>				20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Nitrofurantoin is slightly soluble in water. Nitrofurantoin oral suspension has pH between 4.5 - 6.5.

Nitrofurantoin is stable over a wide pH range from 5.4-9.9; Turns dark when prolonged exposure to light

Nitrofurantoin decomposes when in contact with metal other than aluminum or stainless steel.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b> <b>Do not freeze</b>
<b>Expiry</b>	90 days

**References:**

- Mary H.H. Ensom et al, **Stability of Nitrofurantoin in Extemporaneously Compounded Suspensions**. Can J Hosp Pharm 2006;59: 29-33
- Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 273-274
- Sick Kids Pharmacy Formulation Sheet (updated April 2007)

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# **Ondansetron**

## **0.8mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Ondansetron HCl 8mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Ondansetron hydrochloride is a white to off-white powder that is soluble in water. 1.25mg Ondansetron HCl provides approximately 1mg of Ondansetron base. The natural pH of Ondansetron HCl in aqueous solution is about 4.5. If the solution pH increases above the range of 5.7—7.0, a precipitate of free Ondansetron base develops. Precipitation will redissolve if the solution is retitrated with HCl acid.

**2. Procedure (✓)**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Grind the tablet to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste   |
| 3. | Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Fridge temperature

2 – 8 °C

**Keep away from light**

**Expiry** 42 days

Supported by:

**References:**

- William Cl, Sanders PL, Laizure SC, et al “**Stability of Ondansetron Hydrochloride in syrups compounded from tablets**” Am J Hosp Pharm 1994;51:806-809.
- Trissel’s “Stability of Compounded Formulations, 4th Ed” pg 421

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***Oseltamivir******15mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Oseltamivir Phosphate 75mg</b>				12 capsules		
<b>X-Temp</b>	Pharm-D			qs 60 mL		

**\* Remark:**

White crystalline Oseltamivir phosphate have bitter taste, very soluble in water with aqueous solubility of 588mg/ml at 25°C

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Carefully empty the capsules content into the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature  
25 ± 2 °C  
**Keep away from light**

**Expiry** 35 days

**References:**

- Winiarski K, Infeld MH, Tsherne R et al "Preparation & Stability of Extemporaneous oral liquid formulations of Oseltamivir using commercially available capsules" - J Am Pharm Assoc. 2007;47:747-55
- Secundum Artem Vol 16 No13

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# **Phenobarbitone**

## **10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Phenobarbital 30mg*</b>	Idaman Pharma			20 tablets		
<b>X-Temp</b>	Pharm-D			qs 60 mL		

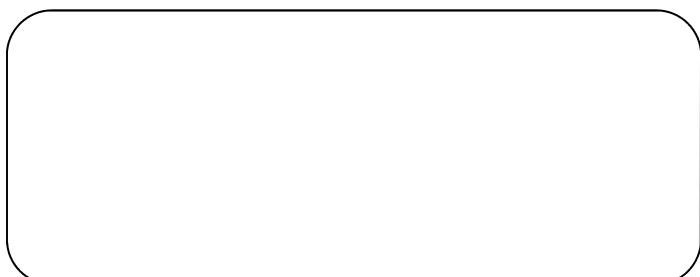
**\* Remark:**

Phenobarbital is an odorless white crystalline powder having a bitter taste.

Phenobarbital is very slightly soluble in water, having aqueous solubility of about 1mg/ml

**2. Procedure ( )**

1. Measure out X-temp
2. Grind the tablets to fine powder in the mortar.  
Add small amount of X-Temp to levigate the powder to form a smooth paste
3. Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed.  
Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4. Make up the final volume in the graduated using more X-temp vehicle. Stir well
5. Transfer the suspension into bottle
6. Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $30 \pm 2$ °C; 75% RH <b>Keep away from light</b>
<b>Expiry</b>	6 months

**References:**

1. Local Stability Study in Malaysia at Zone 4 climate. Conducted by Pharm-D Sdn Bhd (06/08/2014—02/02/2015)
2. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 315-328

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**Prednisone****5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Prednisone 5mg</b>				100 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Prednisone is a white, odorless crystalline powder. It is very slightly soluble in water. In ethanol it has solubility of about 6.7mg/ml. The syrup has a pH between 3.0 and 4.5.

