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Comparative analysis of different brands of prednisolone tablets using spectrophotometric and high performance liquid chromatographic methods

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Abstract
The experiment involves analysis of nine brands of prednisolone, using ultra violet spectrophotometer in the range of (200-400nm) and high performance liquid chromatography (HPLC) in which the samples were dissolved in various solvents and their various absorbance, peak area at various wavelength were determined and compared with that of the standard, wavelength of maximum absorbance at 240nm was used for prednisolone. Percentage and milligram content for each sample was determined so as to note if it was within the acceptable range of (90.0-110.0%) for prednisolone. For those that passed the test or if it was below or above the range for samples that are substandard or highly concentrated. The samples' absorbance and peak area was used along side with the standard absorbance and peak area to calculate the percentage content of each sample. It was observed that of the nine samples of prednisolone tablet, Healthyhour with percentage content of 97.82%, Predlin 97.82%, Perilone 104.02%, Prednicortex 100.77%, QP prednisolone 96.68%, Predilab 106.26%, Osypred 98.27% and GHCL prednisolone 98.50% passed the test but only Perilone with 96.6% passed using HPLC

Keywords: Prednisolone, UV, HPLC

INTRODUCTION

The quality of pharmaceuticals is a global concern and the lack of reliable drug quality assurance systems in many developing countries often contribute to the devastating diseases, particularly those that have build up resistance to traditional first line medicines. USP DQI presently is working in four countries; Africa, Asia, Europe, and South America to facilitate and strengthen their drug quality systems to improve public health. (http;//www.org/orgazindex.html). On the other hand, the selection of one drug product from several generic drugs that have the same active ingredient has been a concern to healthcare practitioners. (Adebolagun *et al.*, 2007).

Prednisolone is a synthetic glucocorticoid, a derivative of cortisol, which is used to treat a variety of inflammatory and auto-immune conditions. It is the active metabolite of the drug prednisone and is used

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especially in patients with hepatic failure, as these individuals are unable to metabolise prednisone into prednisolone (Davis *et al.*, 1978).

Prolonged prednisolone treatment for the initial episode of childhood nephrotic syndrome may reduce relapse rate, but whether this results from the increased duration of treatment or a higher cumulative dose remains unclear. Frequent relapses, according to international criteria, occurred with similar frequency between groups as well (45% versus 50%). In addition, there were no statistically significant differences between groups with respect to the eventual initiation of prednisolone maintenance and/or other immunosuppressive therapy (50% versus 59%), steroid dependence, or adverse effects. In this trial, extending initial prednisolone treatment from 3 to 6 months without increasing cumulative dose did not benefit clinical outcome in children with nephrotic syndrome. Previous findings indicating that prolonged treatment regimens reduce relapses most likely resulted from increased cumulative dose rather than the treatment duration (Nynke Teeninga *et al.*, 2013).

Prednisolone is a corticosteroid drug with predominant glucocorticoid and low mineralocorticoid activity, making it useful for the treatment of a wide range of inflammatory and auto-immune conditions (Czock *et al.*, 2005) such as asthma, uveitis, pyoderma gangrenosum, rheumatoid arthritis, ulcerative colitis, pericarditis, temporal arteritis and Crohn's disease, Bell's palsy, multiple sclerosis (Thrower BW,2009), cluster headaches, vasculitis, acute lymphoblastic leukemia and autoimmune hepatitis,[5] systemic lupus erythematosus, Kawasaki disease (Miura *et al.*, 2011).

EXPERIMENTAL

Different brands of prednisolone were used for the study. Pure sample of the drugs were obtained from NAFDAC which served as standard. The methods employed for the purpose of this study are the UV visible spectrophotometric and high performance liquid chromatographic methods (BP 2008). The tablets were assayed spectrophotometrically using the following procedures (Sani *et al*., 2012). The % content and mg content was determined as

$$\% \text{ content} = \frac{\text{Absorbance of sample} \times 100}{\text{Absorbance of standard}}$$

$$\text{mg content} = \frac{\% \text{ content} \times \text{Manufacturer's claim}}{100}$$

HPLC procedure. 58ml of methanol was added to a quantity of powdered samples containing equivalent of 5mg of prednisolone, shaken for 10min then sufficient water was added to produce 100ml, it mixed and filtered and the same procedure was repeated for the remaining samples. The chromatographic condition was carried out using: Stainless steel column (20cm-4.6mm)packed with octadecyl-silyl silica gel for chromatography (10µ) (spherisorb ODS 1 is suitable); mixture of 42 volumes of water 58 volumes of methanol as the mobile phase with a flow rate of 1ml per minute; and detection wavelength of 254nm (Sani *et al*., 2012).

