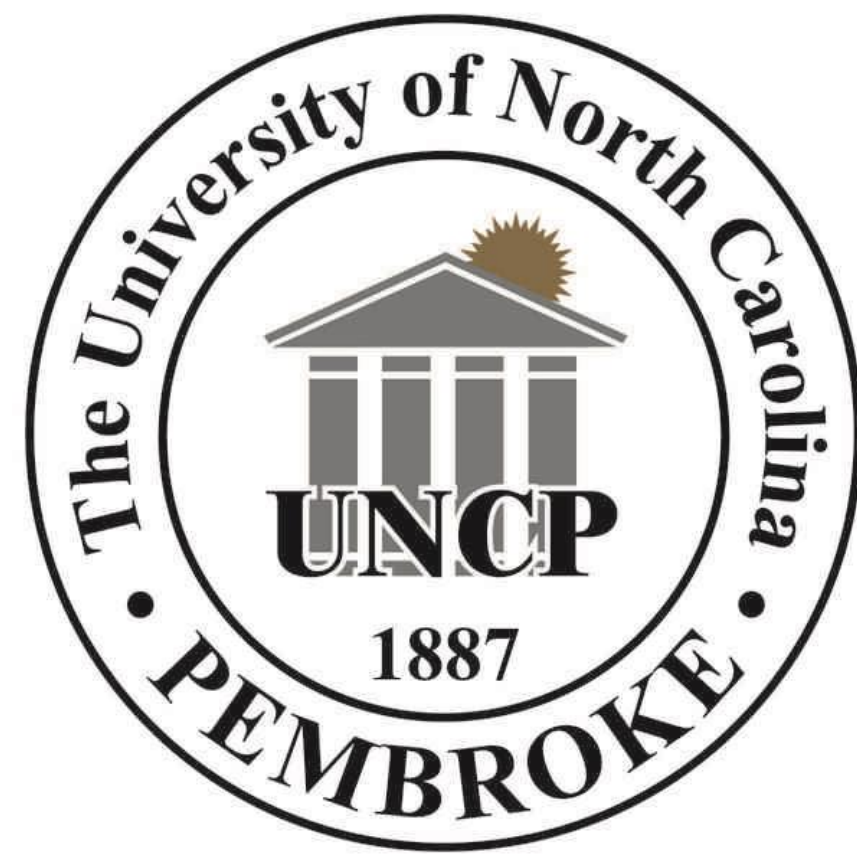# HPLC Method Validation: A Global Application for the Analysis of Amoxicillin

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Abstract

Several factors can determine the purity and efficacy of certain pharmaceutical compounds. These environmental factors play a huge role in how drug manufacturers store and handle compounds. Several countries that are without resources such as dependable electricity and clean water, also suffer from not receiving proper healthcare, which includes not receiving correct medication. The main goal of this research is to validate the HPLC method which will be used to analyze the purity of amoxicillin capsules collected from selected African countries to show the importance of safe and effective pharmaceutical products. Before the samples can be analyzed, it is necessary to meet several criteria for a validated HPLC method. Thus, the aim of this research is to demonstrate the linearity of the HPLC method as well as to show that the method meets the requirements for tailing factor and column efficiency.

