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Research Article

Development and Validation of UV-Spectrophotometric Method for Estimation of Cilostazol in Bulk and Pharmaceutical Dosage Form

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ABSTRACT
A simple efficient, precise and accurate spectroscopic method has been developed and validated for quantitative estimation of Cilostazol in bulk and pharmaceutical dosage form. Cilostazol is soluble in ethanol and phosphate buffer 6.8 pH respectively, so it was used as solvents. The resulting solution was then scanned in the UV range (800-400nm) in a 1 cm quartz cell in a double beam UV spectrophotometer. The λmax of Cilostazol was found to be 258 nm. The method obeys Beers law in the concentration range from 2-10 µg/ml. The correlation coefficient was found to be 0.999 (r^2= 0.999). The LOD and LOQ were found to be 1.7894and 5.4224µg/ ml respectively. The result of estimation of marketed formulation (Pletal) was found to be 99.1 %. The accuracy of the method was determined by recovery studies. The percentage recovery was found to be 100.44%. The method was validated statistically as per ICH guidelines. The method showed good reproducibility and recovery with % RSD less than 2. So, the proposed method was found to be simple, specific, precise, accuracy, linear, and rugged. Hence it can be applied for routine analysis of Cilostazol in bulk drug and the Pharmaceutical formulations**.**

Keywords: Cilostazol, Validation, International Conference of harmonization (ICH), Spectrophotometrically.

INTRODUCTION

Cilostazol is a selective potent inhibitor of III-type phoshodiesterase (PDE3) with therapeutic focus on increasing cAMP. An increase in cAMP results in an increase in the active form of protein kinase A (PKA), which is directly related with an inhibition in platelet aggregation.PKA, also prevents the activation of an enzyme (myosin light-chain kinase) that is important in the contraction of smooth muscle cells, thereby exerting its vasodilatory effect. Cilostazol is a white to off-white crystalline powder, molecular weight: 369.5, Molecular Formula: $C_{20}H_{27}N_5O_2$ melting point: 159 ˚C-160.2 ˚C, Solubility: very slightly soluble in water and freely soluble in ethanol. pKa value:14.42[1-3]. The IUPAC name of Cilostazol [2-(2-amino-1,3-thiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy-2- phenylethyl] amino} ethyl) phenyl] acetamide] 6-[4-(1-Cyclohexyl-1Htetrazol-5-yl) butoxy]-3,4-dihydroquinolin-2(1H)-one[1]. It is very soluble in ethanol, phosphate buffer 6.8 pH and methanol, slightly soluble in water. Brand names available are pletal. A thorough literature search revealed that the degradation profile and RP-HPLC analysis of cilostazol in tablet dosage form has been reported[3,4,9]. UV spectrophotometric and simultaneous method has been reported for this compound in tablet form[9,10] and the best of our information, Stability Indicating HPLC and force degradation study of Cilostazol in pharmaceutical dosage forms[4,5], UV method development and validation study on Cilostazol drug and its dosage form in combine solvents ethanol and phosphate buffer 6.8 pH has not been reported so far. Mechanism of action: Cilostazol is a quinolinone derivative that inhibits cellular phosphodiesterase III, and is used for the inhibition of platelet aggregation and as a vasodilator[1-3].

MATERIALS AND METHOD:

Cilostazol was obtained as a gift sample from Amsal Chem Pvt.Ltd, (Ankleshwar, India). All other chemicals and solvents used were of pharmaceutical or analytical grade.

Instrumentation

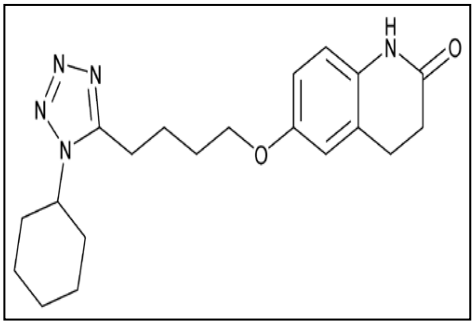

Figure 1: Chemical Structure of Cilostazol.

