Extemporaneous Formulations

Maternity and Children's Hospital – MCH

Qassim

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List Extemporaneous Preparation

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HYDROCHLOROTHIAZIDE SUSPENSION 5 MG/ML

INGREDIENTS	STRENGTH	QUANTITY
Hydrochlorothiazide (Tablets)	25 mg	24 tablets
Vehicle	qs	120 ml

VEHICLE CHOICE:

• Ora-Sweet®: Ora-Plus® (1:1) mixture

PROCEDURE:

Tablets

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

Notes:

1. Keep in a Plastic amber bottle.
2. Storage in refrigerator.
3. Stability: 60 days.
4. Shake well before use and protect from light.

References:

1. https://online.lexi.com/lco/action/doc/retrieve/docid/pdh_f/130129?cesid=1JDzey5Wub6&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3DHydrochlorothiazide%26t%3Dname%26acs%3Dfalse%26acq%3DHydrochlorothiazide

MYCOPHENOLATE MOFETIL SYRUP 100 MG/ML

INGREDIENTS	STRENGTH	QUANTITY
Mycophenolate Mofetil (tablets)	500 mg	2 tablets
Distilled water	ml	2 ml
Simple Syrup	qs	10 ml

PROCEDURE:

Tablets

1. Should be prepared in the **chemotherapy room**.
2. Calculate the required quantity of each ingredient for the amount to be prepared.
3. Crush the tablet to a fine powder using a mortar and pestle.
4. Add 2 ml of distilled water to the powdered tablet to form a uniform paste.
5. Gradually add the simple syrup to complete the volume to 10 ml and mix well.
6. Transfer to amber bottle.
7. Package and label.

Notes:

1. Handle with care (Hazardous agent)
2. Keep in an amber bottle.
3. Storage in refrigerator.
4. Stability:28 days.
5. Shake well before use.

References:

1. Beverley D Glass, Chair of Pharmacy School of Pharmacy and Molecular Sciences, Stability considerations in liquid dosage forms extemporaneously prepared from commercially available products. Published December 14, 2006.
2. Pediatric Drug Formulations. 5th edition.
3. American Journal of Health-System, Stability of mycophenolate mofetil in an extemporaneously compounded oral liquid, 06/1998; 55(9):926-9. Source: PubMed

OMEPRAZOLE SUSPENSION 4MG/ML

INGREDIENTS	STRENGTH	QUANTITY
Omeprazole (capsules)	20 mg	100 capsules
Sodium Bicarbonate Injection	8.4%	10 ampules x 50 ml

PROCEDURE:

Capsules

1. Empty the capsule contents in a flask.
2. Measure 500 mL of sodium bicarbonate 8.4% in a graduated cylinder and pour it into the flask.
3. Stir the mixture with a magnetic stirrer for 30 minutes.
4. Transfer the graduated cylinder's contents into an appropriate size plastic amber oral syringe.
5. Shake well to mix.
6. Label.

Notes:

1. Keep in a Plastic amber bottle.
2. Storage in refrigerator.
3. Stability: 45 days.
4. Shake well before use and protect from light.

References:

1. Pharmaceutical Extemporaneous Preparations Guideline. Available at: https://www.moh.gov.sa/en/Ministry/MediaCenter/Publications/Documents/Pharmaceutical_Extemporaneous_Preparations_Guideline_April_2023.pdf

POTASSIUM CHLORIDE SYRUP 1MMOL/ML

INGREDIENTS	STRENGTH	QUANTITY
Potassium Chloride Powder	Net Weight: 1000 grams	75 grams
Oral-sweet		0.5 liter
Distilled water	qs	1 liter

PROCEDURE:

Powder

1. Weight 75 gram of Potassium Chloride powder.
2. Dissolve the measured powder (75 gram) in 500 ml of oral-sweet until completely dissolve.
3. Then add 500 ml of distilled water to reach the final volume.

