

# Simple UV spectrophotometric assay of Clarithromycin

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## Abstract—

Clarithromycin belongs to semi-synthetic macrolide antibiotic class of drugs that inhibits bacterial protein synthesis. Our aim of study is to develop a efficient least time consuming and simple spectrophotometric method for the assay of clarithromycin. Comparison of assay of five different brands of clarithromycin (klaricid, klaribact, rithmo, clariteck, E-clark) available in public medical store of Karachi, Pakistan has also been done. The assay is based on the ultraviolet UV absorbance maxima at about 210nm wavelength of mefenamic acid, water is used as solvent. A sample of drug was dissolved in water to produce a solution containing mefenamic acid. Similarly, a sample of ground tablets of different brand were dissolved in water and various dilutions were made. The absorbance of sample preparation was measured at 210nm against the solvent blank and the assay was determined by comparing with the absorbance of available brand. Our results reveals that among all the five brands of clarithromycin (klaricid, klaribact, rithmo, clariteck, E-clark) Klaribact shows highest percentage assay i.e 115.3846%. Klaricid and Claritecl shows percentage assay of 107.693%. Rithmo shows a percent assay of 92.307% while E-clark shows lowest value for percentage assay 84.6153%

**Keywords—** clarithromycin, assay, UV spectrophotometry

## INTRODUCTION

Clarithromycin is a semi-synthetic macrolide antibiotic. It is bacterial protein synthesis inhibitor. It is better absorbed and acid-stable. It is widely used in regimens of anti-helicobacter pylori (h pylori). The sustained-release (sr) and immediate-release (ir) clarithromycin formulations available on the market. [1] It decreases activity of CYP3A4 enzyme and thus slowly inhibits of coadministered drugs and its own metabolism. Clarithromycin is a broad-spectrum antibiotic and it is widely used for the treatment of upper and lower respiratory tract and many other infections.[2] It interacts with many drugs on the level of CYP3A hepatic and intestinal metabolizing enzymes.[3] Clarithromycin is rapidly and completely absorbed from the gastrointestinal tract (GI). As clarithromycin undergoes first-pass metabolism, bioavailability of an oral dose as clarithromycin is fifty% to fifty five% in the systemic circulation. It is widely distributed throughout the body and has an apparent volume of distribution that ranges from 126 to 306 liters. Approximately 22% of an oral dose is recovered as the parent compound, 4% being recovered in the feces with 18% being recovered in the urine. The elimination half-life of clarithromycin is time and dose dependent and ranges from 2.7 to 4.8 hours. The average total body clearance ranges is found to be from 29 to 58 liters/hour and the average renal clearance ranges from 6.7 to 12.8 liters/hours in healthy subjects depending on the the number of doses and dose.[4] clarithromycin has been associated with fetal loss in animals. A study shows a doubling in the frequency of miscarriages among pregnant women using clarithromycin.[5]

Clarithromycin acts by binding to the peptidyl transferase region of 23S rRNA and inhibits bacterial protein synthesis. Clarithromycin resistance results from structural changes in the 23S rRNA molecule caused by mutation of the 23S rRNA gene. Transitions of Adenine to guanine at positions 2142 and 2143 are the main 23S rRNA mutations in clarithromycin-resistant isolates[6]. We have already done these types of assay for different drugs [7-10].

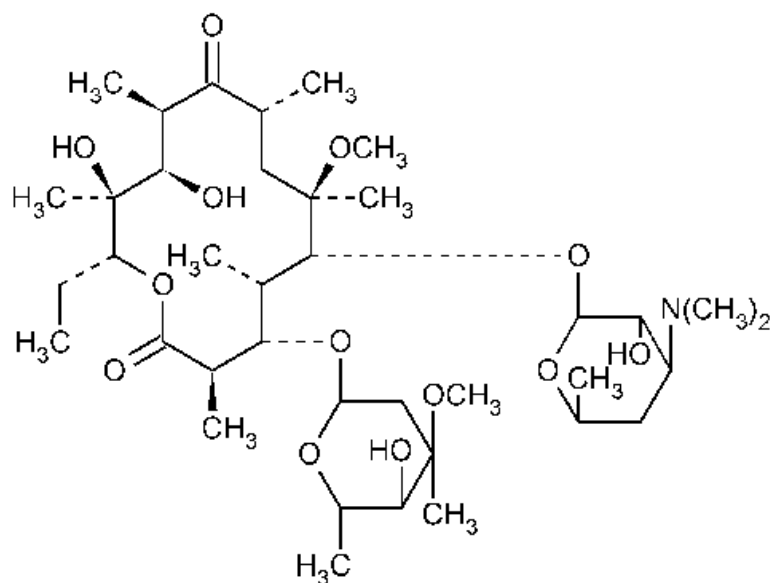


Fig-1 structure of Clarithromycin

## II. EXPERIMENTAL

UV visible 1601 Shimadzu double beam spectrophotometer was used to measurement of spectra. The solvent used for the assay was water.

### Wavelength Selection

About 100 ppm of clarithromycin solution was accurately prepared in water . This solutions were scanned in the 200-400 nm UV region. The wavelength maxima ( $\lambda_{max}$ ) was observed at 210 nm and this wavelength was adopted for absorbance measurement.