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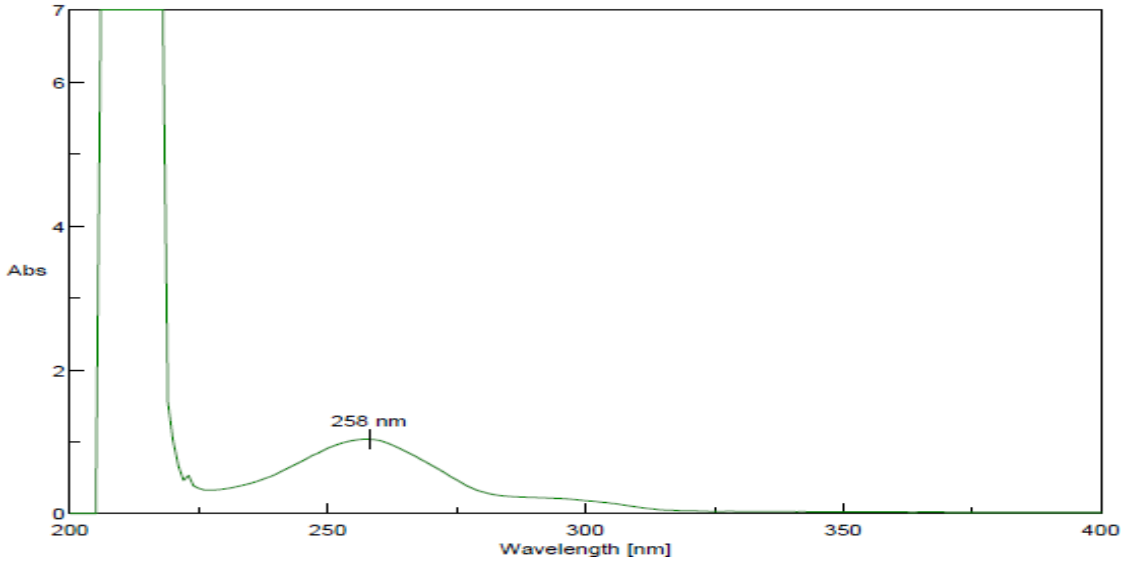

Figure 2: UV spectra of Cilostazol in ethanol and phosphate buffer 6.8 pH.

Table 1: Result of LOD and LOQ of Cilastazol by Blank Method and Calibration Curve Method.

Cal. Slope	0.135	LOD by SD of Blank	LOQ by SD of Blank	LOD by RSD of Cal. Curve	LOQ by RSD of Cal. Curve
SD Blank	0.0732	3.3*(SD Blank/Cal. Slope)	10*(SD Blank/Cal. Slope)	3.3*(RSD/Cal. Slope)	10*(RSD/Cal. Slope)
RSD	0.0502	1.7894	5.4224	1.2293	3.7252

Table 2: Linearity and range study for error (50-90%).

			10-50%			
Sr. No.	Conc.	Abs	Predicted (y')	Observed (y)	Obs.-predict (y-y')	square of error (y-y')2
1	4	0.232	0.425	0.232	-0.193	0.037249
2	5	0.367	0.531	0.367	-0.164	0.026896
3	6	0.488	0.637	0.488	-0.149	0.022201
4	7	0.573	0.743	0.573	-0.17	0.0289
5	8	0.691	0.849	0.691	-0.158	0.024964
	Sum of square error			0.14021		

Table 3: Specificity and selectivity study in the presence of excipient.

						Y=0.0424x+0.0558	
Sr. No.	Drug conc. (ppm)	Level of addition of excipients	Excipients amt in ppm	Abs.	Drug found	% Recovery	Avg.
1.	6	80%	4.8	0.469	6.008	100.14	
2.	6	80%	4.8	0.459	5.919	98.66	99.50
3.	6	80%	4.8	0.466	5.982	99.70	
4.	6	100%	6	0.458	5.910	95.87	
5.	6	100%	6	0.459	5.919	98.66	98.22
6.	6	100%	6	0.469	6.008	100.14	
7.	6	120%	7.2	0.476	6.071	101.19	
8.	6	120%	7.2	0.479	6.098	101.63	101.53
9.	6	120%	7.2	0.48	6.107	101.78	

A UV-visible spectrophotometer (Shimadzu, model 1800) with 1 cm quartz cells was used for the absorbance measurements.