Background

- Amoxicillin is in the beta lactam family that also belongs to the Penicillins.
- Amoxicillin became available when it was introduced to the United Kingdom in 1972.
- Can treat an overabundance of infections including: pneumonia, ear infections, bronchitis, and tonsillitis.
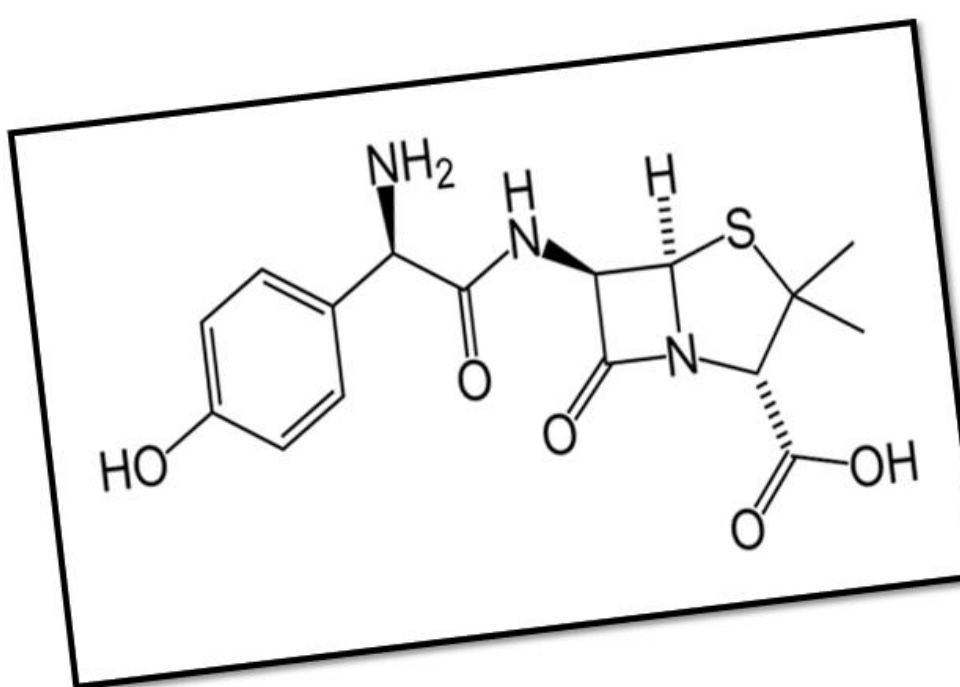
Why Amoxicillin?

- Amoxicillin is dispensed in a variety of forms from tablets to liquid drops, to be taken orally.
- Various dispensing techniques makes it difficult to manage the integrity of the drug.
- Amoxicillin is listed on the World Health Organization's List of Essential Medicines.
- Amoxicillin is one of the most commonly prescribed antibiotics given to treat infections in children.
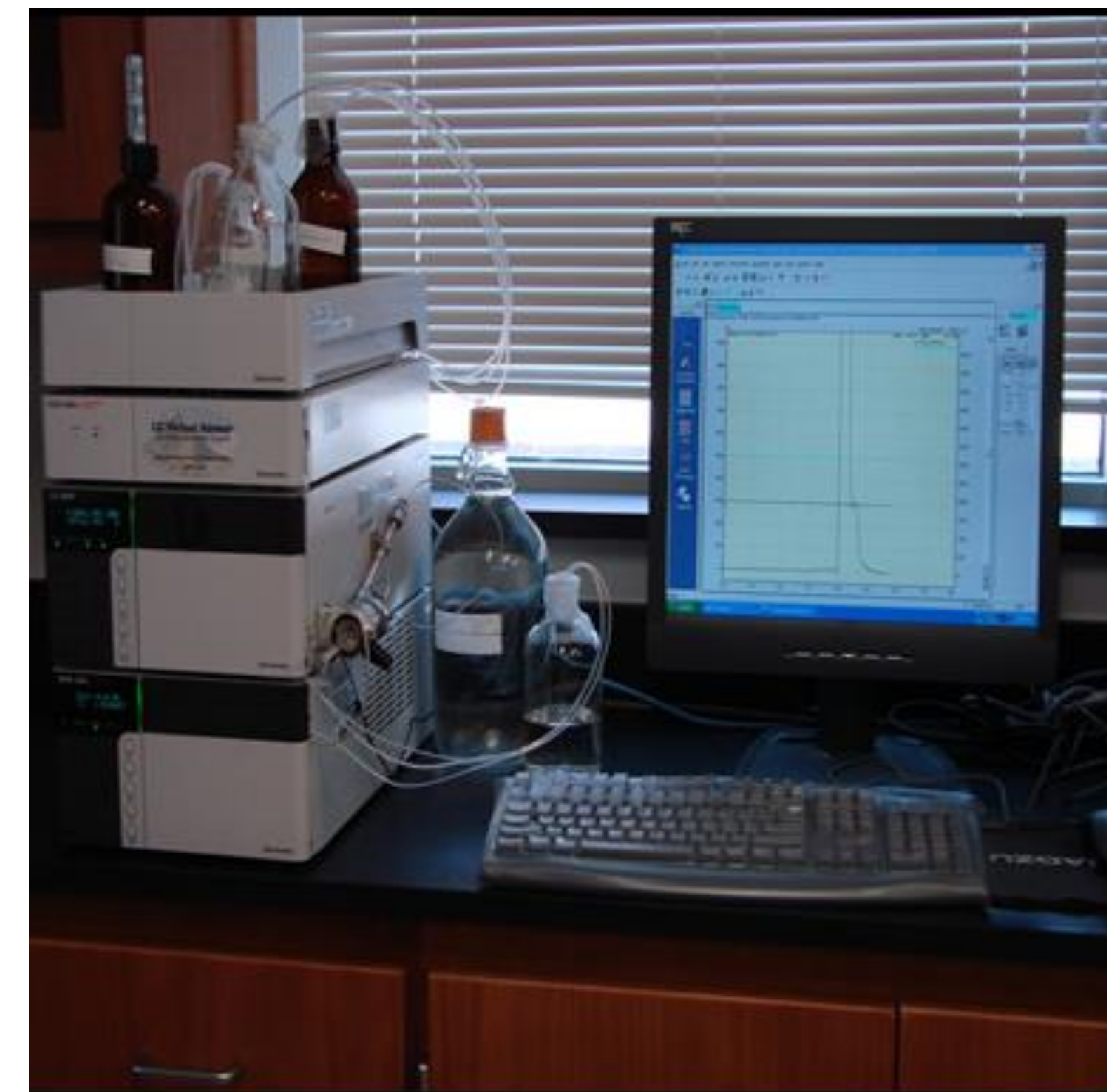
Methodology: HPLC