Notes:

1. Keep in an amber glass bottle.
2. Storage in refrigerator.
3. Stability: 30 days.
4. Shake well before use and protect from light.

References:

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

PROPRANOLOL SUSPENSION 4MG/ML

INGREDIENTS	STRENGTH	QUANTITY
Propranolol (Tablets)	40 mg	100 tablets
Simple Syrup	qs	1000 ml

PROCEDURE:

Tablets

1. Crush tablets in a mortar to a fine powder.
2. Levigate the powder with distilled water until smooth.
3. Add a small amount of simple syrup to form a smooth paste. Add more syrup until a liquid is formed and transfer the contents into a graduate cylinder. Use additional simple syrup to rinse the remaining drug from the mortar.
4. To make up final volume with simple syrup.
5. Transfer the suspension into the amber bottle.
6. Shake well and label.

Notes:

1. Keep in an amber bottle.
2. Storage in refrigerator.
3. Stability: 30 days.

References:

1. PharmInfoTech: Database of Oral Liquid Formulations-eMixt. [Online] Available from: http://www.pharminfotech.co.nz/manual/Formulation/mixtures/propranolol.

SILDENAFIL SUSPENSION 2.5MG/ML

INGREDIENTS	STRENGTH	QUANTITY
Sildenafil (Tablets)	20 mg	100 tablets
Vehicle	qs	800 ml

VEHICLE CHOICE:

• Ora-Sweet®: Ora-Plus® (1:1) mixture

PROCEDURE:

Tablets

1. Crush the tablets in a mortar and triturate them into a fine powder.
2. In a graduated cylinder, mix 400 ml of Ora-Sweet® and 400 ml of Ora-Plus® vehicle.
3. Levigate the powder with a small portion of the mixture to form a smooth paste.
4. Almost to volume, add the vehicle in geometric proportions, mixing well after each addition.
5. Pour the mortar's contents into a graduated cylinder.
6. Rinse the mortar and pestle using the vehicle and pour it into a graduated cylinder to achieve a final volume of 800 ml.
7. Transfer the graduated cylinder's contents into an appropriate size amber bottle.
8. Shake well to mix.
9. Label.

Notes:

1. Keep in a Plastic amber bottle.
2. Storage in refrigerator.
3. Stability: 91 days.
4. Shake well before use and protect from light.

References:

1. Pharmaceutical Extemporaneous Preparations Guideline. Available at: https://www.moh.gov.sa/en/Ministry/MediaCenter/Publications/Documents/Pharmaceutical_Extemporaneous_Preparations_Guideline_April_2023.pdf

SIMPLE SYRUP

INGREDIENTS	STRENGTH	QUANTITY
Sucrose	Net Weight: 5000 grams	850 grams
Distilled water	qs	1 liter

PROCEDURE:

Powder

1. Weigh the sucrose and place it in a beaker.
2. Add distilled water and stir well until the sucrose dissolves.
3. Transfer into a bottle of appropriate size immediately.
4. Shake well.

Notes:

1. Keep in an amber bottle.
2. Storage in refrigerator.
3. Stability: 30 days
4. Shake well before use

References:

1. US PHARMACOPEIA AND NATIONAL FORMULARY

SODIUM BICARBONATE ORAL SOLUTION 1 MMOL/ML (8.4%)

INGREDIENTS	STRENGTH	QUANTITY
Sodium Bicarbonate Powder	Net Weight: 5000 grams	84 grams
Distilled water	qs	1 liter

PROCEDURE:

Powder

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

Notes:

1. Keep in an amber bottle.
2. Storage in room temperature.
3. Stability: 30 days
4. Shake well before use and protect from light.

