International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2020): 7.803

Comparative Study of the Quality Control of Amoxicillin Sold in Niamey City by Thin Layer Chromatography

Salifou Karimoune Fadjimata[1], Amadou Tidjani Ilagouma[2]

[1]Materials, water and environment laboratory (MWEL), Department of Chemistry, Abdou MoumouniUniversity. BP 10662, Niamey (Niger)

[2]Faculty of Sciences and Technik, Department of Chemistry, Abdou MoumouniUniversity. BP 10662, Niamey (Niger)
Corresponding author: *salifoufadjimata[at]gmail.com*

Abstract: ***The present study describes comparative analysis of Amoxicillin sold in Niamey city by Thin Layer Chromatography. This comparison aimed to investigate the quality of on eleven samples distributed as follows whichfive 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 amoxicillin. The percentage of the active ingredient were calculated as per protocol of Clarke's analysis of drugs and poisons in chemistry guidelines. Itvaries from 97,27 to 110,54 and 94,73 to 100 respectively for pharmacies and street vendors. According to the results of the different frontal reports, each sample contains the percentage of active principle recommended by WHO which is 80 to 100 %. This technique can be used for practical work or tutorial and laboratories where drug quality control mechanism is not often checked.***

Keywords: Amoxicillin, TLC, 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]**. The informal drug network experienced a boom in Niger with the advent of a multiparty system from 1991 and the lifting of the ONPPC (National Office ofchemical and pharmaceutical products) monopoly in 1997 **[6 to 8]**. Despite the existence of legislation which specifies the pharmacist's monopoly in the field of drugs, the illicit drug distribution circuit has developed in a diffuse way in all the regions of Niger, by the proliferation of a multitude of street vendors, most often from unemployed youth. The omnipresence of this informal market is a real health problem in Niger [**1 to 5].**

Amoxicillin(figure 1) is an antibiotic; which ispart of the family of beta lactams, the group of penams and the subgroup of Aminopenicillinswhich is most commonly sold as capsules or tablets [**6 to9]**.It is generally used in respiratory infections **[10, 11].**

Its raw formula is $\mathbf{C_{16}H_{19}N_3O_5S}$witha molecular weightof. ItsIUPAC Name (2S,5R,6R)-6-[[(2R)-2-Amino(4-hydroxyphenyl)acetyl] amino]3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0] heptane-2-carboxylicacid [**12].**

There are two types of Amoxicillin:

- Amoxicillin Sodium which the chemical formula is $C_{16}H_{18}N_3NaO_5S$ with a molecular weight of 387.4 $gmol^{-1}$;
- Amoxicillin Tri hydrate whose chemical formula is $C_{16}H_{19}N_3O_5S$, $3H_2O$ and a molecular weight of419.4 $gmol^{-1}$.

Its chemical properties are: A white powder. Soluble 1 in less than 1 of water. Ultraviolet Spectrum Amoxicillin trihydrate, aqueous acid—230 (A 11¼225a), 272 (A11¼26a); aqueous alkali—247nm (A 11¼286b), 291nm (A 11¼62a)[**12]** Several methods have been used for its detection including TLC [**13 à 17].**

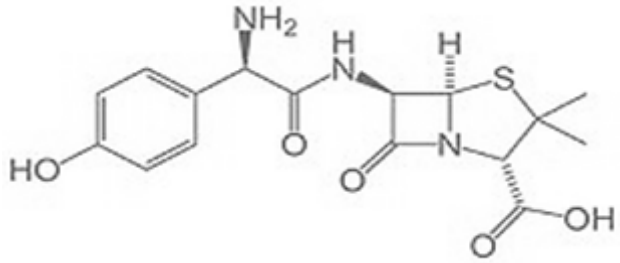

Figure 1: Chemical structure of Amoxicillin

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)**[18to 21].**

2.2 Sampling and Size

Our sample is represented by three (3) types of antibiotics of Amoxicillin, 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 amoxicillin

Hydrochloric acid (HCl) 32-36%, acetone, distilled water, ethyl acetate and acetic acid have been used for this TLC of amoxicillin.

