http://dx.doi.org/10.4314/jpb.v9i2.3
Vol. 9 no. 2, pp. 67-74 (September 2012)
http://ajol.info/index.php/jpb

Journal of
PHARMACY AND BIORESOURCES

Quality assessment of ten brands of loperamide hydrochloride marketed in Maiduguri Metropolitan Council (MMC)

Ali A. Sani[1*], Taiwo E. Alemika[2], Sholy Zakama[3], Pamela I. Dike[1], Musa A. Sani[4], Rafat O. Abdulraheem[5], Sikirat A. Sani[6], Ramat B. Abdulraheem[6] and Mohammed Ilyas[7]

[1]Department of Pharmaceutical Chemistry, Faculty of Pharmacy University of Maiduguri, Maiduguri. Nigeria.
[2]Department of Pharmaceutical Chemistry, Faculty of Pharmaceutical Sciences, University of Jos, Jos. Nigeria.
[3]Department of Ethnopharmacy & Drug Development, Faculty of Pharmacy, University of Maiduguri, Nigeria.
[4]Department of Haematology, University of Ilorin Teaching Hospital, Ilorin. Nigeria.
[5]Department of Food Science and Technology, University of Maiduguri, Maiduguri. Nigeria.
[6]Department of Chemistry, Federal Polytechnic, Damaturu. Yobe State. Nigeria.
[7]Department of Pharmaceutical and Medicinal Chemistry, Ahmadu Bello University, Zaria. Nigeria.

Received 5th June 2012; Accepted 10th August 2012

Abstract
The experiment involves analysis of ten (10) samples of loperamide hydrochloride capsules using HPLC and UV spectrophotometry. The samples were dissolved in dilute hydrochloric acid and acetonitrile; absorbance and wavelength determined and compared with that of the standard. Wavelength of the maximum absorbance in the range of 226nm-260nm was used. From the result obtained in the UV Spectrophotometry, sample A (Diarrachur), sample C (Chibueze) sample D (Zukcure), sample G (AGS) all passed the stated standard required because they had percentage content in the range of 95-105%. Samples that failed included Sample B (Darriatus), Sample E (Diatex), Sample F (Diarecure), Sample H (Seloped), Sample I (Himadium) and Sample J (Imodium) because they gave values either above or below the acceptable range of 95-105%. Percentage content for each sample was determined using their various peak areas to calculate the actual content.

Keywords: Loperamide hydrochloride, HPLC, UV Spectroscopy

INTRODUCTION

Loperamide was discovered by Janssen pharmaceutical in 1969. It is an extremely effective drug against diarrhea resulting from gastroenteritis and inflammatory bowel disease as well as acute non specific diarrhea (Butler, 2008; Vandenbossche *et al*., 2010). Loperamide is available over the counter with the most famous preparation being Imodium AD_1 now a common household name. There is some evidence that the drug may also be beneficial to withdrawing opiod addicts for relief from some opiate withdrawal symptoms. (http://www.thatspoppycock.com/opiates/loperamide/).

When loperamide was first introduced in the United States, it was classified as a Schedule V substance due to the presence of a physical withdrawal syndrome. The physical withdrawal syndrome was observed in patients at the end of a long-term clinical study which used very high doses of

* Corresponding author. *E-mail address*: aliaudusani@gmail.com Tel: +234 (0) 8035890984, 8055297698
ISSN 0189-8442

Loperamide, however, Loperamide was quickly unscheduled and made available as an over the counter drug due to the very, very low abuse potential. (http://www.thatspoppycock.com/opiates/loperamide/).

EXPERIMENTAL

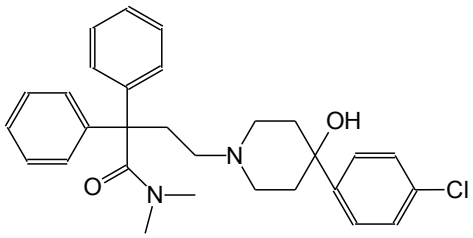
Ten (10) samples of loperamide hydrochloride 2mg were obtained from various pharmaceutical chemist shops situated within Maiduguri Metropolitan Council. The samples were obtained along with their packs containing their batch number, manufacturing date, expiry date and NAFDAC registration numbers (Sani *et al*., 2012a).

