International Journal of Innovation and Scientific Research
ISSN 2351-8014 Vol. 57 No. 1 Oct. 2021, pp. 24-29

http://www.ijisr.issr-journals.org/

# Comparative study of the quality control of Ampicillin sold in Niamey city by Thin Layer Chromatography

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**ABSTRACT:** The objective of this work is to demonstrate the quality of Ampicillin used alongside and in the health centers by the population of Niamey city by using Thin Layer Chromatography method to compare the results achieved in order to contribute to informed decision-making for possible interventions. This comparison aimed to investigate the quality of on eleven samples distributed as follows which five samples are from pharmacies, five samples are from street vendors and one sample specialty used as reference to check the quality control of them. The different reagents used are: Hydrochloric acid (HCl) 32-36%, acetone, distilled water, ethyl acetate and acetic acid. All samples migrated in proposed diluent. This shows that all samples contain the active ingredient substance of ampicillin. The percentage of the active ingredient were calculated as per protocol of Clarke's analysis of drugs and poisons in chemistry guidelines. It varies from 89,46 to 94,73 for pharmacies and street vendors.

According to the results of the different frontal reports, sixty percent of Ampicillin products purchased from each side contains the percentage of active ingredient recommended by WHO.

This technique of quality control can be used for practical work or tutorial and laboratories where drug quality control mechanism is not often checked.

**KEYWORDS:** Ampicillin, Thin Layer Chromatography, pharmacies, street vendors, Niamey.

## 1 INTRODUCTION

The fraudulent sale of drugs in the informal sector, called street drugs, has become a public health problem worldwide, and more particularly in sub-Saharan Africa, including Niger [1 to 5].

Today, this drug supply has become not only a threat to the health of the population but also to the economy and security of our country [6 to 10].

Ampicillin (figure 1) is an antibiotic, which part of the family of beta lactams, the group of penams and the subgroup of Aminopenicillins. It is indicated for the treatment of bacterial infections caused by susceptible germs. It is broad spectrum and acts on BGP (Gram-positive bacteria) and certain BGN (Gram-negative bacteria) [11, 12]. Its formula is $C_{16}H_{18}N_3NaO_4S$; and its molecular weight is 349.4 [13].

Its name according to IUPAC is: (2S,5R,6R) -6- ([(2R) -2-amino-2-phenylacetyl] amino) -3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0] heptane-2- carboxylic acid. Its melting temperature is 208 °C [1, 13]. It is Soluble in water at 21 °C.

Ampicillin belongs to the class of medications called antibiotics, or more precisely penicillin [1, 13]. It is used alone or in combination with other antibiotics to treat and prevent infections which caused by certain types of bacteria. This medicine works by killing bacteria or by preventing their excessive proliferation [1, 12].

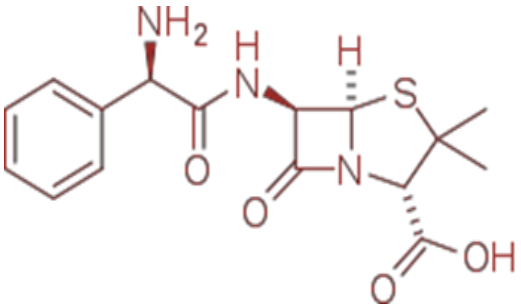


***Fig. 1. Chemical structure of Ampicillin [11]***

Its chemical Properties are: A white crystalline powder which is very soluble in water; practically insoluble in ethanol, acetone, carbon tetrachloride, chloroform and ether.

There are two types of Ampicillin [13]:

✓ **Ampicillin Sodium**

Its formula is $C_{16}H_{18}N_3NaO_4S$ and its molecular weight is 371.4 (Anthony, 2011; 2609, pp. 924-925).

✓ **Ampicillin Trihydrate**

Its formula is $C_{16}H_{19}N_3O_4S,3H_2O$ and its molecular weight is 403.4 (Anthony, 2011; 2609, pp. 924-925).

Their chemical properties are: a white, hygroscopic, crystalline or amorphous powder. Aqueous solutions containing 10% or more deteriorate rapidly on storage. Melting point about 205, with decomposition. Soluble in half of water and acetone; slightly soluble in chloroform; practically insoluble in ether. With ethanol, ampicillin sodium forms a colloidal dispersion which gels on standing **[11,13].**

## 2 MATERIAL AND METHOD

This study was carried out using a survey sheet containing a few questions and a camera allowing the TLC of the different samples to be photographed [12].

