QUALITY EVALUATION OF AMOXICILLIN AND COMBINATION OF AMOXICILLIN – POTASSIUM CLAVULANATE AS PART OF INVESTIGATION OF THE OFFICIAL AND PERIPHERAL DRUG MARKET IN KINSHASA, LUMBUBASHI AND KOLWEZI - DRC.

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Introduction

Drug counterfeiting is a sad and worrisome reality, especially in developing countries where quality control is not effective and sometimes not existing at all despite political will of governments. The consequences are harmful in particular for substandard medicines that pose more threats to populations in those countries due to their direct negative impact on patients such as failure of medical treatment including development of drug resistance and even death. Socio-economic consequences and negative reputation concerning the pharmaceutical industry are also observed. Unfortunately accurate detailed data on such medicines are not easy to obtain [1,2]. Most of the time available data are often estimated from case reports or studies carried out in a specific area and during a defined period.

Purpose/Goals

Health authorities' in the Democratic Republic of Congo are trying to identify this scourge by set up several strategies to fight against. One of them is built on the best knowledge of drugs from several horizons through the assessment of their quality to allow appropriate measurement. In this context, we have focused our study towards amoxicillin alone and/or combined with potassium clavulanate since it is one the very used medicines in pediatric medications. The formulations are powder for suspension.

Materials and Methods

Two analytical methods were developed based on the USP monograph [3], applying isocratic liquid chromatography with a mixture methanol - phosphate buffer as mobile phase pumped at 0.8 mL/min through an WX-Bridge column (RP-18, 100 mm x 4.6 mm, 3.5µm dp) at 25°C. UV-Vis detection was @ 230 nm for amoxicillin and 220 nm when combined with potassium clavulanate. Prior to their application in routine, we evaluated the suitability of these methods through validation applying the accuracy profile of total error. Since it was planned to transfer the methods to DRC, several operating factors were taken into account namely operator, day and equipment (Waters and Lachrom).

Results and discussion

Interesting results were obtained in terms of trueness (relative biases below than 2.3%), precision (RSD of Intermediate precision below 2.8%), accuracy (beta-expectation tolerance intervals between -6.0% and 3.8%) for the concentration levels of interest. The latter were able to allow monitoring the quality of the two active ingredients here above in the 50

samples from Congolese market. They were collected in Kinshasa, Lumbubashi and Kolwezi at official and non official medicines distributors, in peripheral area.

Conclusion

The dramatic results obtained confirm that substandard and counterfeit medicines remain a crucial problem on public health in low-income countries. Appropriate measures are really needed to set up the drug quality improvement.

References

[1] USP-USAID-WHO report: http://www.usp.org/worldwide, Consulted on September 1, 2016.
[2] J.K. Mbinze et al., J. Pharm. Biomed. Anal. 2013, 85, 83-92
[3] US Pharmacopeia; USP 39-NF 34 (2016), www.uspnf.com