The methods employed for the purpose of this study are the UV-visible spectrophotometry and high performance liquid chromatographic method (Savić *et al*., 2009; Sani *et al*., 2012b).

RESULTS

Detailed information on the various samples used is presented in Table 1. The chromatograms and accompanying UV data print-out in respect of the HPLC and UV analyses are also shown below. The % content and actual amount of drug found are summarized in Tables 2 (for UV method) and 3 (for HPLC method).

Chemical data of Loperamide



4-[4-(4-chlorophenyl)-4-hydroxypiperidin-1-yl]-*N*,*N*-dimethyl-2,2-diphenylbutanamide

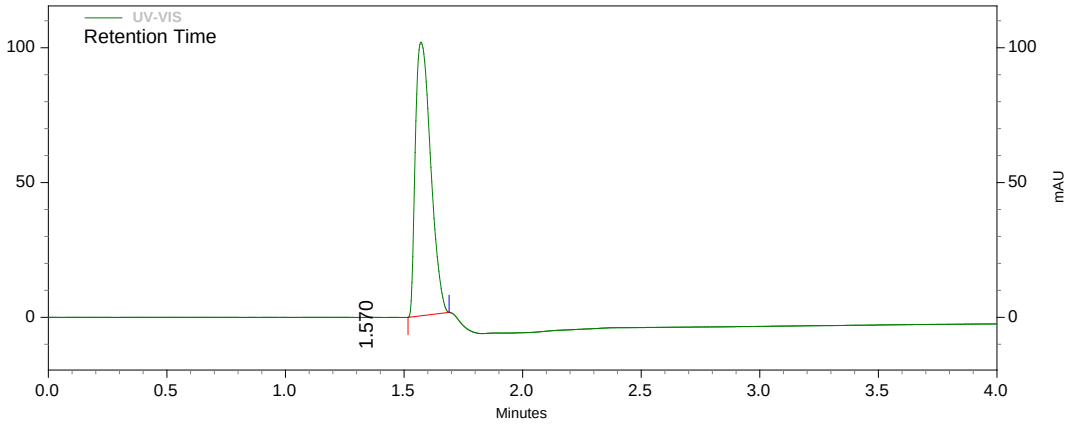
Pharmacokinetic data: Bioavailability - Not significantly absorbed from the gut; Protein binding = 97%; Metabolism – hepatic; Half-life = 9.1-14.4h (average 10.8h) (http://en.wikipedia.org/wiki/Loperamide)

Table 1: Information on the various samples

Sample code	Brand	Batch No.	Manufacture Date	Expiration Date	NAFDAC Reg. No.	Labeled
A	Diarrachur	100862	08/2010	07/2012	A4-1230	2mg
B	Darriatus	DC-40	07/10	01/2013	G-1267	
C	Chibueze	K803	Oct. 2008	Sept. 2012	04-8552	2mg
D	Zukcure	P200403	04/2010	03/2014	A4-0686	2mg
E	Diatex	M-905	Dec. 2009	Nov. 2013	04-9158	2mg
F	Diarecure	A-287	07/2011	06/2014	DD-541	2mg
G	AGS	20AE11CO2	06/2011	05/2014	A4-5446	2mg
H	Seloped	M00601	June 2010	May 2013	A4-4956	2mg
I	Himodium	HD/01	2/2011	01/2014	A4-4768	2mg
J	Imodium	8648	Sept. 2010	Aug. 2015	006159	2mg