2.4 The Methodology

Before proceeding to the actual operating mode (MO), we made a preliminary test as follows: take a chromatoplate 20cm * 20cm 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. Identifyin 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.

2.3.3 Amoxicillin TLC

In the extraction solvent contained in a 100 ml flask were introduced: 18 ml of distilled water, 2 ml of 36% hydrogen chloride (HCl 32) and 80 ml of acetone. We weighed a powder test sample corresponding exactly to 25 mgby 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 I: Average of weights of the different samples of Amoxicillin

Sample identity	Weight (mg)	Average (mg)
Reference	670,690, 710	690
P_1	520,570,530,570,570, 550,590,550,520,560	553
P_2	570,640,620,600,590, 590,590,590,610,570	597
P_3	580,590,610,600,560, 600,590,590,570,590	588
P_4	610,590,610,600,560, 600,590,590,570,590	591
P_5	610,640,640,660,670, 640,560,580,630,630	626
V_1	600,600,630,610,650, 590,610,600,570,570	603
V_2	610,720,490,560,740, 350,580,660,260,940	591
V_3	600,800,200,600,560, 450,700,590,790,380	567
V_4	720,510,730,430,730, 480,680,390,740,550	596
V_5	580,380,800,560,710, 460,550,750,370,550	571

P: pharmacy; V: street vendor

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:

$\boldsymbol{RF = \frac{X}{Y}}$**[22]**, 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:

$\boldsymbol{T = (\frac{RF\ éch}{RF\ réf})}$ **×100 % [22],** 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.

The plates of the iodine chromatograms were photographed and represented in the form of the figure below (Figure 2).

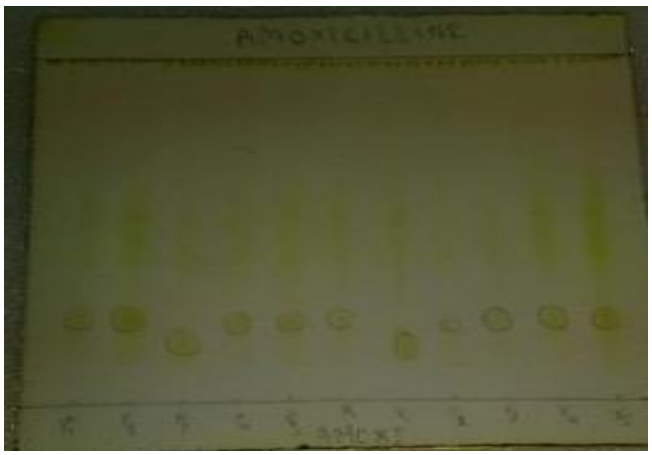

Figure 2: TLC plate photograph ofAmoxicillin samples

Through the photographs of the various thin layer chromatography (TLC) of the samples per molecule, it has been observed that the samples of all the molecules have

migrated; which leads us to conclude that the active ingredient 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 II), then we calculated the RF of each sample (Table III).

Table II: Presentation of the distances covered by the samples (cm)

Sample and solvent	Distance (cm)
Solvent	7,7
Reference	1,9
P_1	2
P_2	2
P_3	2,1
P_4	2
P_5	1,9
V_1	1,8
V_2	1,8
V_3	1,9
V_4	1,9
V_5	1,9

P: pharmacy; V: street vendor

Table III: Presentation of frontal reports of the various Amoxicillin samples

Sample identity	RF	% a.i.
Reference	0,2467	
P_1	0,2597	97,27
P_2	0,2597	97,27
P_3	0,2727	110,54
P_4	0,2597	97,27
P_5	0,2467	100
V_1	0,2337	94,73
V_2	0,2337	94,73
V_3	0,2467	100
V_4	0,2467	100
V_5	0,2467	100

RF: frontal reports; P: pharmacy; V: street vendor; a.i.: active ingredient

This table shows us that the Amoxicillin samples traveled on average the same distances as the Reference. Therefore, consequently they have roughly the same frontal ratios.