### 2.1 POPULATION

The population is represented by the antibiotics (from pharmacies and street vendors) most commonly sold in the Urban Community of Niamey and used in hospitals and health centers (Niamey National Hospital, Amirou Garga Hospital of Lamordé, University Hospital Center and Maternity Issaka Gazobi) **[15 to 18].**

### 2.2 SAMPLING AND SIZE

Our sample is represented by three (3) types of antibiotics of Ampicillin, namely:

- Reference antibiotic;
- The antibiotics most commonly used in health centers (HNN, HNL, CHR and MIG) sold in pharmacies;
- Antibiotics sold by itinerants.

Thus, our study extended on the size of eleven (11) samples distributed as follows:

- 5 samples for pharmacies;
- 5 samples for street vendors;
- 1 sample specialty used as reference for the molecules to be analyzed.

### 2.3 Reagents Used For Thin Layer Chromatography (TLC) Of Ampicillin

Hydrochloric acid (HCl) 32-36%, acetone, distilled water, ethyl acetate and acetic acid have been used for the TLC of ampicillin [14].

### 2.4 The Methodology

Before proceeding to the actual operating mode (MO), we made a preliminary test as follows: take a chromatoplate 20 cm * 20 cm which we divide in half and cut the length of the desired chromatoplate, then using the pencil and from the graduated ruler, draw a line of 1.5 cm from the bottom of the sheet that will serve as a baseline.

Identify in pencil the different products to be analyzed by personal codes, separating them by 1cm so as to occupy the entire baseline according to the number of products to be spot on this same baseline; finally prepare the usage and mobile phase solutions, and number the test tubes according to the seller's category.

### 2.5 Preparation Of The Mobile Phase Of The Ampicillin TLC

In the extraction solvent contained in a 100 ml flask were introduced: 18 ml of distilled water, 2 ml of 37 % hydrogen chloride acid (HCl 32) and 80 ml of acetone [14].

We weighed a powder test sample corresponding exactly to 25 mg by using the average weight of each sample (table I), which we introduced into a 10 ml flask, then complete with the extraction solvent up to the dipstick and shake it.

***Table 1. Weights and Average of weights of the Ampicillin samples***

| Sample identity | Corresponding Weight of 500 mg (mg) | Average of weight (mg) |
|---|---|---|
| **Reference** | 580, 573, 566 | 573 |
| **$P_1$** | 550,580,580,570,580, 590,590,550,580,560 | 573 |
| **$P_2$** | 600,620,600,640,610,590,590,610,560,600 | 602 |
| **$P_3$** | 630,620,600,620,590, 600,610,630,600,620 | 614 |
| **$P_4$** | 580,570,600,600,600, 560,620,550,610,560 | 588 |
| **$P_5$** | 600,620,580,600,590,590,620,540,600,590 | 593 |
| **$V_1$** | 580,730,530,810,430, 590,490,610,830,400 | 600 |
| **$V_2$** | 740,510,790,400,910, 300,420,800,600,610 | 608 |
| **$V_3$** | 790,500,800,430,830, 440,820,600,740,540 | 649 |
| **$V_4$** | 780,500,800,400,560, 620,600,400,740,540 | 594 |
| **$V_5$** | 740,500,780,440,840,400,700,420,720,520 | 606 |

*P = pharmacy; V= seller*

The mobile phase was prepared in the chromatographic tank into which 60 ml of ethyl acetate, 20 ml of acetic acid and 20 ml of distilled water were introduced (10).

The tank was closed and well agitated. Wait at least 15 minutes for the chromatographic chamber to be saturated and at the same time place the different samples on the chromatoplate (10). Finally, the chromatographic sheet was immersed in the chromatographic tank and wait for migration. The chromatoplate was taken out of the chromatographic chamber to dry it in the free area, then put it in the chromatographic tank in order to observe and verify the migration of stains.