Figure 1: High Performance Liquid Chromatography (HPLC) is used to separate, identify, and quantify each component in a

Flow
- 0.5 mL/min
- 20 µL Injection Volume
- 230 nm wavelength

Column
- Column stationary phase – Symmetry C18 Column
- 100 x 4.6 mm

Mobile Phase
- 20 mM Monosodium phosphate buffer (pH: 4.4)
- Methanol (95:5 % v/v)

Results

Linearity Data
- Each data point represents three individual samples being tested
- The acceptable R^2 point is to be ≤ 0.98
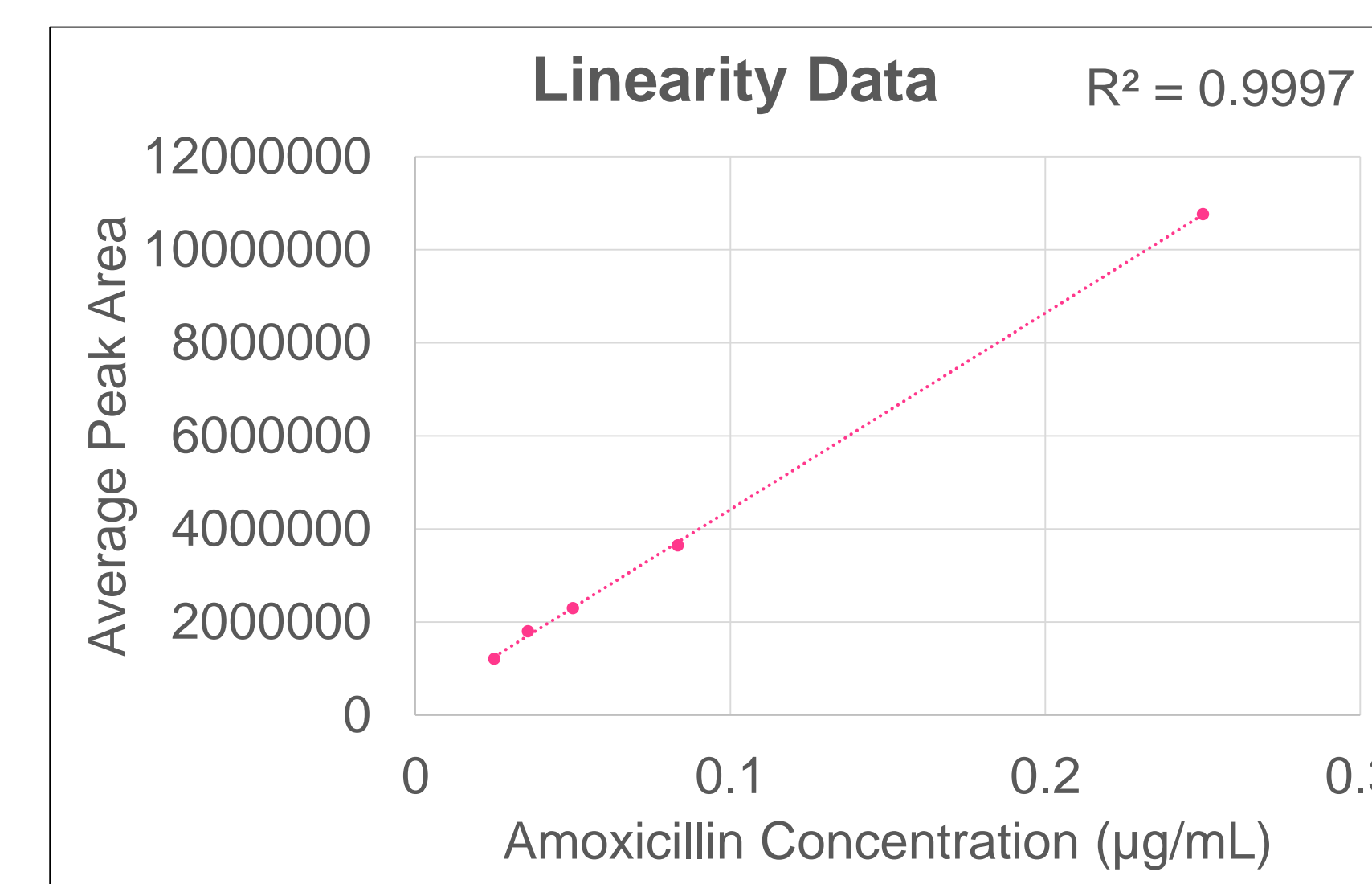- Figure 1 displays a R^2 value of 0.99 which is creditable
- n=5