Figure 1: Sample Chromatograms and UV Data Print-Out

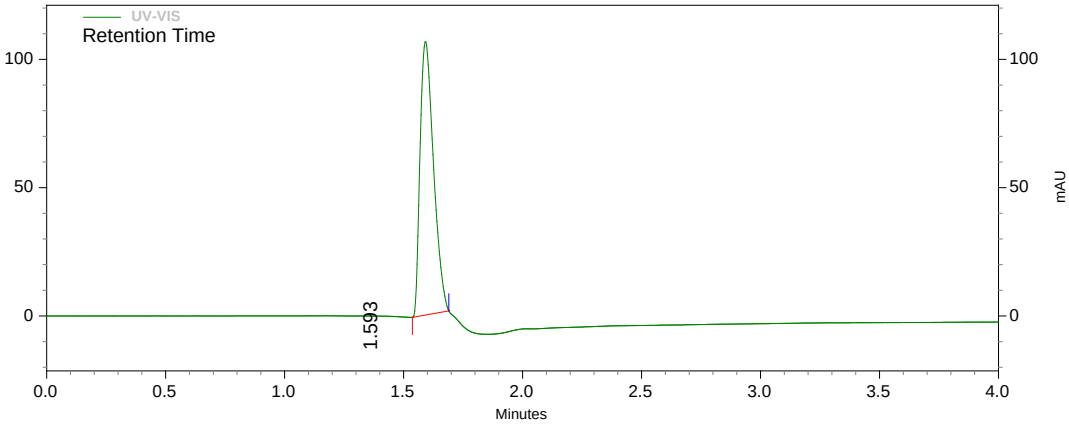
Sample ID: DIARRAHCUR 0.02 281211 Vial: 200 Injection Volume: 20



UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.570	1820393	100.000	MM
Totals		1820393	100.000	

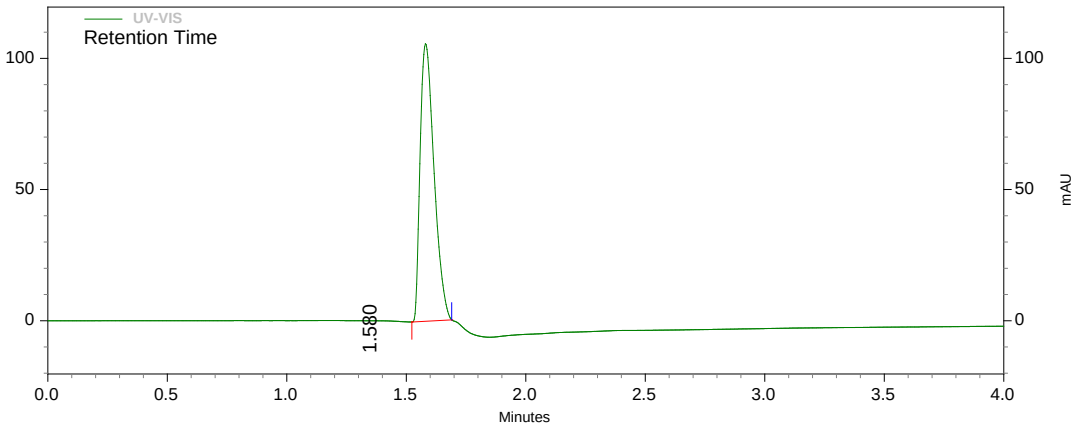
Sample ID: DARRIATUS 0.02 281211 Vial: 200 Injection Volume: 20



UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.593	1676401	100.000	MM
Totals		1676401	100.000	

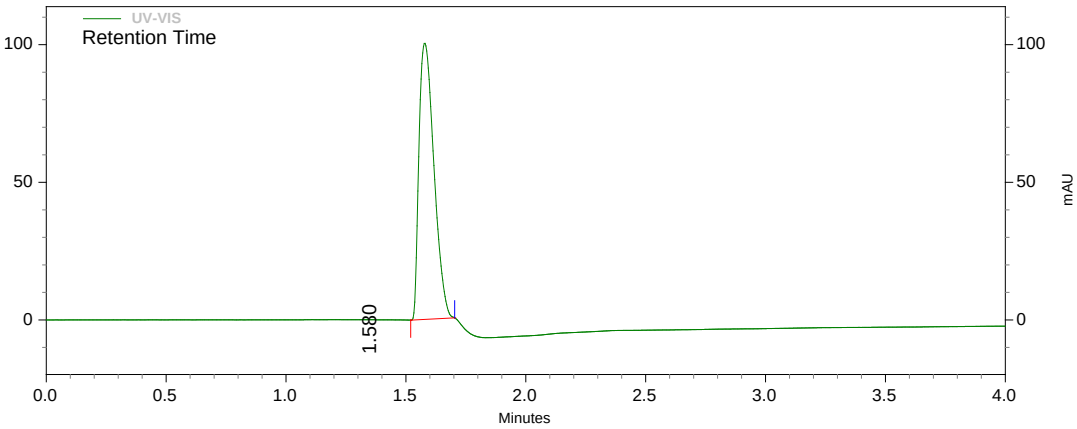
Sample ID: ZUKCURE0.02 281211 Vial: 200 Injection Volume: 20



UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.580	1713935	100.000	MM
VIT A				
VIT E				
Totals		1713935	100.000	

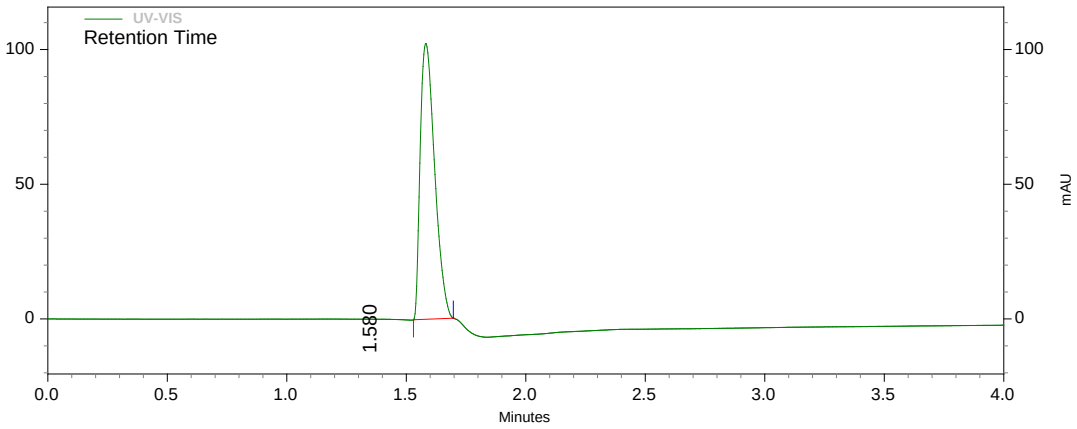
Sample ID: DIATEX 0.02 281211 Vial: 200 Injection Volume: 20



UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.580	1745798	100.000	MM
Totals		1745798	100.000	

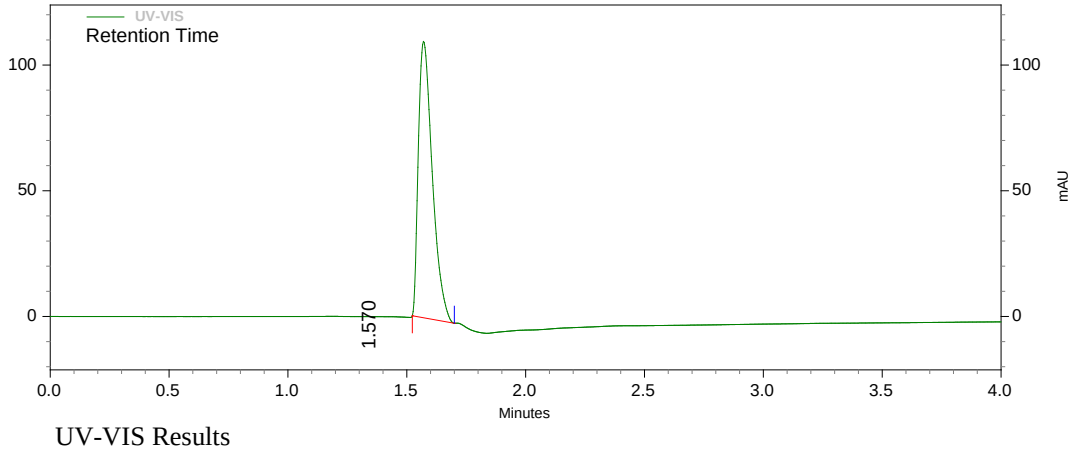
Sample ID: DIARECURE0.02 281211 Vial: 200 Injection Volume: 20



UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.580	1722631	100.000	MM
VIT A				
VIT E				
Totals		1722631	100.000	