**2. Procedure ( )**

1.	Measure out X-temp.
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste.
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well.
5.	Transfer the suspension into bottle.
6.	Label and affix shrink seal.

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	90 days

**References:**

1. Friciu M, Plourde K, Leclair G, Danopoulos P, Savji T “**Stability of Prednisone in Oral Mix Suspending Vehicle.**” International Journal of Pharmaceutical Compounding (IJPC) 2015, 19(4):337 – 339.
2. Trissel’s “Stability of Compounded Formulations, 4th Ed” pg 467.

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# **Procainamide**

## **50mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Procainamide 250mg</b>				20 capsules		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Procainamide HCl is a white hygroscopic, odorless crystalline powder. Procainamide HCL is very soluble in water, with an aqueous solubility of about 4g/ml.

Procainamide should be protected from light. Exposure to air causes darkening of the solution.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Carefully empty the capsules content into the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	60 days

**References:**

- Am J Health-Syst Pharm. 1996;53:2073—78
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 469

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# ***Propranolol***

## ***2mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Propranolol 40mg</b>				5 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Propranolol HCl is a white to off-white odorless crystalline powder having a bitter taste. Propranolol HCl is soluble in water and ethanol, with solubility around 50mg/ml.

The pH of maximum stability was reported to be 2.8 to 4. The drug undergoes rapid decomposition in alkaline solution.

**2. Procedure (✓)**

1.	Measure out X-temp.
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste.
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well.
5.	Transfer the suspension into bottle.
6.	Label and affix shrink seal.

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	120 days

**References:**

- Mary H.H. Ensom et al “**Stability of Propranolol in Extemporaneously Compounded Suspensions**” Can J Hosp Pharm 2013; 66(2):118-124
- Trissel’s “**Stability of Compounded Formulations**, 4th Ed” pg 478.

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# ***Propranolol***

## ***5mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Propranolol 40mg</b>				15 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Propranolol HCl is a white to off-white odorless crystalline powder having a bitter taste. Propranolol HCl is soluble in water and ethanol, with solubility around 50mg/ml.

The pH of maximum stability was reported to be 2.8 to 4. The drug undergoes rapid decomposition in alkaline solution.

**2. Procedure (✓)**

1.	Measure out X-temp.
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste.
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well.
5.	Transfer the suspension into bottle.
6.	Label and affix shrink seal.

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	120 days

**References:**

- Mary H.H. Ensom et al “**Stability of Propranolol in Extemporaneously Compounded Suspensions**” Can J Hosp Pharm 2013; 66(2):118-124
- Trissel’s “**Stability of Compounded Formulations**, 4th Ed” pg 478.

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***Propylthiouracil***  
***5mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Propylthiouracil 50mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Propylthiouracil is a white powder having a bitter taste & a starch-like appearance. It has an aqueous solubility of about 1.1mg/ml

**2. Procedure (✓)**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Grind the tablets to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Fridge temperature 2 - 8 °C
<b>Expiry</b>	91 days

**References:**

- Am J Health-Syst Pharm. 2000;57:1141—43
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 79
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 481

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**Pyrazinamide**  
**100mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Pyrazinamide 500mg</b>				20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Pyrazinamide is sparingly soluble in water

**2. Procedure ( )**

- |    |   |
|----|---|
| 1. | Measure out X-temp  |
| 2. | Grind the tablets to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste   |
| 3. | Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed.<br>Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well  |
| 5. | Transfer the suspension into bottle   |
| 6. | Label and affix shrink seal   |

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2$ °C <b>Keep away from light</b>
<b>Expiry</b>	60 days

**References:**

- Am J Health Syst.Pharm 55(17): 1804-1809,1998
- M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 344-350
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006

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# **Quinidine Sulfate**

## **10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Quinidine 200mg</b>				5 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Quinidine sulphate is a white, odorless, crystalline powder having a bitter taste.

Quinidine sulfate dehydrate 241mg & Quinidine sulfate anhydrous 230mg are approximately equivalent to Quinidine anhydrous 200mg. Quinidine sulfate has an aqueous solubility of about 10mg/ml.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	60 days

**References:**

- Am J Health-Syst Pharm. 1998;55:1804—1809
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 83
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 489

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**Rifabutin**  
**20mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Rifabutin 150mg</b>				4 capsules		
<b>X-Temp</b>	Pharm-D			qs 30 mL		

**\* Remark:**

Rifabutin is very slightly soluble in water having aqueous stability of about 0.19mg/ml.