After TLC, the RF of each sample was calculated by the following formula:

$$RF = \frac{X}{Y} \text{ [19]}$$

Where:

RF: is the frontal report

X: Distance traveled by the solute

Y: Distance traveled by the solvent

After this the active ingredient content of each sample was calculated by the following formula:

$$T = \left(\frac{RF\ éch}{RF\ réf}\right) \times 100\ \%\ [19]$$

Where:

*RF éch:* is the frontal report of the sample;

*RF réf:* is the frontal report of the reference.

## 3 Results And Discussion

### 3.1 Presentation Of TLC Analysis Results

After having carried out the procedure from the spotage to the observation of the iodine chromatograms, the plates were photographed and represented in the form of the figure below (Figure 2).

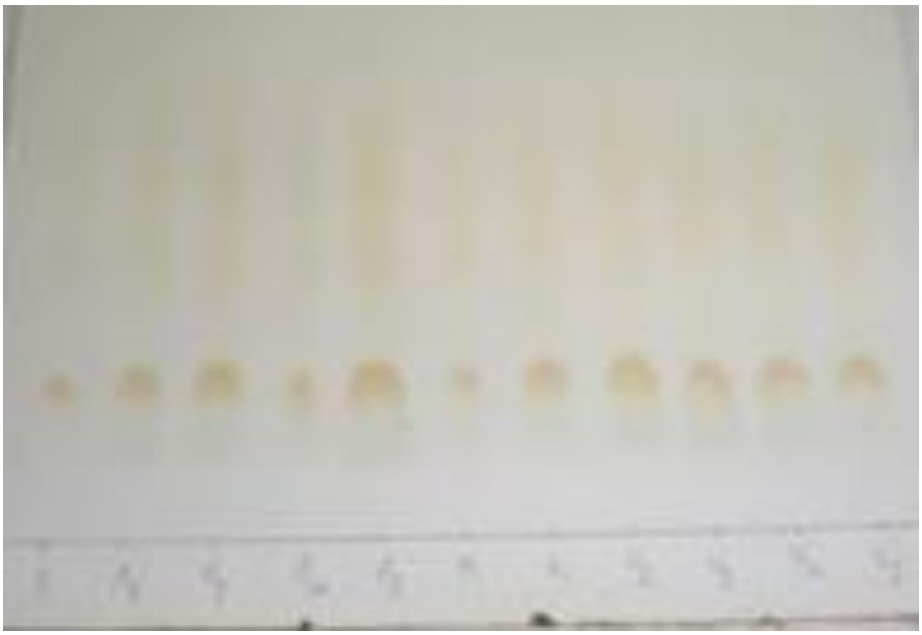

***Fig. 2. TLC plate photograph of Ampicillin samples***

Through the photographs of the various thin layer chromatography (TLC) of the samples of ampicillin. It has been observed that all of the samples have migrated; which leads us to conclude that the active ingredient (a.i.) exists in these samples and that whatever the content.

After presenting the TLC photographs of the different samples by molecule, we measured the distances traveled by the different solvents and samples in cm (Table 2).

Then we calculated the Frontal Report (RF) of each sample (Table 3).

### 3.2 PRESENTATION OF THE MIGRATION RESULTS

*Table 2. Presentation of the distances covered by the samples (cm) of Ampicillin*

| Sample and solvent | Distance of migration (cm) |
|---|---|
| **Solvent** | 7,7 |
| **Réf** | 1,9 |
| **$P_1$** | 1,8 |
| **$P_2$** | 1,75 |
| **$P_3$** | 1,7 |
| **$P_4$** | 1,75 |
| **$P_5$** | 1,7 |
| **$V_1$** | 1,7 |
| **$V_2$** | 1,85 |
| **$V_3$** | 1,7 |
| **$V_4$** | 1,75 |
| **$V_5$** | 1,8 |

*Réf: reference; P: pharmacy; V: street vendor*

According to the results of the table above, the distances traveled by the samples are close to that traveled by the reference.

*Table 3. The frontal ratios of the different samples of Ampicillin*

| Samples | Frontal Ratio (cm) | % a.i. |
|---|---|---|
| **Réf** | 0,2467 | |
| **$P_1$** | 0,2337 | 94,73 |
| **$P_2$** | 0,2272 | 92,09 |
| **$P_3$** | 0,2207 | 89,46 |
| **$P_4$** | 0,2272 | 92,09 |
| **$P_5$** | 0,2207 | 89,46 |
| **$V_1$** | 0,2207 | 89,46 |
| **$V_2$** | 0,2402 | 94,73 |
| **$V_3$** | 0,2207 | 89,46 |
| **$V_4$** | 0,2272 | 92,09 |
| **$V_5$** | 0,2337 | 94,73 |

*P: pharmacy; V: street vendor*

This table shows us that the Ampicillin samples traveled on average almost all the same distances as the Reference.

