

**Doctor of pharmacy program**

**Pharmacy skills laboratory (pharm 321)**



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***Chloramphenicol Suspension***

**Product formula:**

| No. | Ingredients | Quantity | Dispensed by | Checked by |
| --- | --- | --- | --- | --- |
| 1 | Chloramphenicol palmitate | 4g | Nima | Bara |
| 2 | Glycerin | 20g | Nima | Bara |
| 3 | Xanthan gum | 0.2g | Nima | Bara |
| 4 | Flavoring agent | qs | Bara | Nima |
| 5 | Simple syrup | 50g | Bara | Nima |
| 6 | Water | qs 100ml | Bara | Nima |

**Pharmaceutical drug in pharmacy:**

* **Trade name:** Chloramphenicol oral suspension
* **Company:** Wedgewood pharmacy
* **Active pharmaceutical ingredient:** Chloramphenicol

**About product:**

* **Product name:** Chloramphenicol suspension.

**Components and their role:**

| No | Ingredient | Role |
| --- | --- | --- |
| 1 | Chloramphenicol | Broad spectrum antibiotic |
| 2 | Glycerin | Wetting agent |
| 3 | Xanthan gum | Suspending agent |
| 4 | Flavoring agent | Flavor |
| 5 | Simple syrup | Sweetening agent |
| 7 | Purified water | Vehicle |

**Counseling**

1. **Indications**Chloramphenicol is a broad spectrum antibiotic meaning that it acts on both gram positive and gram negative bacteria, it’s bacteriostatic but in high concentrations or when used with susceptible organisms it’s bacteriocidal. Chloramphenicol is lipid soluble and it can pass through the plasma membranes of bacteria and reversibly bind to the 50S subunit of the ribosome thus inhibiting protein synthesis. Due to its toxicity it’s only indicated for serious infection were other antibiotic are contraindicated or have no effect. It is being replaced with other antibiotic to treat some diseases like the third generation cephalosporins for treating meningitis, clindamycin or metronidazole for anaerobic infection, however in some cases chloramphenicol is still the only choice. It is also used for rickettsial infection that are treated with parenteral antibiotic when other antibiotics are contraindicated.   
   Chloramphenicol is contraindicated for the treatment of common colds, flu, throat infections, the routine treatment of typhoid carrier states and prophylactic treatment. It mustn’t be used in pregnancy, lactation, liver impairment or in pediatrics. [1]
2. **Administration**The recommended dose for adults is 50mg/kg/day which is 12.5/kg/dose taken four times or 100mg/kg/day = 25mg/kg/dose taken twice a day depending on the susceptibility of the bacteria and the seriousness of the infection. While the usual dose for premature to infants up to two weeks old is 6.25mg/kg four times a day, the dose for infants 2 weeks and up is 12.5mg/kg four times a day.  
   It’s advised that chloramphenicol is taken with a glass of water on an empty stomach or 1-2 hours before meals to maximize absorption. The patient should also take the full course of medication even if they feel better.   
   While taking chloramphenicol, serum concentration of chloramphenicol should be monitored as well as getting regular CBS tests to make sure there’s no bone marrow suppression or a plastic anemia.[1]
3. **Side effects**Chloramphenicol has many serious side effects including aplastic anemia, bone marrow depression which can cause increased risk of microbial infections, delayed healing and gingival bleeding, and gray baby syndrome which is encountered especially if the infant is given as inappropriately high dose because they can’t conjugate it to glucourinide, gray baby syndrome is due to high concentrations of chloramphenicol in the blood, it precipitates as vomiting, gray discoloration, hypotension, blue discoloration of the skin and lips, hypothermia, cardiac collapse and irregular respiration. [1]

**Storage conditions:**Store in a refrigerator, away from the reach of children.

**Calculations:**Product strength:   
4g chloramphenicol → 100 ml   
               ?      → 5 ml  
(4\*5)/100   
= 0.2g/5ml   
= 200mg/5ml chloramphenicol

**Main label:**

**Pharmacy name:** Drug Restaurant

**Pharmacists’ name:** Nima Farhan, Bara Al-Khateeb

**Product name:** Chloramphenicol suspension.

**Product strength:** 200mg/5ml

**Expiration date:** 4/4/2018 (2 weeks after preparation)

**Amount prepared:** 100 ml

**Use:** Broad spectrum antibiotic used as a last line treatment of serious infections.

**Auxiliary label:**

* Shake well before use
* Store in a refrigerator.
* For oral use only

***Aromatic Elixir USP***

**Product formula:**

| No. | Ingredients | Quantity | Dispensed by | Checked by |
| --- | --- | --- | --- | --- |
| 1 | Rose oil (diluted) | 6mL | Nima | Bara |
| 2 | Peppermint oil | One drops (0.06mL) | Nima | Bara |
| 3 | Simple syrup | 37.5mL | Nima | Bara |
| 4 | Talc | 3g | Bara | Nima |
| 5 | Alcohol (Ethanol 70%) | 25mL | Bara | Nima |
| 6 | Purified water | qs 100mL | Bara | Nima |

**Pharmaceutical drug in pharmacy:**

* **Trade name:** N/A
* **Company:** N/A
* **Active pharmaceutical ingredient:** N/A

**About product:**

* **Product name:** Aromatic Elixir.