### Standard Stock solution

Accurately weighed 10 mg of clarithromycin standard was transferred to a volumetric flask and add sufficient water to produce 100 ml.

### Sample Preparation

The five different brands (klaricid, klaribact, rithmo, clariteck, E-clark) were purchased from different medical store located in Karachi, Pakistan. All tablets of each brand have same batch number and were labeled to contain clarithromycin 10mg per tablet. All the five brands have 5 year shelf life.

20 tablets of five different brands (klaricid, klaribact, rithmo, clariteck, E-clark) from the marketed sample were weighed and crushed uniformly with the help of a mortar and pestle. By calculating the average weighed sample powder equivalent to 10 mg of clarithromycin was transferred into a volumetric flask containing 10mL water. The solutions were sonicated for about 5 min and then make up volume upto 100 ml with water.

### Procedure

After preparation of standard and tablet solutions, strength of solution 100 ppm in 100 ml absorbance of the sample preparation and standard preparation in 1cm cell at the wavelength of maximum absorbance at about 210nm, using a spectrophotometer, using the blank solution. Calculate the quantity in mg, of clarithromycin per tablet.

### Result

The absorbance of sample preparation was measured at 210nm against the solvent blank and the assay was determined by comparing with the absorbance of available brand. Our results reveals that among all the five brands of clarithromycin (klaricid, klaribact, rithmo, clariteck, E-clark) Klaribact shows highest percentage assay i.e 105.3846%. Klaricid and Clariteck shows percentage assay of 105.693%. Rithmo shows a percent assay of 95.307% while E-clark shows lowest value for percentage assay 94.6153%. All the drugs have assay within the range of specified USP and BP. The deviation may be due to the handling error or instrumental error,

This method is applicable for daily routine quantification of clarithromycin.

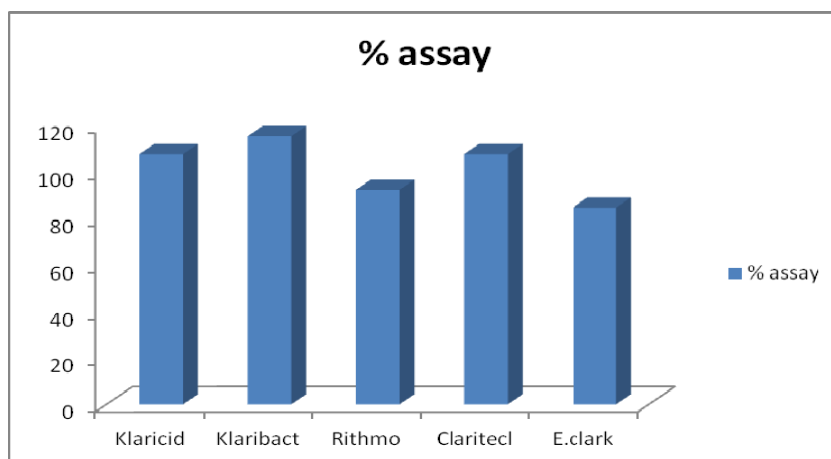


Fig-2 percent assay of different brands of Clarithromycin

Table 1:% assay of different brands of Clarithromycin

Brand Name	Average wt of tablet mg	Wt for 100 ppm	% assay
Klaricid	519	0.0207	105.6
Klaribact	541	0.0216	105.3
Rithmo	511	0.0204	95.3
Claritecl	505	0.0202	105.6
E.clark	419	0.0167	94.6

Table 2:ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	823.334	4	205.834	53.920	.000
Within Groups	76.348	20	3.817		
Total	899.682	24			

Table 3:Multiple Comparisons

(I) Brands	(J) Brands	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Klaricid	Klaribact	.30200	1.23570	.809	-2.2756	2.8796
	Rithmo	10.27800*	1.23570	.000	7.7004	12.8556
	Claritecl	.02000	1.23570	.987	-2.5576	2.5976
	E.clark	13.08000*	1.23570	.000	10.5024	15.6576
Klaribact	Klaricid	-.30200	1.23570	.809	-2.8796	2.2756
	Rithmo	9.97600*	1.23570	.000	7.3984	12.5536
	Claritecl	-.28200	1.23570	.822	-2.8596	2.2956
	E.clark	12.77800*	1.23570	.000	10.2004	15.3556
Rithmo	Klaricid	-10.27800*	1.23570	.000	-12.8556	-7.7004
	Klaribact	-9.97600*	1.23570	.000	-12.5536	-7.3984
	Claritecl	-10.25800*	1.23570	.000	-12.8356	-7.6804
	E.clark	2.80200*	1.23570	.035	.2244	5.3796
Claritecl	Klaricid	-.02000	1.23570	.987	-2.5976	2.5576
	Klaribact	.28200	1.23570	.822	-2.2956	2.8596
	Rithmo	10.25800*	1.23570	.000	7.6804	12.8356
	E.clark	13.06000*	1.23570	.000	10.4824	15.6376
E.clark	Klaricid	-13.08000*	1.23570	.000	-15.6576	-10.5024
	Klaribact	-12.77800*	1.23570	.000	-15.3556	-10.2004
	Rithmo	-2.80200*	1.23570	.035	-5.3796	-.2244
	Claritecl	-13.06000*	1.23570	.000	-15.6376	-10.4824

\*. The mean difference is significant at the 0.05 level.

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