Standard solution

10 mg of standard Cilostazol (API) was transferred to 10 ml flask and made up with the ethanol solution and labeled as 1000ppm of standard solution of Cilostazol and dilutions were prepared with phosphate buffer 6.8 pH

Determination of λmax

The solutions prepared were scanned between wavelength range of 200 to 400 nm and λmax was found to be 256 nm for the standard solution of Cilostazol.

Method Development

Preparation of stock solution

10mg of the pure drug was weighed and transferred to a 100ml volumetric flask; 100ml ethanol was added to the

Table 4: Intra-day (Repeatability) precision determined for three different concentrations.

Intraday			Precision				1.00 PM	
Sr. No.	drug amt in %	Drug conc.ppm	Abs.	drug found in ppm	% recovery	Avg. % recovery	std dev (SD)	RSD
1.	80%	4.8	0.32	4.678	97.47	97.16	0.5369	0.5526
2.	80%	4.8	0.315	4.633	96.54			
3.	80%	4.8	0.32	4.678	97.47			
4.	100%	6	0.598	7.160	119.34	118.89	0.9051	0.7612
5.	100%	6	0.599	7.169	119.49			
6.	100%	6	0.588	7.071	117.85			
7.	120%	7.2	0.612	7.285	101.19	102.18	0.8680	0.8495
8.	120%	7.2	0.623	7.383	102.55			
9.	120%	7.2	0.625	7.401	102.80			
						sqrt(3)=	1.732050	

Table 5: Intra-day (Repeatability) precision study of Cilostazol by Confidence Interval.

	Confidence interval					
Intraday		80%		1.00 pm		
µ95%=mean±1.96(sẍ)		µ99%=mean±2.58(sẍ)		µ68%=mean±1(sẍ)		
Sẍ=std error of mean		Sẍ=std error of mean		Sẍ=std error of mean		
Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]		
n=3 (replicate)1.732		n=3 (replicate)1.732		n=3 (replicate)1.732		
mean of 80%=97.16		mean of 80%=97.16		mean of 80%=97.16		
Sẍ=	0.3100	Sẍ=	0.3100	Sẍ=	0.3100	
1.96*Sẍ=	0.6076	2.58*Sẍ=	0.7998	1*Sẍ=	0.3100	
µ95%=97.16±0.6076		µ99% = 97.16±0.7998		µ68%= 97.16±0.3100		

Table 6: Intra-day (Repeatability) precision study of Cilostazol by Confidence Interval.

	Confidence interval					
Intraday		100%		1.00 pm		
µ95%=mean±1.96(sẍ)		µ99%=mean±2.58(sẍ)		µ68%=mean±1(sẍ)		
Sẍ=std error of mean		Sẍ=std error of mean		Sẍ=std error of mean		
Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]		
n=3 (replicate)1.732		n=3 (replicate)1.732		n=3 (replicate)1.732		
mean of 100%=118.89		mean of 100%=118.89		mean of 100%=118.89		
Sẍ=	0.5226	Sẍ=	0.5226	Sẍ=	0.5226	
1.96*Sẍ=	1.0242	2.58*Sẍ=	1.3483	1*Sẍ=	0.5226	
µ95%=118.89±1.0242		µ99%=118.89±1.3483		µ68%=118.89±0.5226		

Table 7: Intra-day (Repeatability) precision study of Cilostazol by Confidence Interval.