RESULTS

Tables 1 and 2 show results of UV spectrophotometric analysis which was used to calculate the percentage content and milligram content of the drugs.

HPLC analysis. The calculation below shows the result from the HPLC method of analysis.

$$\% \text{ content} = \frac{\text{Peak area of sample}}{\text{Peak area of standard}} \times 100$$

$$\text{mg content} = \frac{\% \text{ content}}{100} \times \text{Standard claim}$$

DISCUSSION

As stated by the British Pharmacopoeia, a prednisolone tablet should contain not less than 90% and not more than 110% of prednisolone. (BP 2008). The standard prednisolone tablet has an

absorbance of 189.18 at a wavelength 240nm. From the result obtained using UV visible spectrophotometer, Healthyhour with percentage content of 97.82%, Predlin 97.82%, Perilone 104.02%, Prednicortex 100.77%, QP prednisolone 96.68%, Predilab 106.26%, Osypred 98.27%, GHCL prednisolone 98.50% are said to have passed the test because as they fell within the range specified by the BP. While Pred-med with percentage content of 118.7% is said to failed because it above the limit specified by the BP.

Table 1: UV absorbance of prednisolone at a wavelength of 240 (E1%)

Sample	Absorbance (A)
Healthyhour	185.06
Predline	185.06
Perilone	196.79
Prednicotex	190.64
QP	180.89
Predilab	201.00
Osypred	185.91
GHCL Pred	186.35
Predmed	224.55

Table 2: Percentage content and milligram content of different brands of prednisolone using UV

Sample	% content	mg content
Healthyhour	97.82	4.89
Predline	97.82	4.89
Perilone	104.02	5.20
Prednicotex	100.77	5.04
QP	96.68	4.83
Predilab	106.26	5.31
Osypred	98.27	4.91
GHCL Pred	98.50	4.93
Predmed	118.7	5.93

Sample ID: QP- 200313 **Vial: 190** **Injection Volume: 20**

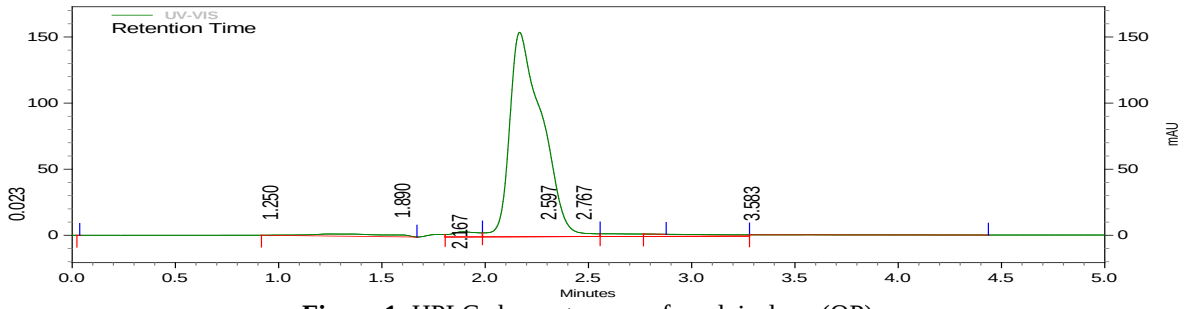

Figure 1: HPLC chromatogram of prednisolone (QP)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	0.023	18	0.000	BB
	1.250	185307	2.521	MM
	1.890	135100	1.838	BV
	2.167	6764638	92.020	VV
	2.597	257578	3.504	VB
	2.767	273	0.004	MM
	3.583	8361	0.114	MM
Totals		7351275	100.000	