**2. Procedure ( )**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Carefully empty the capsules content into the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic bottle 50ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	84 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Am J Health Syst Pharm 1999; 56:333-6
3. Paddock Laboratories Secundum Artem Vol 15 No 1
4. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 336

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**Rifampicin**  
**25mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Rifampicin 300mg capsules</b>				10 capsules		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Rifampicin slightly soluble in water; Oxidation occurred at alkali pH, can be slowed by addition of Ascorbic acid

**2. Procedure ( )**

1.	Measure out X-temp
2.	Open & carefully empty the content of capsules into mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2$ °C <b>Keep away from light</b>
<b>Expiry</b>	28 days

**References:**

- Am J Health Syst Pharm, 55 (17):1804 –1809,1998
- Lawrence A. Trissel “Stability of Compounded Formulations, 2nd Ed” pg 336-338
- SickKids Pharmacy Formulation Sheet (updated April 2007)

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# **Sildenafil**

## **2.5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Sildenafil 50mg (citrate)</b>				5 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Solubility of Sildenafil is 3.5mg/ml

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**      **HDPE plastic  
bottle 50ml**

**Storage**      Room temperature  
 $25 \pm 2^{\circ}\text{C}$

**Expiry**      91 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
2. Am J Health Syst.Pharm 2006; 63: 254-7
3. Paddock Laboratories Secundum Artem Vol 14 No 1
4. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 363-367

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# **Sodium Phenylbutyrate**

## **200mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Vetyrate 5g</b>	Pharm-D			5 sachets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Sodium Phenylbutyrate is an off-white crystalline powder. 1gram of oral powder provides 0.94gram of sodium butyrate or 3gram of sodium butyrate per 3.2gram of powder. Sodium Butyrate is very soluble in water, 500mg/ml. The excipients in the tablets & oral powder are much less soluble in water than in sodium butyrate

**2. Procedure (✓)**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Weigh the amount of powder and ground to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**      **HDPE plastic  
bottle 120ml**

**Storage**      Room temperature  
 $25 \pm 2^{\circ}\text{C}$

**Expiry**      90 days

**References:**

- Caruthers RL, Johnson CE "Stability of extemporaneously prepared sodium phenylbutyrate oral suspensions" Am J Health Syst Pharm. 2007;64:1513-5
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 510
- M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 377—379

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# **Sotalol**

## **5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Sotalol 80mg (hydrochloride)</b>				5 tablets		
<b>X-Temp</b>	Pharm-D			qs 80 mL		

**\* Remark:**

Sotalol HCl is freely soluble in water

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

Packaging bottle	HDPE plastic bottle 100ml
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Storage	Fridge temperature 2 – 8 ° C
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Expiry	84 days
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**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 347-348
3. Sick Kids Pharmacy Formulation Sheet (updated April 2007)
4. Paddock Laboratories Secundum Artem Vol 14 No 3

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# ***Spironolactone***

## ***1.25mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Spironolactone 25mg</b>	Pharmaniaga			5 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Spironolactone tablet is insoluble in water & stable at pH about 4.5

**2. Procedure ( )**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**      **HDPE plastic  
bottle 100ml**

**Storage**      Room temperature  
 $25 \pm 2^{\circ}\text{C}$

**Expiry**      60 days

Supported by:

**Reference:**

Local Stability Study in Malaysia at Zone 4 climate. Conducted by Pharm-D Sdn Bhd (29/12/09—  
25/02/10)

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# **Spironolactone**

## **5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Spironolactone 25mg</b>	Remedica			20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Spironolactone tablet is insoluble in water & stable at pH about 4.5

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle</b>
<b>Storage</b>	Room temperature $30 \pm 2$ °C; 75% RH
<b>Expiry</b>	180 days

**Reference:**

- Local Stability Study in Malaysia at Zone 4B climate. Conducted by Pharm-D Sdn Bhd (10/10/2017 – 09/04/2018).
- Lawrence A. Trissel "Stability of Compounded Formulations, 4th Ed" pg 515

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# **Sulfasalazine**

## **100mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Sulfasalazine 500mg</b>	Pharm-D			24 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Sulfasalaine is bright yellow or brownish yellow fine powder. It is practically insoluble in water. It should be protected from sun light. The suspension pH is about 4.4.