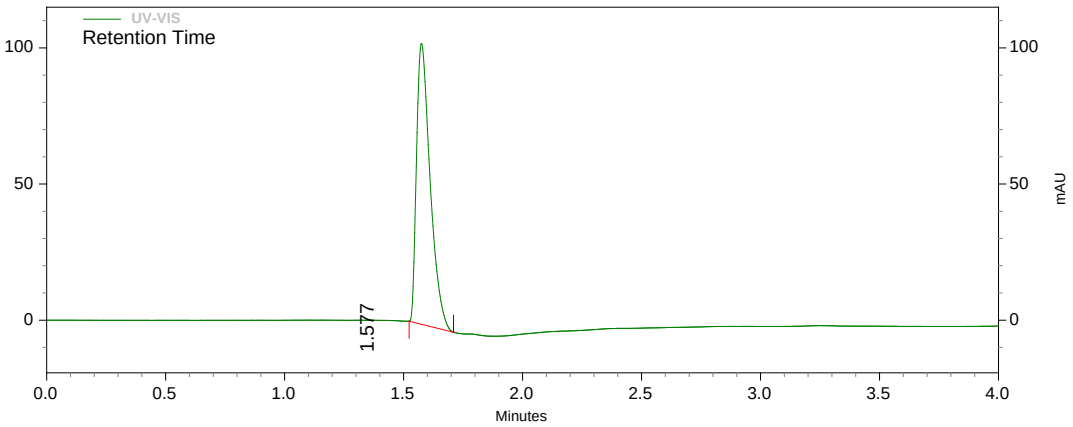
Sample ID: HIMADIUM 0.02 281211 Vial: 200 Injection Volume: 20



UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.570	1794714	100.000	MM
VIT A				
VIT E				
Totals		1794714	100.000	

Sample ID: IMODIUM 0.02 281211 Vial: 200 Injection Volume: 20

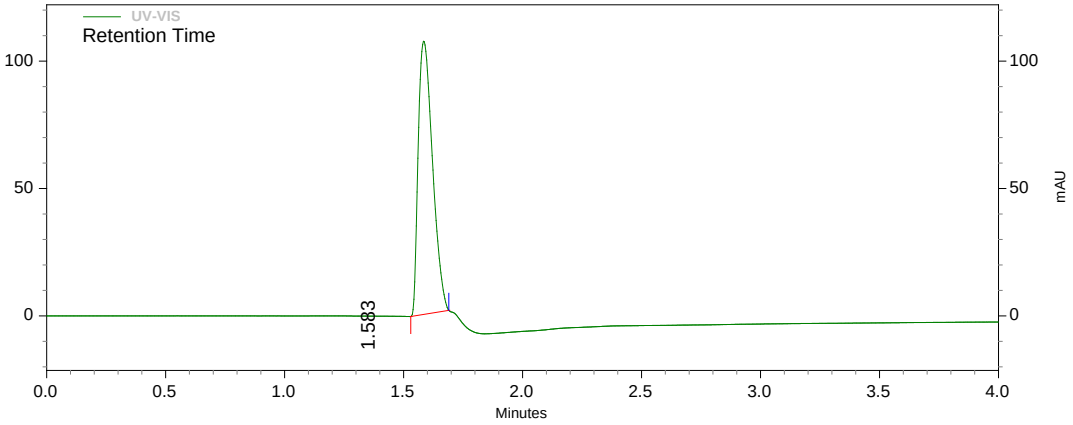


UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.577	1641283	100.000	MM

Totals		1641283	100.000	

Sample ID: LOPERAMIDE STD 0.02 281211 Vial: 200 Injection Volume: 20



UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.583	1794221	100.000	MM
VIT A				
VIT E				

Totals		1794221	100.000	

Table 2 Percentage Content (%) (UV) and Drug Content UV (mg)

Samples	Percentages Content	Drug Content (mg)
A (Diarrachur)	97.5	2.0
B (Darriatus)	140	2.8
C (Chibueze)	100	2.0
D (Zukcure)	102	2.05
E (Diatex)	132.5	2.6
F (Diarecure)	85	1.7
G (AGS)	105	2.1
H (Seloped)	137.5	2.8
I (Himadium)	115	2.3
J (Imodium)	120	2.4