**Components and their role:**

| No. | Ingredients | Role |
| --- | --- | --- |
| 1 | Rose oil (diluted) | Flavoring agent |
| 2 | Peppermint oil | Flavoring agent |
| 3 | Simple syrup | Sweetening agent |
| 4 | Talc | Absorbs excess amounts of oil |
| 5 | Alcohol (Ethanol 70%) | Solvent |
| 6 | Purified water | Vehicle |

**Counseling:**

1. **Indications**Aromatic elixir is used as a vehicle for numerous drugs. It’s sweetened using simple syrup and flavored using essential oils, so medications that use it as a vehicle are intended for oral administration.
2. **Administration**Since aromatic elixir is only a vehicle for numerous drugs; its administration depends on the drug added to it. It’s designed for drugs intended for oral administration. Medications delivered using aromatic elixir as a vehicle should be shaken before use.
3. **Side effects**Aromatic elixir contains alcohol, so it’s best to avoid alcoholic beverages while taking medications delivered using this vehicle. It also contains simple syrup, which is prepared from sucrose, so diabetics should be cautious while taking medications in this vehicle.

**Storage conditions:**Aromatic elixir should be stored at room temperature, away from direct heat and light. It’s stored in a closed amber bottle. It should be kept out of the reach of children. Its expiration date is in 1 month after preparation.

**Calculations:**

There are no calculations for this experiment.

**Main label:**

**Pharmacy name:** Drug Restaurant

**Pharmacists’ name:** Nima Farhan, Bara Al-Khateeb

**Product name:** Aromatic Elixir

**Product Strength:** N/A

**Expiration date:** 21/4/2018 (1 month after preparation)

**Amount prepared:** 100 ml

**Use:** Vehicle for medicine.

**Auxiliary label:**

* Shake well before use.
* Store at room temperature.
* Keep away from direct heat or light.
* Store in a closed container.

***Paracetamol Elixir***

**Product formula:**

| No. | Ingredients | Quantity | Dispensed by | Checked by |
| --- | --- | --- | --- | --- |
| 1 | Paracetamol (Acetaminophen) | 1200mg(1.2g) | Nima | Bara |
| 2 | Ethyl alcohol | 6mL | Nima | Bara |
| 3 | Propylene glycol | 5mL | Nima | Bara |
| 4 | Water | 5mL | Bara | Nima |
| 5 | Glycerin | 50mL | Bara | Nima |

**Pharmaceutical drug in pharmacy:**

* **Trade name:** Tylenol
* **Company:** McNeil Consumer Healthcare
* **Active pharmaceutical ingredient:** Paracetamol (Acetaminophen).

**About product:**

* **Product name:** Paracetamol Elixir

**Components and their role:**

| No. | Ingredients | Role |
| --- | --- | --- |
| 1 | Paracetamol (Acetaminophen) | Antipyretic, and analgesic for mild to moderate pain |
| 2 | Ethyl alcohol | Solvent |
| 3 | Propylene glycol | Co-solvent |
| 4 | Water | Vehicle |
| 5 | Glycerin | Co-solvent, sweetening agent |

**Counseling:**

1. **Indications**Paracetamol elixir is used to relieve mild to moderate pain (analgesic) and to reduce high temperatures during fevers (antipyretic) in pediatrics. It can be used for pain in headaches, cold, flu, sore throats, toothaches, teething, and other sources of pain for children. It’s usually used in infants of the ages 2-3 months who have been vaccinated recently to relieve post-vaccination fevers. [2]

Paracetamol elixir has been mostly replaced with other paracetamol dosage forms due to its high content of alcohol.

1. **Administration**Paracetamol elixir is intended for use on pediatrics, so an adult should administer it to the patient. It is intended for oral use only. It should be given using a dose-measuring spoon or cup to ensure an accurate dose. The bottle should be shaken for 10 seconds before use. [2]

Paracetamol elixir’s dose depends on the age and weight of the patient. For infants aged 2-3 months, suffering from post-vaccination fever, the dose is 2.5mL, once daily, or if required, another dose could be given after at least 4 hours from the first dose. No more than 2 doses should be given to infants at that age. [2]

For older ages, the doses are as follows:-

* 3-6 months: 2.5mL
* 6-24 months: 5mL
* 2-4 years: 7.5mL
* 4-6 years: 10mL

For those ages, the doses should be given four times daily, and at least 4 hours should be left between doses. No more than 4 doses should be given to patients at those ages. [3]

For adults, the maximum amount of paracetamol that can be taken in one dose is 1g, while the maximum daily amount that can be taken is 4g. 4 hours should also be left between doses.