Do avoid use enteric-coated tablets.

**2. Procedure ( )**

1.	Measure out X-temp
2.	Weigh the amount of tablet and ground to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**    HDPE amber plastic bottle 120ml

**Storage**              Room temperature  
25 ± 2 °C

**Keep away from light**

**Expiry**                91 days

**References:**

1. Lingertat-Walsh K, Walker SE, Law S et al “**Stability of Sulfasalazine oral suspension**” Can J Hosp Pharm. 2006;59:194-200
2. Rita K Jew, Winson Soo-Ho, Sarah C Erush “Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients” 2nd Ed pg 94
3. Secundum Artem Vol 14 No 3

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**Tacrolimus****0.5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Tacrolimus 5mg</b>				6 capsules		
<b>X-Temp</b>	Pharm-D			qs 60 mL		

**\* Remark:**

Tacrolimus is practically insoluble in water (1-2mcg/ml) Tacrolimus exhibits maximum stability at pH 2-6; higher pH will increase degradation rate.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablet to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** **Amber glass bottle**  
**120ml**

**Do not use PVC bottle**

**Storage** Room temperature

25 ± 2 °C

**Shake well before use.**

**Expiry** 90 days

**References:**

1. Friciu M et al. "Stability of Extemporaneously Compounded Tacrolimus in Glass Bottles and Plastic Syringes." Can J Hosp Pharm 70(1),2017
2. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
3. Jacobson PA et al, **Stability of Tacrolimus in an extemporaneously compounded oral liquid.** Am J Health Syst Pharm 1997;54:178-80
4. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 103-109
5. Trissel's "Stability of Compounded Formulations, 4th Ed" pg 526-528

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***Terbinafine***  
***25mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Terbinafine 250mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Terbinafine is slightly soluble in water

**2. Procedure ( )**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic  
**bottle 100ml**

**Do not freeze**

**Storage** Room temperature  
 $25 \pm 2^{\circ}\text{C}$   
**Keep away from light**

**Expiry** 42 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Lawrence A. Trissel "Stability of Compounded Formulations, 2nd Ed" pg 360
3. Am J Health Syst Pharm 1999; 56:243-5
4. Paddock Laboratories Secundum Artem Vol 15 No 1

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# **Theophylline**

## **5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Theophylline 300mg</b>				1 tablet		
<b>X-Temp</b>	Pharm-D			qs 60 mL		

**\* Remark:**

Theophylline is a white odorless crystalline powder with bitter taste. It has an aqueous solubility of about 8.3mg/ml. Oral suspension of theophylline can be extemporaneously prepared from bulk, USP, powder and also from crushed theophylline extended-release tablets. The formula from bulk powder was most palatable, while from the crushed tablets was the least palatable, though it was still acceptable .

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Grind the tablet to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Gradually add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature

25 ± 2 °C

**Keep away from light**

**Expiry** 90 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
2. Johnson CE et al, **Stability of anhydrous theophylline in extemporaneously prepared alcohol-free oral suspensions**. Am J Health Syst Pharm 2005;62:2518-20
3. Trissel's "Stability of Compounded Formulations, 4th Ed" pg 542-544

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**Thiamine**  
**20mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Thiamine 100mg</b>				20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Solubility of Thiamine is 1g/ml. Rapid deconstruction of thiamine occurs if pH of the solution is above 5.5. For longer shelf-life, powder form is preferred than tablets form. Beyond-used-date for thiamine suspension using powder can last up to 91 days in room temperatures.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Carefully empty the capsules content into the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle** HDPE amber plastic bottle 100ml

**Storage** Room temperature  
25 ± 2 °C  
**Keep away from light**

**Expiry** 28 days

**References:**

1. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 396—403
2. Secundum Artem Vol 14 No 3
3. Can J Hosp Pharm 2005; 58:26-30

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**Tramadol****5mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Tramadol 50mg</b>				12 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Tramadol HCl is a white bitter odorless crystalline powder.

