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QUALITY CONTROL OF SOME BRANDS OF CHLOROQUINE TABLETS AVAILABLE IN NIGERIA

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Abstract
The aim of this study is to examine the quality of twenty brands of chloroquine tablets available in Nigeria. The identification, assay and *in vitro* studies of twenty (A-T) commercial brands of chloroquine tablets readily available in Nigeria were examined using official methods. All the brands passed the uniformity of weight test and the chemical identification tests. Their infra red (IR) spectra patterns were similar to that of reference sample. Brands F and H did not give any melting point. Only brand K failed the hardness test; 8 brands each out of twenty failed the friability and the assay test. The result of brands E and K did not comply with the specification for disintegration of tablet in the monograph. The dissolution test results for all the brands except F and H were in conformity with the specification in British Pharmacopoeia (BP). Only five brands out of twenty brands examined passed all the tests that were carried out. The results therefore indicated that most brands of Chloroquine tablets in the market are not of good quality.

Keywords: *Quality control*; *chloroquine*; *malaria*

INTRODUCTION

Malaria remains one of the commonest tropical disease (O'neil *et al.,* 1985) and efforts at its eradication have failed and the extent of *Plasmodium falciparum* resistant strains to standard antimalaria drugs is at an alarming rate (Iwalewa *et al.,*1990). Chloroquine, an antimalaria drug, is used for both the treatment and prophylaxis of malaria and has a low therapeutic index. In Nigeria market, there are different brands available under various trade names by different manufacturers. Due to the variation in the manufacturing processes, different brands of the same drug may not contain the same amount of active ingredient and their release rate may also not be adequate. The overall effect is that a patient changing from one brand to another may not obtain the desired effect at the required time.

Thus, the value of chloroquine lower than the official books specifications may result in reduced drug delivery to the patient and possible therapeutic failure and resistance. The bulk of the needed drugs in West African Sub-region are imported. Since the economy is bad, there are faking, profiteering and adulteration in drug trade (Essien, 1988). The quality of antimalarials in African countries especially chloroquine is not good enough, the amount of active substance is often too low (Haak, 2003). Counterfeiting of pharmaceutical is a global problem (Akunyili, 2004). These observations coupled with the increasing prevalence of chloroquine resistant malaria in Nigeria point to the need for strict routine quality control of all drugs in our

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environment. This work is designed to examine the quality of twenty brands of chloroquine using official methods.

MATERIAL AND METHODS

Material

Drugs

Twenty commercial brands of 200 mg tablets used in this study were purchased from local pharmacy shops in Zaria, Nigeria. Their relevant information are shown in table 1.

Reagents

All reagents and chemicals were obtained from the Department of Pharmaceutical and medicinal chemistry. Zaria. Nigeria.

Methods

Uniformity of weight test, identification, friability, hardness, disintegration, assay and dissolution test were carried out by employing the official methods in British Pharmacopoeia (1998) and European Pharmacopoeia (1998).

RESULTS AND DISCUSSION

All the brands studied compiled with the requirement for uniformity of weight test (Fig. 1). Their IR spectra patterns were similar to that of the reference sample.

Brands F and H did not melt Table 2, brands F and H failed the assay and dissolution test (Figs 2 and 3). Only brand K failed hardness test (Fig. 4), it also failed the assay (Fig. 2) and disintegration tests (Fig. 5) Results of friability test are shown in Fig. 6. 8 brands out of 20 failed the test. 5 brands failed the assay test (Fig. 2), and 5 brands complied with the official requirement of all the tests conducted.

There are differences as well as similarities in the results of various test conducted on the various brands of chloroquine tablets. For example brands F and H which did not melt also failed the dissolution test. These brands together with brands A, C, D, E, H, J, L, M, R and S also failed either friability or the assay test. The active ingredient used to formulate these brands is probably not of suitable purity or the mixing operation was inefficient. Brand E and K failed disintegration test but brand K failed the hardness test too. Increase in hardness of tablets may result in an increase in the disintegration time (Kitazawa *et al.,* 1977). The type and amount of disintegrant employed may also affect the disintegrating time.

Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities after administration in the same dose are similar (Birkett, 2003). The results of brands B, M, P, Q, and T however established the superiority of these brands over other brands. Although chemical equivalence may not necessarily infer bioequivalence. This investigation shows the need for stringent quality control of all drugs meant for use in our environment (Bakare *et al.,* 1988). Bioequivalence of generic drugs enables the pharmacist without reference back to the prescriber, to dispense a different brand of the drug. It also gives the assurance that the generic substitution will not impair safety and efficacy of treatment.

Table 1: Relevant information on the brands of chloroquine analyzed

BRAND CODE	COUNTRY OF ORIGIN	BATCH NO	MANUFACTURING DATE	EXPIRY DATE
A	Nigeria	3155B	09/2001	09/2004
B	England	010404	07/2001	07/2004
C	Nigeria	990803	08/2000	08/2004
D	Nigeria	CNA028	06/2000	06/2004
E	Nigeria	JH122023	08/2001	08/2005
F	India	000301	07/2000	07/2004
G	Nigeria	BOD2P	09/2000	09/2004
H	London	CQ48	09/1999	09/2008
I	Nigeria	IN464	05/2001	05/2005
J	Nigeria	9908D3	09/2000	09/2004
K	Nigeria	9920	11/2001	11/2005
L	Nigeria	LT08	10/2001	09/2005
M	England	ET1107	01/2001	09/2005
N	England	0017AGR	03/2001	02/2005
O	Germany	MO.00	11/2001	10/2005
P	England	2001100	10/2001	10/2005
Q	England	010403	10/2001	10/2004
R	Nigeria	LE00149	01/2001	01/2005
S	Nigeria	085	07/2001	07/2005
T	Nigeria	10020	07/2001	07/2006
Reference	Nigeria	Not Applicable	08/2001	08/2006

The drugs were not expired at the time of analysis

Table 2: Melting Point of Chloroquine Tablets

Brand code	Melting point range (^{0}C)	Remark
A	203-205	Pass
B	203-205	Pass
C	205-208	Pass
D	204-209	Pass
E	204-209	Pass
F	-	Fail
G	204-206	Pass
H	-	Fail
I	204-206	Pass
J	204-206	Pass
K	205-207	Pass
L	204-206	Pass
M	204-206	Pass
N	204-206	Pass
O	205-207	Pass
P	206-208	Pass
Q	207-209	Pass
R	204-206	Pass
S	203-205	Pass
T	202 204	Pass

KEY
P=Pass
F=Fail

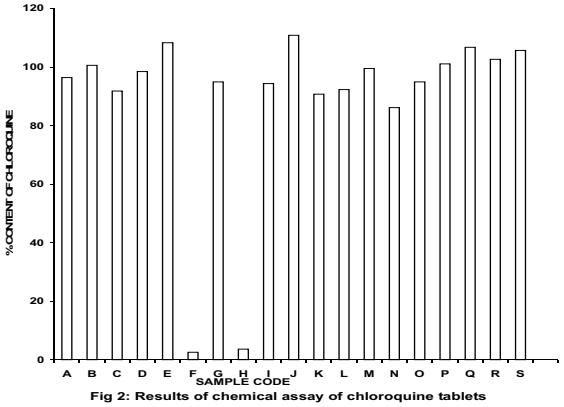

Fig 2: Results of chemical assay of chloroquine tablets

Specification:92.50-107.50% of stated amount (B.P 1998)