If paracetamol elixir doesn’t improve symptoms it’s intended to improve in 3 days, a doctor should be consulted. [3]

1. **Side effects**Side effects reported about paracetamol are related to allergic reactions. Those include rash, itchy skin, swelling of lips, eyes, or tongue, and difficulty breathing. In case any of these symptoms appear, paracetamol elixir should be stopped immediately, and a doctor should be consulted for an alternative. [2]

In case of an overdose of paracetamol elixir, side effects such as pallor, nausea, vomiting, anorexia, and abdominal pain may appear. Even in case those symptoms don’t appear upon an overdose, the patient should be taken to emergency immediately with the medications bottle, since paracetamol can cause delayed, serious liver damage. [2]

Paracetamol elixir shouldn’t be given to a patient with liver or kidney problems. Alcoholic beverages should be avoided while taking this medication. A doctor or pharmacist should be consulted before taking paracetamol elixir with other medications including other medications that contain paracetamol, medications used for cold or flu, anticoagulants, medications for nausea and vomiting, anticonvulsants, barbiturates, and antidepressants. [2]

**Storage conditions:**Paracetamol elixir should be stored in a cool, dark place. It is stored in a closed amber bottle. It should be kept away from direct heat and light. The expiration date of paracetamol elixir is in 1 month after preparation.

**Calculations:**

Product strength:

Paracetamol: 1200mg → 50 mL  
 ? → 2.5mL   
(1200\*2.5)/50 = 60mg  
Strength = 60mg/2.5ml  
 = 120mg/5ml  
 = 180mg/7.5ml

= 240mg/10ml

**Main label:**

**Pharmacy name:** Drug Restaurant

**Pharmacists’ name:** Nima Farhan, Bara Al-Khateeb

**Product name:** Paracetamol Elixir

**Product strength:** 60mg/2.5mL, 120mg/5ml, 180mg/7.5ml, 240mg/10ml paracetamol

**Expiration date:** 21/4/2018 (1 month after preparation)

**Amount prepared:** 50 ml

**Use:** Analgesic for mild to moderate pain, and antipyretic to reduce high temperatures during fevers, used mainly in pediatrics.

**Auxiliary label:**

* Shake well before use.
* Store in a cool and dark place.
* Keep away from direct heat or light.
* Store in a closed container.

**Questions:**

1. Because suspension don’t undergo disintegration so they’re absorbed much faster than solid dosage forms and they exert the needed effect in a short period of time which is appropriate in emergencies.
2. Elixirs are contraindicated in neonates as they can affect their liver function, cause gastric irritation in addition to neurological depression some kinds of alcohol can cause serious problems; benzyl alcohol can cause gasping syndrome which is characterized by a deterioration of organ functions and death, and propylene glycol can cause seizures in preterm infants, they also can’t be used if the patient cannot consume alcohol, for example if they have allergies, or if they’re taking other CNS depressing medicines, as well as in patients with impaired liver function. Elixirs are not to be used during pregnancy and lactation unless strictly necessary, as well as in elderly with heart problem as they’re more sensitive to tachycardia and hypertension.
3. Because elixirs have a high content of volatile alcohols and oils.
4. Chloramphenicol is lipid soluble and it can pass through the plasma membranes of bacteria and reversibly bind to the 50S subunit of the ribosome thus inhibiting protein synthesis. Its side effects are quite serious for example it can cause bone marrow depression which might in itself have other effects on health like increasing the risk of infections and delayed healing, in addition to aplastic anemia and gray baby syndrome
5. 3-6 months old: 2.5 ml, 6months-2 years: 5ml, 2-4 years: 7.5ml, 4-6 years: 10ml all are taken 4 times a day.
6. Alcohols are self-preserving when they make up more than 10%-12% of the preparation, to calculate the percentage of alcohol in this preparation:   
   - 90 ml ethanol → 100 ml water  
    ? → 14 ml   
   (90\*14)/100 = 12.6 ml ethanol   
   - percentage of ethanol = (alcohol content/ overall volume of preparation) \* 100%  
    = 12.6/100  
    = 12.6%

Thus its concentration is sufficient for it to self-preserve.

**References:**

1. https://www.drugs.com/pro/mineral-oil.html
2. PAEDIATRIC PARACETAMOL ELIXIR BP. (2011, August). Retrieved March 27, 2018, from https://www.drugs.com/uk/paediatric-paracetamol-elixir-bp-leaflet.html
3. Paediatric Paracetamol Elixir BP. (2017, November 2). Retrieved March 27, 2018, from https://www.medicines.org.uk/emc/product/4509