Tramadol HCl is readily soluble in water

**2. Procedure (v)**

1.	Measure out X-temp
2.	Grind the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	90 days

**References:**

- Am J Health-Syst Pharm. 2003;60:1268—1270
- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 105
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 559

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# **Trimethoprim**

## **10mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Trimethoprim 100mg</b>				10 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Trimethoprim occurs as white to cream-colored odorless bitter-tasting crystals. Trimethoprim is very slightly soluble in water, having an aqueous solubility of about 0.4mg/ml.

**2. Procedure (✓)**

1.	Measure out X-temp.
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste.
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate.
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well.
5.	Transfer the suspension into bottle.
6.	Label and affix shrink seal.

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 100ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
<b>Expiry</b>	92 days

**References:**

- Mary H.H. Ensom et al “**Stability of Extemporaneously Compounded Trimethoprim in Glass and Plastic Bottles and Plastic Syringes**” Can J Hosp Pharm 2016, 69(2):171-173.
- Nahata MC. “**Stability of Trimethoprim in an extemporaneous liquid dosage form**” J Pediatrr Pharm Pract. 1997;2:82-84
- Trissel’s “**Stability of Compounded Formulations**, 4th Ed” pg 568.

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# ***Ursodeoxycholic 25mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Ursodeoxycholic 300mg</b>				10 capsules		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Ursodeoxycholic acid is a naturally occurring bile acid that is white crystalline powder having a bitter taste. Ursodeoxycholic is practically insoluble in water.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Carefully empty the capsules content into the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle</b>
<b>Storage</b>	Room temperature 23 - 25 °C
<b>Expiry</b>	60 days

**References:**

1. Mallet MS et al, **Stability of ursodiol 25mg/ml in an extemporaneously prepared oral liquid.** Am J Health Syst Pharm. 1997;54:1401-1404.
2. Lawrence A. Trissel "Stability of Compounded Formulations, 4th Ed" pg 574
3. Sick Kids Pharmacy Formulation Sheet (updated April 2007)
4. Paddock Laboratories Secundum Artem Vol 14 No 3

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***Ursodeoxycholic  
50mg/ml Oral Suspension***

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Ursodeoxycholic 250mg</b>				20 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Ursodeoxycholic acid is a naturally occurring bile acid that is white crystalline powder having a bitter taste. Ursodeoxycholic is practically insoluble in water.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE amber plastic bottle 100ml</b>
<b>Storage</b>	Room temperature 23 - 25 °C
<b>Expiry</b>	90 days

**References:**

1. Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products.** JPPS 9(3): 398-426,2006
2. Johnson C.E and Streetman D.D. **Stability of oral suspensions of ursodiol made from tablets.** Am J Health Syst Pharm 59(4):361-363,2002
3. Lawrence A. Trissel "Stability of Compounded Formulations, 4th Ed" pg 574

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# **Valganciclovir**

## **60mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Valganciclovir 450mg</b>				16 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**Remarks:**

Valganciclovir HCl is a white crystalline powder. It has an aqueous solubility of 70mg/ml.

Valganciclovir was found to be most stable at pH values of 3.5 and lower.

**CYTOTOXIC**– Must use designated cytotoxic equipment and prepare in segregated area. Wear protective equipment

**2. Procedure (✓)**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Wet the tablets with small of X-Temp before crushing the tablet to prevent exposure to medicine powder. Crush the tablets to form a smooth paste.  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal. Additional label: <b>Cytotoxic</b>  |

**3. Sample label : Affix here****Special Instruction**

Packaging bottle	Glass amber bottle
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Storage	Fridge temperature 2 – 8 ° C
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Expiry	35 days
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**References:**

- Beverley D Glass, **Stability consideration in liquid dosage forms extemporaneously prepared from commercially available products**. JPPS 9(3): 398-426,2006
- Am J Health Syst.Pharm 2003; 60: 687-90
- Rita K Jew, Winson Soo-Ho, Sarah C Erush "Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients" 2nd Ed pg 161
- Paddock Laboratories Secundum Artem Vol 14 No 3

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# **Vancomycin**

## **50mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Vancomycin HCl 500mg injection</b>				5 vials		
<b>X-Temp</b>	Pharm-D			qs 50 mL		

**\* Remark:**

Vancomycin HCl is freely soluble in water, having an aqueous solubility greater than 100mg/ml. Vancomycin injection has a pH of 3 to 5. Reconstituted vancomycin HCl injection has a pH of about 3.9.