Sample ID: GHCLPRED- 200313 **Vial: 180** **Injection Volume: 20**

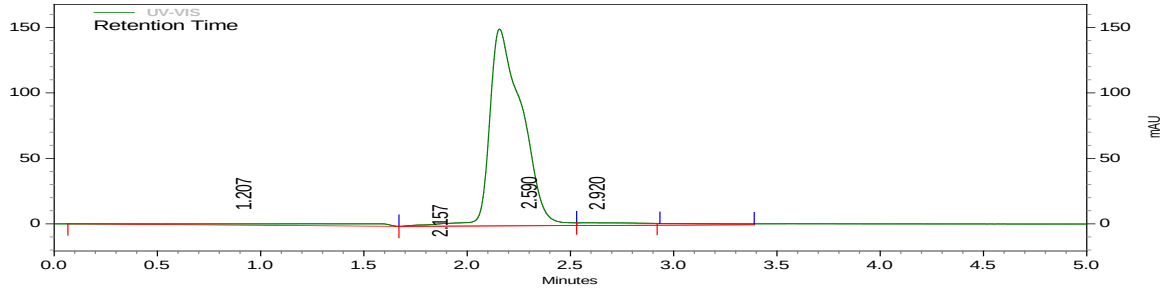

Figure 2: HPLC chromatogram of prednisolone (GHCL PRED)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.207	339264	4.721	MM
	2.157	6564943	91.348	BV
	2.590	282538	3.931	VB
	2.920	0	0.000	MM
Totals		7186745	100.000	

Sample ID: HEALTHYHOUR 200313 **Vial: 197** **Injection Volume: 20**

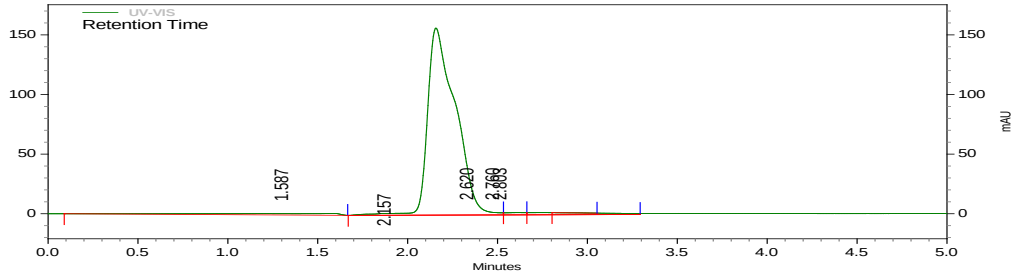

Figure 3: HPLC chromatogram of prednisolone (Healthyhour)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.587	260506	3.575	MM
	2.157	6758947	92.750	BV
	2.620	56736	0.779	VV
	2.760	208653	2.863	VB
	2.803	2436	0.033	MM
Totals		7287278	100.000	

Sample ID: OSYPRED 200313 **Vial: 190** **Injection Volume: 20**

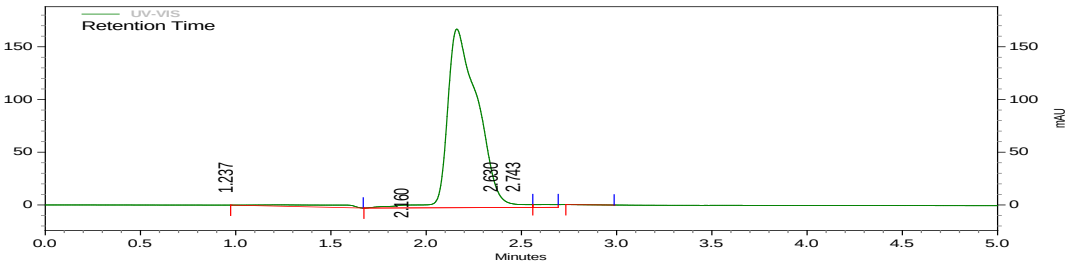

Figure 4: HPLC chromatogram of prednisolone (Osypred)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.237	217710	2.770	MM
	2.160	7558166	96.164	BV
	2.630	82491	1.050	VB
	2.743	1325	0.017	MM
Totals		7859692	100.000	

Sample ID: PERILON 200313 **Vial: 198** **Injection Volume: 20**

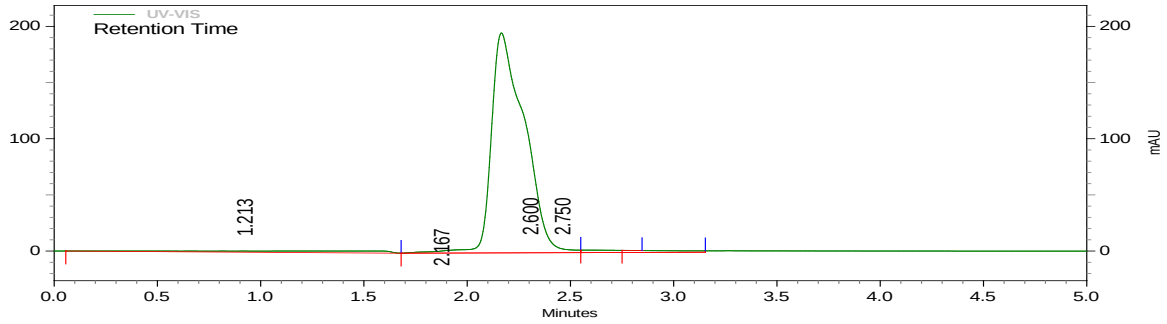

Figure 5: HPLC chromatogram of prednisolone (Perilone)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.213	344838	3.700	MM
	2.167	8729542	93.666	BV
	2.600	245274	2.632	VB
	2.750	252	0.003	MM
Totals		9319906	100.000	