References:

1. Pharmaceutical Extemporaneous Preparations Guideline. Available at: https://www.moh.gov.sa/en/Ministry/MediaCenter/Publications/Documents/Pharmaceutical_Extemporaneous_Preparations_Guideline_April_2023.pdf

SODIUM CHLORIDE 6% SOLUTION 1 MMOL/ML

INGREDIENTS	STRENGTH	QUANTITY
Sodium chloride powder	Net Weight: 1000 grams	60 grams
Distill water	qs	1 liter

PROCEDURE:

Powder

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

Notes:

1. Keep in an amber bottle.
2. Storage in room temperature.
3. Stability: 30 days
4. Shake well before use and protect from light

References:

1. Nahata, M. C., & Pai, V. B. (2014). Pediatric Drug Formulations (6th Edition, Revised ed.). Harvey Whitney Books company.
2. Laboratory solution preparation. Available at : https://www.snc.edu/chemicalhygiene/docs/labsafety/SolutionPrep.pdf

SPIRONOLACTONE SUSPENSION 25 MG/ML

INGREDIENTS	STRENGTH	QUANTITY
Spironolactone (Tablets)	25 mg	120 tablets
Vehicle	qs	120 ml

VEHICLE CHOICE:

• Ora-Sweet®: Ora-Plus® (1:1) mixture or

• Ora-Sweet SF®: Ora-Plus® (1:1) mixture

PROCEDURE:

Tablets

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

Notes:

1. Handle with care (Hazardous agent)
2. Keep in a Plastic amber bottle.
3. Storage in refrigerator.
4. Stability: 60 days.
5. Shake well before use and protect from light.
6. Ora-Sweet SF® should not be used in neonates ≤28 days corrected age.

References:

1. Pharmaceutical Extemporaneous Preparations Guideline. Available at: https://www.moh.gov.sa/en/Ministry/MediaCenter/Publications/Documents/Pharmaceutical_Extemporaneous_Preparations_Guideline_April_2023.pdf

TACROLIMUS ORAL SUSPENSION 1 MG/ML

INGREDIENTS	STRENGTH	QUANTITY
Tacrolimus (Capsules)	5 mg	24 Capsules
Vehicle	qs	120 ml

VEHICLE CHOICE:

• Ora-Sweet®: Ora-Plus® (1:1) mixture

PROCEDURE:

Capsules

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

Notes:

1. Handle with care (Hazardous agent)
2. Keep in a Plastic amber bottle.
3. Storage in room temperature.
4. Stability: 28 days.
5. Shake well before use and protect from light.

References:

1. Pharmaceutical Extemporaneous Preparations Guideline. Available at: https://www.moh.gov.sa/en/Ministry/MediaCenter/Publications/Documents/Pharmaceutical_Extemporaneous_Preparations_Guideline_April_2023.pdf
2. ASHP. Extemporaneous Formulations for Pediatrics, Geriatrics and Special Needs Patients. 4th Edition.

URSODEOXYCHOLIC ACID SUSPENSION 50 MG/ML

INGREDIENTS	STRENGTH	QUANTITY
Ursodeoxycholic Acid (Capsules)	250 mg	24 Capsules
Vehicle	qs	120 ml

VEHICLE CHOICE:

• Ora-Sweet®: Ora-Plus® (1:1) mixture

PROCEDURE:

Capsules

1. Empty the contents of the capsules in a mortar.
2. In a graduate cylinder, mix 60 ml of Ora-Sweet® and 60 ml of Ora-Plus® vehicle to form the diluent.
3. Add diluent (prepared diluent) to form a smooth paste.
4. Gradually add the diluent and transfer to the final measuring flask, rinsing the mortar well. Mix well.
5. Transfer the suspension to an appropriate size amber bottle.
6. Shake well to mix.
7. Label.

Notes:

1. Keep in a Plastic amber bottle
2. Storage in refrigerator.
3. Stability: 30 days.
4. Shake well before use and protect from light.

References:

1. NZ standardised batch sheets : Pharmaceutical Society of NZ. Available at: https://www.psnz.org.nz/practicesupport/oralliquid .
2. Allen LV, Jr. Secundum Artem, 2009; 14(3).
3. Johnson CE, Streetman DD. Am J Health Syst Pharm, 2002; 59(4): 361-3.