	Confidence interval					
Intraday		120%		1.00 pm		
µ95%=mean±1.96(sẍ)		µ99%=mean±2.58(sẍ)		µ68%=mean±1(sẍ)		
Sẍ=std error of mean		Sẍ=std error of mean		Sẍ=std error of mean		
Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]		
n=3 (replicate)1.732		n=3 (replicate)1.732		n=3 (replicate)1.732		
mean of 120%=102.18		mean of 120%=102.18		mean of 120%=102.18		
Sẍ=	0.5011	Sẍ=	0.5011	Sẍ=	0.5011	
1.96*Sẍ=	0.9822	2.58*Sẍ=	1.2930	1*Sẍ=	0.5011	
µ95%=102.18±0.9822		µ99%=102.18±1.2930		µ68%=102.18±0.5011		

above flask and dissolved the volume was made up with the phosphate buffer 6.8 pH.

Method validation

Analytical method development and validation of the Cilastazol bulk drug and its dosage form by ICH guideline

Limit of Detection (LOD) and Limit of Quantitation (LOQ)

Limit of detection (LOD)[16-20]

It is the smallest quantity of an analyte that can be detected, and not necessarily determined, in a quantitative manner. It was calculated by the following formula;

$$LOD = 3.3 \times \frac{S.D}{S}$$

Where; S. D=Standard Deviation. S = Slope

Limit of Quantization (LOQ)[16-20]

It is the lowest concentration of an analyte in a sample that

Table 8: Inter-day (Intermediate) precision determined for three different concentrations.

Interday Precision Thursday								
Sr. No.	Drug amt in %	Drug conc.ppm	Abs.	Drug found in ppm	% recovery	Avg. % recovery	Std dev(sd)	Rsd
1.	80%	4.8	0.32	4.67	97.47			
2.	80%	4.8	0.319	4.66	97.28	97.34	0.1073	0.1103
3.	80%	4.8	0.319	4.66	97.28			
4.	100%	6	0.442	5.76	96.13			
5.	100%	6	0.447	5.81	96.87	96.62	0.4295	0.4445
6.	100%	6	0.447	5.81	96.87			
7.	120%	7.2	0.597	7.15	99.33			
8.	120%	7.2	0.591	7.09	98.58	98.95	0.3720	0.3759
9.	120%	7.2	0.594	7.12	98.95			

Table 9: Inter-day (Intermediate) precision study of Cilostazol by Confidence Interval.

Confidence Interval					
Interday		80%		Thurday	
µ95%=mean±1.96(sẍ)		µ99%=mean±2.58(sẍ)		µ68%=mean±1(sẍ)	
Sẍ=std error of mean		Sẍ=std error of mean		Sẍ=std error of mean	
Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]	
n=3 (replicate)1.732		n=3 (replicate)1.732		n=3 (replicate)1.732	
mean of 80%=97.34		mean of 80%=97.34		mean of 80%=97.34	
Sẍ=	0.06200	Sẍ=	0.0620	Sẍ =	0.0620
1.96*Sẍ=	0.1215	2.58*Sẍ=	0.1599	1* Sẍ =	0.0620
µ95%=97.34±0.1215		µ99%=97.34±0.1599		µ68%=97.34±0.0620	

Table 10: Inter-day (Intermediate) precision study of Cilostazol by Confidence Interval.

Confidence interval					
Interday		100%		Thurday	
µ95%=mean±1.96(sẍ)		µ99%=mean±2.58(sẍ)		µ68%=mean±1(sẍ)	
Sẍ=std error of mean		Sẍ=std error of mean		Sẍ=std error of mean	
Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]	
n=3 (replicate)1.732		n=3 (replicate)1.732		n=3 (replicate)1.732	
mean of 100%=96.62		mean of 100%=96.62		mean of 100%=96.62	
Sẍ=	0.2480	Sẍ=	0.24801	Sẍ =	0.2480
1.96*Sẍ=	0.4861	2.58*Sẍ=	0.6398	1* Sẍ =	0.2480
µ95%=96.62±0.4861		µ99%=96.62±0.6398		µ68%=96.62±0.2480	

Table 11: Inter-day (Intermediate) precision study of Cilostazol by Confidence Interval.