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. Amoxicillin samples from pharmacies have Active Ingredient Content like standards between 80 and 120% while street antibiotics have Active Ingredient Contentlower or higher than the standard recommended by the WHO.

References

[1] HamaniAbdouIdrissa,2005,Thèse,LesMédicamentsdel arueàNiamey : Modalitésde vente etcontrôle de qualité de quelquesmédicamentsanti-infectieux,Université deBamako ; 140p.
[2] Hadiza Moussa Abdallah, 2000, Thèse, La Pharmacie par terre au Niger : une alternative à l'échec de la politique pharmaceutique nationale. Etude de cas de la Commune Niamey III, Université d'Ouagadougou, 112p.
[3] Ouédrago Samiratou,2008,Thèse, Les Médicaments de la rue enzone défavoriséed'Ouagadougou,Université Mohamed deRabat,p111.
[4] Diallo Moustapha, 2005, Thèse, Contributionàl' évaluation dumarchéillicite du médicamentau Nigeràpartirdesstatistiques douanièresd' importationdes médicaments, réactifs de Laboratoire et consommables médicauxde1999 à 2003, FSS, p12.
[5] Didier Fassir, Revue N° 89-07-87, Le réseau de vente illicite des médicaments au Sénégal, Vol.25, cahier 98 (985), pp.161-177.
[6] ORDONNANCE N°97-002 du 10 Janvier 1997 portant législation pharmaceutique, 52p.
[7] Strategie Pharmaceutique de l'OMS, 2000 : Cadre d'action pour lesMédicaments essentiels et politiques pharmaceutiques 2000-2003 Genève, OMS,70 p.
[8] Caroline Krissi, 2006, Contrefaçon des médicaments et stratégies technologiques pour sécuriser la chaine d'approvisionnement pharmaceutique, Ecole polytechnique de Montréal, 179p.
[9] Absi Moumouni, 2004, Bacteriology Course, Chapter on Antibiotics, ENSP of Niamey.
[10] https://fr.wikipedia.org/wiki/Amoxicilline, 06/01/2016 at 4:50 p.m).
[11] M. Hamel Vincent, 2006, Thèse, La vente illicite de médicaments dans les pays en développement : analyse de l'émergence d'un itinéraire thérapeutique à part entière, situé en parallèle du recours classique aux structures officielles de santé, Université Claude-Bernard, Lyon I, p91.
[12] Anthony Moffat ; 2609, PP. 923-925
[13] SidibéMoussa,2006,Contrôleanalytiquedesformespharmaceutiquescompriméset gélulesdesmédicamentsà based' amoxicillineetd'Ampicilline vendussurlesmarchésde Conakry, p82.
[14] Candice Legris, 2007, Thèse, La détection des médicaments contrefaits par investigation de leur authenticité ; Etude pilote sur le marché pharmaceutique illicite de Cote d'Ivoire, 165 p.
[15] Richard W. O. Jähnke, 2008,Guide concis de contrôle dequalité des médicaments essentiels et autres agents actifs : Test deRéactions Colorées, pp. 44-48-72-76-128.
[16] Emillienne Pola Yissibi, 2012, Intérêt d'un laboratoire régional de contrôle de qualité des produits pharmaceutiques en zone CEMAC, 16p.
[17] Carmen A.D, 2009, Publication, La Contrefaçon du Médicament : Ampleurdu fléau et méthode de détection, Vol.2, p335.
[18] HNN Supervisor Service,
[19] Supervisor Service of the NHL
[20] MIG HR Department,
[21] Epidemiology Service of CHR Poudrière)
[22] http://lycees.ac-rouen.fr/galilee/iesp27/chromato/image0RE.JPG, 21/ 08/ 2015