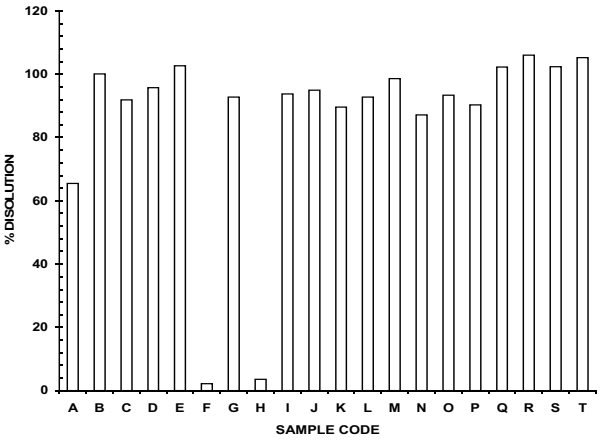

Fig 3: Results of dissolution test of chloroquine tablets

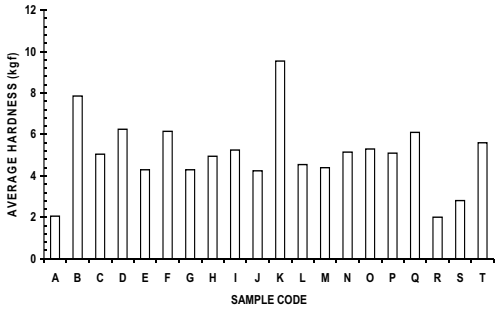

Fig 4: Results of hardness test of chloroquine tablets

Specification: Resistant to crushing of tablets is between 2-7.9kgf (BP.1998)

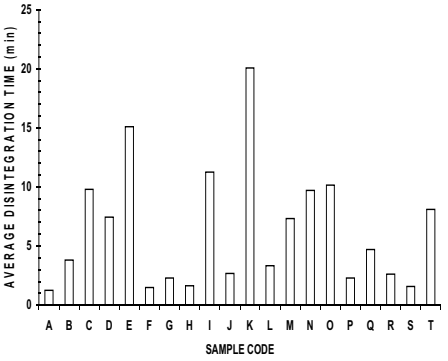

Fig. 5: Results of disiintegration tests

BP.Specification: Uncoated tablet should disintegrate within 15min.

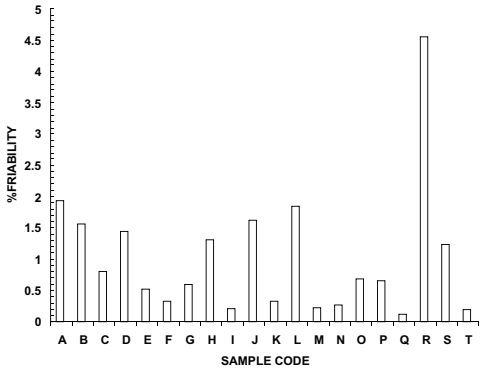

Fig. 6: Results of friability tests of chloroquine tablets

Specification: A maximum loss of 1% of the mass of tablet tested is considered acceptable (BP. 1998).

Conclusion

Out of the twenty brands of Chloroquine brands tablets examined. Only five brands complied with all the tests conducted. The results of this study support the earlier observation that the quality of antimalarials in African countries especially chloroquine is not good enough (Haak, 2003).

References

Akunyili D. (2004): What are Fake/counterfeit drugs? Pharmnews 26, p.43.

Bakare M.T. , Mustapha A. and Abdu-Aguye I. (1988): Comparative study of the contents of some commercial brands of paracetamol syrup in Nigeria. *Nig. J. Pharm.* 5: 166 and 175.

Birkett D.J. (2003): Generic-equal or not? Australian prescriber. 26:85-87.

British Pharmacopoeia(1998): University Press. Cambridge Vol. I and II. : 828

Essien E.E., (1988): Drug regulation and control in West African sub region. *Pharm. World J.* 5, 7.

European Pharmacopoeia methods (1998): Vol. II Appendix XVII G and H. University Press. Cambrige. :

Haak H, (2003): The quality of antimalarials : A study in selected African countries. In : essential drug monitor. W.H.O 33, 32.

Iwalewa E O. , Lege-Oguntoye L. , Rai P.P., Iyaniwura T.T. , and Etkin N.L. (1990): *In-vitro* antimalarial activity of leaf extracts of Cassia *occidentialis* and *Guira Senegalensis* in *Plasmodium Yolelii* Migeriensis. *W. Afr. J. Pharmacol. Drug. Res.* 4, 19-21

Kitazawa S. , Johno I.G., Minouchi T. and Okada J. (1977): Interpretation of dissolution rate data from in-vitro testing of compressed tablets. *J. Pharm. Pharmacol.* 29:453-459.

O'Neil M. J. , Bray D.H., Boardman P. , Phillipson J.D. and Warhurst D.C. (1985): Plants as sources of the evaluation of crude extract from plants. *Plants Medica* . 61, 394-397.