Figure 1: Linearity Data

Quality Control Chart
- Theoretical Plate is when the liquid and gaseous phases are at equilibrium.
  - >1700
- Tailing Factor is when the distance from the front slope of the peak to the back slope divided by twice the distance of the peak.
  - < 2.5
- K' is the reverse rate constant of the reaction.
  - 1.1-2.2

Quality Control Chart

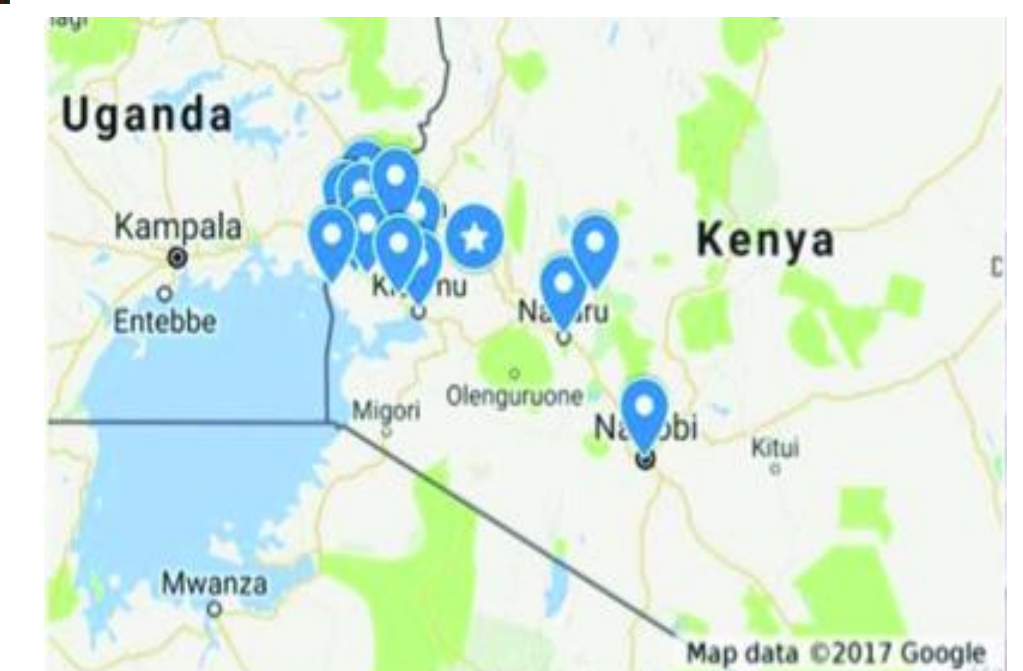| Date	Theoretical Plate	Tailing Factor	k'
11-Feb	3808.634	1.133	2.024
18-Feb	3111.859	1.185	1.523
18-Feb	3148.853	1.198	1.522
18-Feb	3028.968	1.240	1.554
19-Mar	2724.039	1.009	1.041