Sample ID: PREDILAB 200313 **Vial: 200** **Injection Volume: 20**

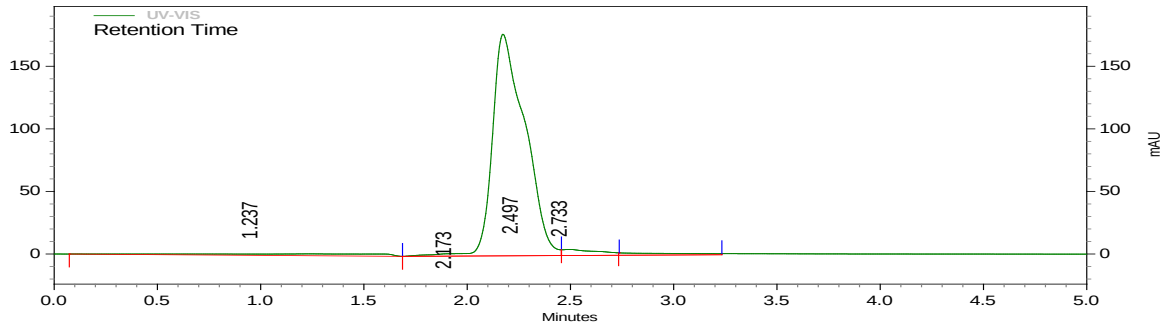

Figure 6: HPLC chromatogram of prednisolone (Predilab)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.237	334585	3.918	MM
	2.173	7826693	91.645	BV
	2.497	378905	4.437	VB
	2.733	0	0.000	MM
Totals		8540183	100.000	

Sample ID: PREDILIN 200313 **Vial: 20** **Injection Volume: 20**

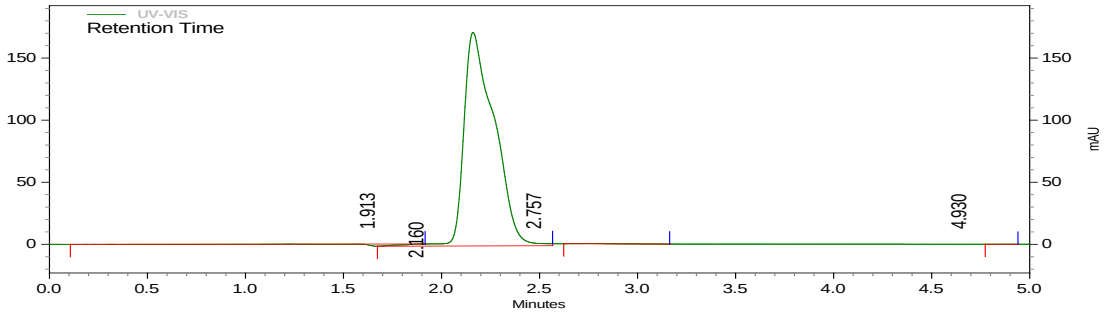

Figure 7: HPLC chromatogram of prednisolone (Predilin)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.913	95559	1.279	MM
	2.160	7368696	98.589	BB
	2.757	8511	0.114	MM
	4.930	1379	0.018	BE
Totals		7474145	100.000	

Sample ID: PREDMED 200313 **Vial: 170** **Injection Volume: 20**

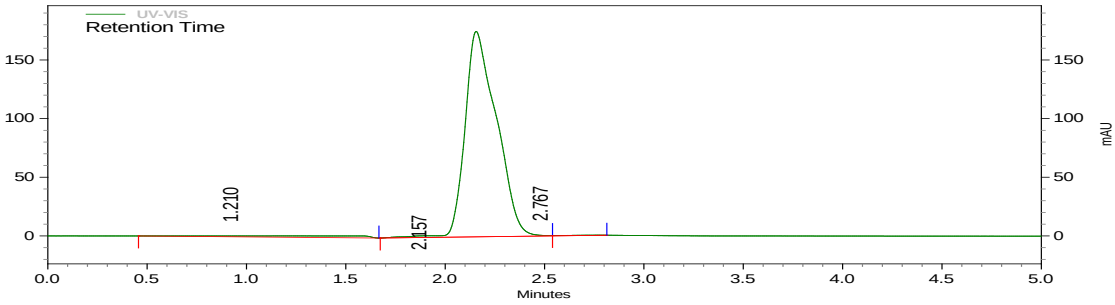

Figure 8: HPLC chromatogram of prednisolone (Predmed)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	1.210	243343	3.048	MM
	2.157	7725037	96.775	BV
	2.767	14076	0.176	VI
Totals		7982456	100.000	

