Comparative Study of the Quality Control of Métronidazole Sold in Niamey City by Thin Layer Chromatography (TLC)

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Abstract: *This work describes a comparative analysis study of Métronidazole sold in Niamey city by Thin Layer Chromatography. 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. Chloroform, diethylamine and acetone are the different reagents used. All samples migrated in proposed diluent. This shows that all samples contain the active ingredient substance of Métronidazole. 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 94,4 to 100,4 and 76 to 86 respectively for pharmacies and street vendors. According to the results of the different frontal reports, all sample of pharmacies contains the percentage of active principle recommended by WHO which is 90 to 110 % while none of those from street vendors meet the same WHO standards. This technique can be used for practical work or tutorial and laboratories where drug quality control mechanism is not often checked.*

Keywords: Metronidazol, TLC, pharmacies, street vendors, Niamey

1. Introduction

Metronidazole is an Antiprotozoal, Antibacterial which It is part of the imidazole family.This product is an antibiotic and antiparasitic belonging to nitroimidazoles. It inhibits nucleic acid synthesis and is used for the treatment of infections associated with anaerobic bacteria as well as protozoa. [1]. Its chemical formula is $C_6H_9N_3O_3$ with molecular weight of 171.2. Its IUPAC Name is 2-Methyl-5-nitroimidazole-1-ethanol. Its chemical properties are:a white to pale yellow crystalline powder or crystals. It darkens on exposure to light. Soluble in 100 water, in ethanol and in chloroform; soluble in dilute acids; slightly soluble in ether. [2, 12]

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 [2 to 5; 10; 11]. The omnipresence of this informal market is a real health problem in Niger [6 to 9]. The informal drug network experienced a boom in Niger with the advent of a multiparty system from 1991 and the lifting of its ONPPC(National Office ofchemical and pharmaceutical products) monopoly in 1997 [13 to 17].
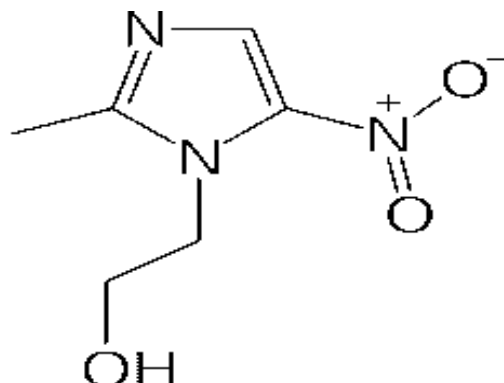

Figure 1: Chemical structure of Metronidazole [1]

2. Materials 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) [18 to 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 Metronidazole TLC

For the TLC of Metronidazole: Chloroform, diethylamine and acetone were used.

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 The Metronidazole TLC

The mobile phase was prepared in the chromatographic tank with 90mL of chloroform and 10mL [22]. A test portion of 20 mg of metronidazole calculated by using the average weight of each sample(table I) is introduced into the test tubes identified by using the markers and immersed in 1ml of acetone, heated slightly to dissolve the substance; then we spotted with the capillary tubes on the chromatographic sheets.Afterplacing the chromatoplate in the chromatographic chamber in order to follow the migration. After removing the plate from the chromatographic chamber, it was air dried and the iodine chromatogram examined (See the Metronidazole plate).

Table I: Average weights of the different samples of Metronidazole

Sample identity	Equivalent weight of 500 mg	Average (mg)
Reference	670,680, 690	680
P_1	660,700,700,680,680,710,700,680,680,690	688
P_2	680,660,670,670,680,670,670,650,690,680	672
P_3	590,620,600,630,600,610,590,590,580,570	598
P_4	560,590,610,630,610,600,610,620,580,600	601
P_5	690,650,700,660,660,600,610,620,580,600	637
V_1	640,660,700,610,640,660,680,660,600,620	647
V_2	720,700,740,760,720,760,660,620,760,700	714
V_3	710,860,490,680,1010, 410,670,980,1010,700	752
V_4	720,1000,315,680,420,980,700,880,500,760	695,5
V_5	820,780,1160,460,1240,400,400,1200,520,1060	804

P: pharmacy; V: street vendor

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

$$RF = \frac{X}{Y} [23],$$ 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:

$$T = \left(\frac{RF\ éch}{RF\ réf}\right) \times 100\ \% \ [23],$$ where

RF éch: is the frontal report of the sample;
RF réf: is the frontal report of the reference.

3. Results and Discussion

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 ofMetronidazol samples

Through the photograph of the thin layer chromatography (TLC) of the samples of Metronidazol, it has been observed that the samples 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, we measured the distances traveled by the different solvents and samples in centimeter (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 identity and solvent	Distances (cm)
Solvent	7,2
Reference	5
P_1	4,3
P_2	4,2
P_3	4,25
P_4	4,1
P_5	4

V_1	4,05
V_2	4
V_3	3,8
V_4	4,2
V_5	4,3

P: pharmacy; V: street vendor

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

Sample identity	RF	% a.i.
Reference	0,6944	
P_1	0,6972	100, 4
P_2	0,6833	98
P_3	0,6902	99,4
P_4	0,6694	96,4
P_5	0,6555	94,4
V_1	0,5625	81
V_2	0,5555	80
V_3	0,5277	76
V_4	0,5833	84
V_5	0,5972	86

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

This table shows us that Metronidazole 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 migration was effective following the TLC used methodology. This reveals the presence of Active Ingredient in the samples.

Metronidazol samples from pharmacies have Active Ingredient Content like standards between 90 and 110 % while street antibiotics have Active Ingredient Content lower than the standard recommended by the WHO.

It also largely demonstrates that street vendors such as pharmacists must in no case sell drugs without first having carried out a complete analysis of the drugs and having a Marketing Authorization.

So, it would be better to think of remedying the problem by raising public awareness of the health consequences and apparently only very large financial actions could wipe out the sale of Street Medicines which is only gaining ground.

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