On the five antibiotics purchased at pharmacies; two did not meet the standards recommended by the WHO, which is 90 to 110 % active ingredient content (a.i.) [14]. This is because ampicillin is not often sold like other antibiotics; it must always be combined with other antibiotics for better treatment efficiency.

The same goes for street vendors; two of the products tested do not meet the standards required by the WHO. This could be explained with the hypothesis put forward at the level of pharmacies; but also, that these products are too exposed to heat which would degrade their active ingredient (a.i.).

## 4 CONCLUSION

The results of the study reveal that in the two cases (pharmacy and street vendors) the following lessons for the TLC.

The results show that the migration was effective for all the samples; therefore, this reveals the presence of Active Ingredient in the samples.

Sixty percent of Ampicillin products purchased from each side (pharmacies and street vendors) meet WHO standards; Active Ingredient Content like standards between 90 and 110 %; while forty percent are below the same standards.

**ACKNOWLEDGMENT**

The authors are very thankful to:

- Niamey National Hospital,
- Amirou Garga Hospital of Lamordé,
- Poudrière regional Hospital Center,
- Maternity Issaka Gazobi
- Pharmacies
- Street vendors

**REFERENCES**

[1] HAMANI ABDOU IDRISSA, 2005, Thesis, Street drugs in Niamey: Sales methods and quality control of some anti-infective drugs, University of Bamako; 140 p.
[2] EMILLIENNE POLA YISSIBI, 2012, Article, Interest of a regional laboratory quality control of pharmaceutical products in the CEMAC zone, 16 p.
[3] CANDICE LEGRIS, 2007, Thesis, Detection of counterfeit medicines by investigating their authenticity; Pilot study on the illicit pharmaceutical market in Cote d'Ivoire, 165 p.
[4] OUEDRAGO SAMIRATOU, 2008, Thesis, Street drugs in the area disadvantaged of Ouagadougou (Burkina Faso), Mohamed University of Rabat, p. 111.
[5] DIALLO MOUSTAPHA, 2005, Thesis, Contribution to the evaluation of the illicit drug market in Niger from customs import statistics for drugs, laboratory reagents and medical consumables from 1999 to 2003, FSS, p 12.
[6] HADIZA MOUSSA ABDALLAH, 2000, Thesis, the street Pharmacy of Niger: an alternative to the failure of national pharmaceutical policy. Case study of the Niamey III Commune, University of Ouagadougou, 112 p.
[7] SIDIBE MOUSSA, 2006, Analytical control of the pharmaceutical form tablets and capsules of the drugs based on amoxicillin and Ampicillin sold on the markets of Conakry, p82.
[8] JOCELYNE SAMBIRA, 2013, Memory, Counterfeit medicines: a problem in Africa, The Magnitude of the Profits and the Lightness of the Sentences Fuel Crime, p. 35.
[9] MANUSCRIT N ° 3117, 2007 of Public health, the informal circuit of drugs in Yaoundé and Niamey: Study of the population of sellers and of the quality of the drugs distributed, pp. 113-117.
[10] Counterfeit Medicines 2013, a health problem in Africa, p5.
[11] https://fr.wikipedia.org/wiki/Ampicilline, 06/01/2016 at 4: 50 pm.
[12] ABSI MOUMOUNI, 2004, Bacteriology Course, Chapter on Antibiotics, ENSP of Niamey.
[13] CLARKE'S Analysis of Drugs and poisons, Volume 2, Third Edition, page 635.
[14] http://apps. WHO Pharmacopoeia CCM.htm, 08/21/2016 at 16h 25mn.
[15] HNN Supervisor Service.
[16] Supervisor Service of the NHL.
[17] MIG HR Department.
[18] Epidemiology Service of CHR Poudrière.
[19] http://lycees.ac-rouen.fr/galilee/iesp27/chromate /image0RE.JPG, 08/21/2015 at 10h30mn.