Confidence interval					
Interday		120%		Thurday	
µ95%=mean±1.96(sẍ)		µ99%=mean±2.58(sẍ)		µ68%=mean±1(sẍ)	
Sẍ=std error of mean		Sẍ=std error of mean		Sẍ=std error of mean	
Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]		Sẍ=SD/[(SQRT(n)]	
n=3 (replicate)1.732		n=3 (replicate)1.732		n=3 (replicate)1.732	
mean of 120%=98.95		mean of 120%=98.95		mean of 120%=98.95	
Sẍ=	0.2147	Sẍ=	0.2147	Sẍ =	0.2147
1.96*Sẍ=	0.4209	2.58*Sẍ=	0.5541	1* Sẍ =	0.2147
µ95%=98.95±0.4209		µ99%=98.95±0.5541		µ68%=98.95±0.2147	

may be determined with acceptable accuracy and precision. It was calculated by the following formula;

$$LOQ = 10 \times \frac{S.D}{S}$$

Method based on Standard stock solution of blank

Analysis were carried out using blank solvent as Methanol, the absorbance of resulting solution was measured 10 times at 258nm.

Method based on Calibration Curve

Prepare 0.001ppm to 1.0 ppm of Cilastazol drug was dissolved in ethanol and after volume in each were adjusted to 10ml with phosphate buffer pH 6.8. The absorbance of resulting solution was measured 10 times at 258nm. In this study, LOD and LOQ were based on the standard deviation of the response and the slope of the corresponding curve using the following equations Cut off range was found to be 0.07

Linearity and Range

Linearity

Linearity indicates the ability to produce results that are directly proportional to the concentration of the analyte in samples[12,13,15,16].

Range

Range is an expression of the lowest and highest levels of analyte that have been demonstrated to be determinable for the product[12,13,15,16]. Standard stock solution Cilastazol (1.0 ml) were transferred to a 10ml of volumetric flask and the volume were adjusted to 10 ml with phosphate buffer. The absorbance of resulting solution was measured at 258nm against blank. The absorbance of the samples in the range

Table 12: Reproducibility precision determined for three different concentrations.

Sr. No.	API (A) ppm	level of addition of API(B)	API PPM(B)	Abs	Conc. found for both API+API (A+B)	% Recovery	Avg. % Recovery	Std. Dev.
1.	6	80%	4.8	1.012	10.85	100.52	100.44	0.2187
2.	6	80%	4.8	1.013	10.86	100.61		
3.	6	80%	4.8	1.008	10.82	100.19		
4.	6	100%	6	1.112	11.75	97.91	99.18	1.4491
5.	6	100%	6	1.16	12.17	101.48		
6.	6	100%	6	1.115	11.77	98.13		
7.	6	120%	7.2	1.281	13.25	100.44	99.56	0.7622
8.	6	120%	7.2	1.262	13.08	99.16		
9.	6	120%	7.2	1.261	13.08	99.09		
					11.96	99.731		

Table 13: Accuracy/recovery for three different concentrations of mirabegron (n=3).

		Different Analyst & Different Instrument						
Sr. No.	Analyst And Instrument	Drug Conc. (PPM)	Abs	Drug Conc. Found (PPM)	% Recovery	Avg. % Recovery	Std Dev	RSD
1.	1	6	0.458	5.910	98.51			
2.		6	0.463	5.955	99.25	99.05	0.4783	0.4829
3.		6	0.464	5.964	99.40			
4.	2	6	0.459	5.919	98.66			
5.		6	0.464	5.964	99.40	99.20	0.4783	0.4821
6.		6	0.465	5.973	99.55			
7.	3	6	0.464	5.964	99.40			
8.		6	0.466	5.982	99.70	99.50	0.1718	0.1726
9.		6	0.464	5.964	99.40			

Table 14: Trueness for three different concentrations of Cilastazol drug and tablets.