Table 3 Percentage content (HPLC %) and Drug Content (mg)

Samples	Percentage content	Drug Content (mg)
A (Diarrachur)	101.5	2.0
B (Darriatus)	93.4	1.9
C (Chibueze)	99.9	2.0
D (Zukcure)	95.5	1.9
E (Diatex)	97.3	1.9
F (Diarecure)	96	1.9
G (AGS)	98	2.0
H (Seloped)	100	2.0
I (Himadium)	100	2.0
J (Imodium)	91	1.8

DISCUSSION

From the results obtained in the UV-Spectrophotometry, some of the samples such as sample A (Diarrachur), sample C (Chibueze) sample D (Zukcure), sample G (AGS) all passed the stated standard required because they fell in the range of 95-105% (BP, 2008). Some other samples that failed included sample B (Darriatus), sample E (Diatex), Sample F (Diarecure), Sample H (Seloped), Sample I (Himadium) and sample J (Imodium). They gave values either above or below the stated standard and did not fall within the range of 95-105%.

The results of the high performance liquid chromatography were identified by the use of adequate standard at retention time of 1.583min. From the percentage content of HPLC, sample B (Darriatus) and sample J (Imodium) failed the test because they had values below the range (BP, 2008). Their results had wide margin of passes and the drug content in milligram was close to manufacturer's claims.

With the results obtained in the UV Spectrophotometry and HPLC, it was observed that HPLC gave more accurate results, also indicating that the contents of the loperamide hydrochloride capsules as claimed by the manufacturers was valid.

CONCLUSION

From the quantitative analysis made, it can be concluded that; out of the ten (10) samples of loperamide hydrochloride subjected to qualitative analysis only four (4) fell within the acceptable range. The remaining six (6) samples were below or above the acceptable range of 95-105% $^{w}/_{w}$ of the stated drug content (2mg). This can result in increased drug resistance and could be complicated by patient non-compliance.

In the samples which were analyzed using HPLC method, only two (2) failed the test - sample B (93.4%) sample J (91%) while eight (8) of the samples passed the test. They fall within the acceptable range of (95-105%).

So it would be concluded that of the ten (10) samples of loperamide hydrochloride selected at a random from ten (10) different reputable and reliable pharmacies in Maiduguri used for the quality assessment, only four (4) samples based on the test when analyzed using an automated ultraviolet spectrophotometer passed the test, falling within acceptable range (95-105%) with an actual content of 2 mg. For the HPLC eight (8) samples passed the test giving the actual content of (1.9-2mg). Those that failed the test are said to be substandard.

REFERENCES

British Pharmacopoeia (2008). Her Majesty's Stationery Office, UK.

Butler TC (2008). "Loperamide for the treatment of traveler diarrhea: broad or narrow usefulness? *Clinical infectious diseases* 47(8):1015-6 dio10. 1056/591704.

Sani AA, Alemika ET, Khalil OS, Abdulraheem RO, Abdulkareem SS, Sani M, Abdulraheem RB and Ilyas M (2012a). Quantitative Analysis Of Ten (10) Different Brands of Chlorpheniramine Tablet Marketed In Maiduguri Metropolitan Council (MMC). *Journal of Chemical and Pharmaceutical Research* 4(7): 3637-3650

Sani AA, Alemika ET, Bala FM, Sani M and Ramat B (2012b), Analysis of Different Brands Of Paracetamol 500mg Tablets Used In Maiduguri, Using Ultra Violet Spectrophotometric and High Performance Liquid Chromatographic (HPLC) Methods, *International Research Journal of Pharmacy;*3(8) , 165-167

Savić IM., Nikolić GS., Marinković VD. (2009) Quantitative analysis of Loperamide hydrochloride in the presence its acid degradation products *Hemijska Industrija* 63(1), 39-46

Vandenbossche J, Huisman M, Xu Y, Sanderson-Bongiovanni D, Soons P. (2010). Loperamide and P-glycoprotein inhibition: assessment of the clinical relevance. *J. Pharm. Pharmacol.* 62(4):401-12.