Sample ID: PREDNICORTEX 200313 **Vial: 199** **Injection Volume: 20**

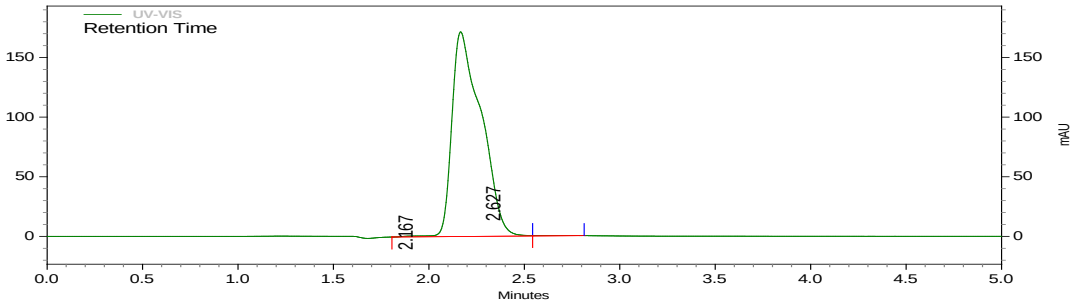

Figure 9: HPLC chromatogram of prednisolone (Prednicortex)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	2.167	7337170	99.776	BV
	2.627	16448	0.224	VI
Totals		7353618	100.000	

Sample ID: PREDNISOLNE TABLET STD 2 200313 Vial: 200 Injection Volume: 20

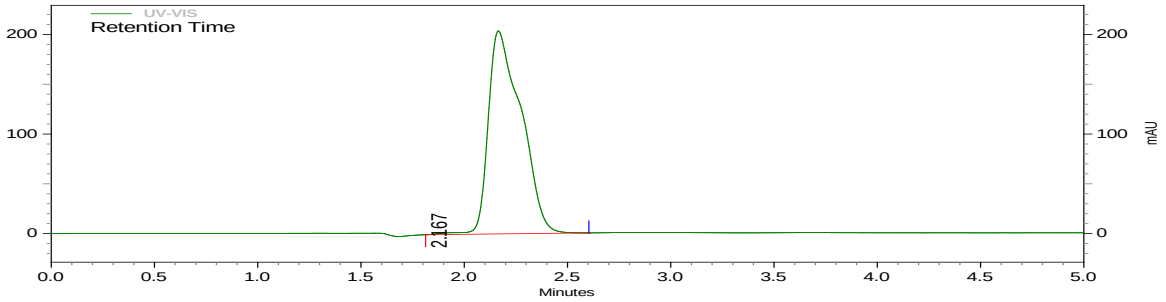

Figure 10: HPLC chromatogram of prednisolone (Std)

UV-VIS Results

Name	Retention Time	Area	Area Percent	Integration Codes
	2.167	9036235	100.000	BB
Totals		9036235	100.000	

Table 8: Percentage and milligram content of different brands of prednisolone using HPLC

Sample	% content	mg content
Healthyhour	74.8	3.7
Predline	81.6	4.1
Perilone	96.6	4.8
Prednicotex	81.2	4.1
QP	74.9	3.7
Predilab	86.6	4.3
Osypred	83.6	4.2
GHCL Pred	72.7	3.6
Predmed	85.5	4.3

For prednisolone, Perilone with percentage content of 96.6% is said to have passed the test as it fell within the set range while QP with percentage content of 74.9%, GHCL 72.7%, Healthyhour 74.8%, Osypred 83.6%, Predilab 86.6%, Predilin 81.6%, Predmed 85.5% and Prednicortex 81.2% and are said to have failed the test as they all fell below the BP specified limit.

Conclusion

Following the BP specification, it can be concluded that Perilone, Healthyhour, Predlin, Prednicotex, QP, Predlab, Osypred and GHCL contain the correct amount of the active principle using UV and are said to have passed but Predmed failed while using HPLC all the samples failed except Perilone.

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