Figure 2: Quality Control Chart
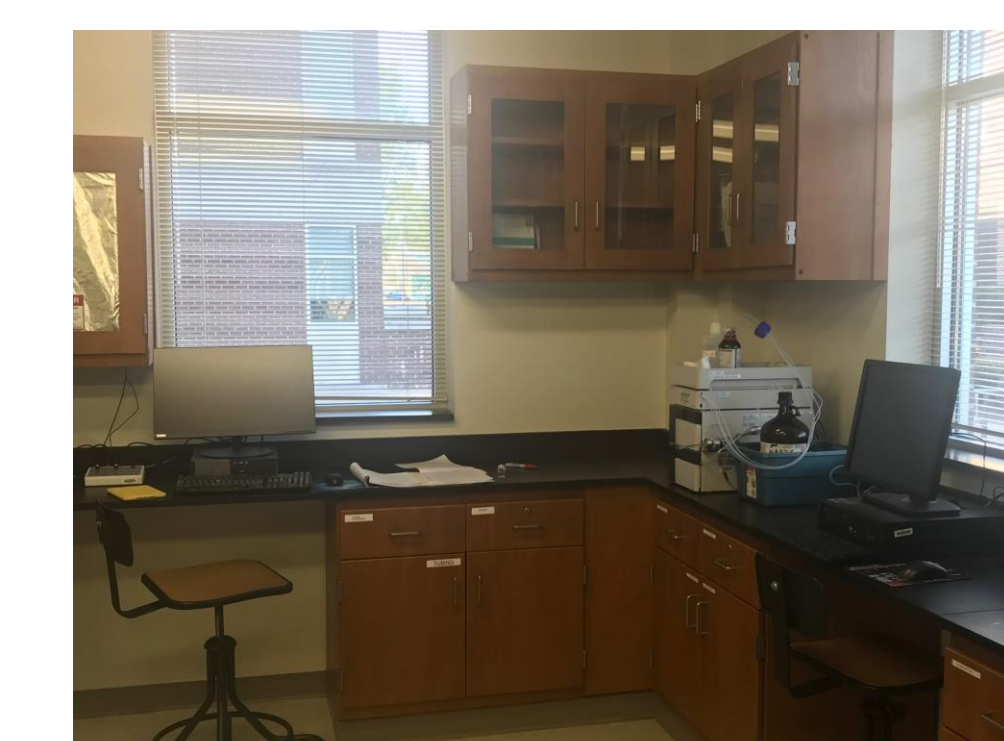
Africa to UNC-Pembroke

Street pharmacy in local African communities

Covert shoppers visit various locations in West Kenya

Moi Teaching and Referral Hospital

Sample in-take process at Notre Dame

Laboratory at samples UNCP where the Amoxicillin are tested

Acknowledgements

- Tablets Manual "Online Information about Amoxicillin". http://www.tabletsmanual.com/online/amoxil
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