**2. Procedure (✓)**

1.	Measure out X-temp.
2.	Reconstitute the Vancomycin HCl injection with sterile water according to the instruction.
3.	Make up the final volume in the graduated using X-temp vehicle. Stir well.
4.	Transfer the suspension into bottle.
5.	Label and affix shrink seal.

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle</b>
<b>Storage</b>	a) Room temperature 25 ± 2 °C b) Fridge temperature
<b>Expiry</b>	a) 36 days b) 91 days

**References:**

- Mary H.H. Ensom et al. **Vancomycin 50mg/ml Suspension in Oral Syrup: Stability in Plastic Bottles and Syringes at 2 Temperature.** Can J Hosp Pharm 2017, 70(3):247-249.
- Trissel's "Stability of Compounded Formulations, 4th Ed" pg 579.

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**Verapamil**  
**50mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Verapamil 80mg</b>				75 tablets		
<b>X-Temp</b>	Pharm-D			qs 120 mL		

**\* Remark:**

Verapamil HCl is white, nearly odorless crystalline powder having a bitter taste. It is soluble in water. The Injection should be protected from light & freezing. Maximum stability occurs in the pH range of 3.2 - 5.6.

**2. Procedure (✓)**

1.	Measure out X-temp
2.	Crush the tablets to fine powder in the mortar. Add small amount of X-Temp to levigate the powder to form a smooth paste
3.	Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate
4.	Make up the final volume in the graduated using more X-temp vehicle. Stir well
5.	Transfer the suspension into bottle
6.	Label and affix shrink seal

**3. Sample label : Affix here****Special Instruction**

**Packaging bottle**      **HDPE plastic  
bottle 50ml**

**Storage**      Room temperature  
25 ± 2 °C

**Expiry**      91 days

**References:**

- Allen LV, Erickson MA "Stability of labetolol hydrochloride, metoprolol tartarate, verapamil hydrochloride and spironolactone with hydrochlorothiazide in extemporaneously compounded oral liquids." Am J Health Syst Pharm. 1996;53:2304-9
- Paddock Laboratories Secundum Artem Vol 6 No 1
- Lawrence A. Trissel "Stability of Compounded Formulations, 4th Ed" pg 584

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# **Warfarin**

## **0.2mg/ml Oral Suspension**

Batch No.:	Batch Size:	Date Prepared:	EXP date:	Prepared by:	Final Checked by:
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**1. Raw Materials Quality Control**

Ingredients	Grade/ Manufacturer	Batch no.	EXP date	Quantity/ measurement	Measured by	Checked by
<b>Warfarin 5mg</b>				4 tablets		
<b>X-Temp</b>	Pharm-D			qs 100 mL		

**\* Remark:**

Warfarin Sodium is a white odourless amorphous hygroscopic powder with slightly bitter taste.  
 Warfarin sodium is very soluble in water, having solubilities greater than 1g/ml. Warfarin sodium is discoloured by light and have to be protected from excessive temperatures of 40°C or more.

**2. Procedure (✓)**

- |    |  |
|----|--|
| 1. | Measure out X-temp   |
| 2. | Grind the tablets to fine powder in the mortar.<br>Add small amount of X-Temp to levigate the powder to form a smooth paste  |
| 3. | Add X-temp vehicle in small amounts to the paste, mix well until a liquid is formed. Transfer the contents into the graduate. Use additional vehicle to rinse the remaining drug from the mortar and add to the graduate |
| 4. | Make up the final volume in the graduated using more X-temp vehicle. Stir well   |
| 5. | Transfer the suspension into bottle  |
| 6. | Label and affix shrink seal  |

**3. Sample label : Affix here****Special Instruction**

<b>Packaging bottle</b>	<b>HDPE plastic amber bottle 120ml</b>
<b>Storage</b>	Room temperature $25 \pm 2^{\circ}\text{C}$
	<b>Keep away from light</b>
<b>Expiry</b>	7 days

**References:**

1. M. Jackson & A. Lowey "Handbook of Extemporaneous Preparation" pg 415
2. Trissel's "Stability of Compounded Formulations, 4th Ed" pg 591

Supported by:

