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DECLARATON

I hereby declare that the work presented in this study for the award of the Master of Public Health degree has not been presented wholly or in part for any other study program and is not being submitted for any other study program. This work is entirely the result of my own independent investigations. The various persons and so to which am indebted are acknowledged.

Researcher: _____ Signature: _____

Date: ____/____/____

ABSTRACT

Apart from struggling with the burden of communicable diseases, developing countries such as Zambia are also faced with the challenge of the availability of counterfeit and substandard medicines on their markets which are an insidious threat to health and the risks they pose have been largely underestimated to date. Almost all areas of the world are affected by the availability of substandard and counterfeit medicines, but mounting evidence shows that the problem is disproportionately severe in developing and emerging market countries, which also have a high burden of infectious diseases. In poor countries, essential and life-saving drugs used to treat infectious diseases such as tuberculosis and malaria are often the drugs under threat

This was a cross sectional study whose objective was to determine the quality of 3 types of fixed dose combination (FDC) anti TB drugs namely 4FDC, 3FDC and 2FDC tablets available in Lusaka District by assessing the presence of active ingredients and the percentage content of these active ingredients according to the British pharmacopoeia 2008. Samples of five 4FDC, five 3FDC and seven 2FDC anti TB drugs from Lusaka district were analyzed for presence of active ingredients and percentage content. The drug samples that were analyzed had a shelf life of at least one year. A sample comprised two blister packs each containing 28 tablets. The tablets were number coded before taking them to Tejay Pharmaceuticals Laboratory for analysis.

For presence of active ingredient, all the seventeen samples that were tested gave a positive result indicating that each sample had the correct active ingredients as indicated on the label claim. However, 1 in 5 of the 4FDC samples were none compliant to the BP 2008 specification for percentage content. One sample had a percentage content of 106.3% of Isoniazid that was above the BP 2008 specification of 95% to 105%. All the 3FDC samples were compliant to the

BP 2008 specification of 95% to 105%, but 1 in 7 of the 2FDC samples had a percentage content of 105.6% for Isoniazid that was marginally above the BP. 2008 specification of 95% to 105%.

This study has shown that substandard anti Tuberculosis drugs are present in Lusaka district. The results have shown that 1/5 of the samples for 4FDC were none compliant for Isoniazid to the BP 2008 specifications for percentage content and 1 in 7 the samples for 2FDC were none compliant to the BP 2008 specifications for percentage content for Isoniazid.

DEDICATION

This research is dedicated to my wife Mwamba for her unwavering support and encouragement, my brothers Phaniel, Will, Hidings, Norwell, Cowell, G and my sisters Grace and Phyllis for believing in me.

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ABBREVIATIONS

1. **ADRs** - Adverse drug reactions
2. **AIDS** - Acquired Immune Deficiency Syndrome
3. **BHCP** - Basic health care package
4. **CDC** - Centre for Infectious Diseases Control
5. **CSO** - Central Statistical Office
6. **DEC** - Drug Enforcement Commission
7. **DOTs** – Directly observed treatment short course
8. **FDC** – Fixed dose combination
9. **GMP** - Good manufacturing practices
10. **HIV** - Human Immunodeficiency Virus
11. **MDGs** - Millennium Development Goals
12. **MDR** – Multi drug resistance
13. **MOH** - Ministry of Health
14. **PHC** - Primary health care
15. **PRA** - Pharmaceutical Regulatory Authority
16. **TB** – Tuberculosis
17. **TLC** – Thin layer chromatography
18. **UNZA** - University of Zambia
19. **UNZA BREC** - University of Zambia Biomedical Research Ethics Committee.
20. **USP** - United States Pharmacopoeia
21. **UV** – Ultra violet
22. **WHO** - World Health Organization
23. **ZDHS** - Zambia Demographic and Health Survey

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OPERATIONAL DEFINITIONS

1. **Analysis** – Careful examination of something in order to understand it better or find out what it consists of.
2. **Counterfeit drug** – A drug that has been deliberately mislabeled for identification and/or source. It could be a perfect imitation containing the same active ingredients, same formulation, and identical packaging.
3. **Drug** – A medicine or a substance for making medicine.
4. **Drug Resistant TB** – Tuberculosis that is still smear positive after five months of treatment.
5. **FDC TB drug** – Rifampicin / Isoniazid / Pyrazinamide / Ethambutol (4FDC), Rifampicin / Isoniazid / Pyrazinamide (3FDC) and Rifampicin / Isoniazid (Rifinah) tablets
6. **Official monographs** – Pharmaceutical Standard Reference books such as the British Pharmacopoeia and the United States Pharmacopoeia.
7. **Quality** – The combination of attributes or characteristics of a product that determine the degree of acceptability and efficacy of the product.
8. **Spectrophotometry** – A method of drug analysis involving absorbance using ultraviolet light.
9. **Substandard drug** – A drug with genuine packaging but with incorrect quantity of ingredients or different or absence of active ingredient as stated on the label.
10. **Thin Layer Chromatography** – A method used to analyze drugs in the laboratory
11. **Tuberculosis** – A bacterial infectious disease caused by mycobacterium Tuberculae