Sr. No.	Tab. ppm	level of addition of API	API PPM	Abs	Conc. found for both Tab. +API	% Recovery	Avg. % Recovery	Std. Dev.
1.	6	80%	4.8	1.013	10.86	100.61		
2.	6	80%	4.8	1.014	10.87	100.69	100.52	0.2187
3.	6	80%	4.8	1.009	10.83	100.28		
4.	6	100%	6	1.113	11.75	97.99		
5.	6	100%	6	1.115	11.77	98.13	98.11	1.3313
6.	6	100%	6	1.116	11.78	98.21		
7.	6	120%	7.2	1.244	12.92	97.94		
8.	6	120%	7.2	1.266	13.12	99.43	98.93	0.8591
9.	6	120%	7.2	1.266	13.12	99.43		
					AVG	99.19		

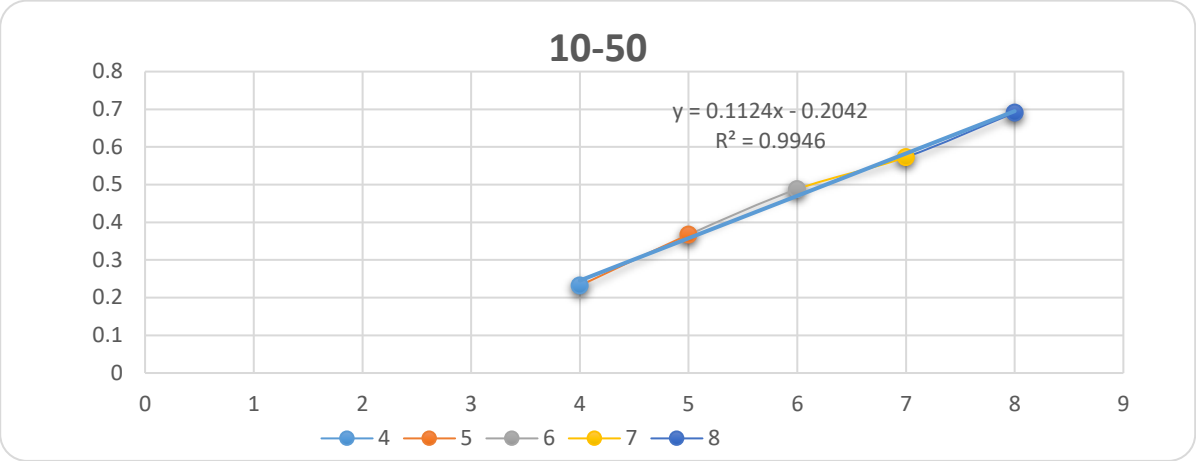

Figure 3: Calibration Curve of Cilostazol in ethanol and phosphate buffer 6.8 pH

Table 15: Bias for three different concentrations of Cilastazol drug and tablets.

Bias	
% purity of reference(API)	99.73169
% purity of Tab.	99.19332
Bias/Error	0.53837

of 0.5–0.9µg/mL was linear with a correlation coefficient (R2) 0.993.

Specificity

Specificity (selectivity) is the ability to measure unequivocally the desired analyte in the presence of components such as excipients and impurities[12,13,17,18]. Standard solution of Cilastazol (0.4 ml) from stock solution, now spiking Cilastazol in 3 different levels 80,100,120% respectively from stock solution B, make up the volume to 10ml with phosphate buffer, the absorbance of resulting solution was measured at 258nm against blank. Spiking Cilastazol in 3 different levels 80,100,120% respectively from stock solution B to determine the amount of %recovery.

Precision

Precision is the degree of agreement among individual results. The complete procedure should be applied repeatedly to separate, identical samples drawn from the same homogeneous batch of material[12,13,15,17,18]. Prepare 20µg/ml of Cilastazol solution in three sets from stock solution. Spike standard Cilastazol in concentration of 50,100,150% respectively. Analysis were carried out using ethanol; 3.0 ml were added and mixed, immediately sonicate and volume adjusted to 10 ml with phosphate buffer, the absorbance of resulting solution was measured at 258nm against blank. The same complex solution were taken and the absorbance were measured at 258nm at 4 different time intervals (i.e. at 30 minutes, 60 minutes, 90 minutes,120 minutes). The Interday precision and intraday precision are applied to determine the sample stability. The Interday precision and intraday precision was found RSD is less than 2%.

Intraday Precision

Interday Precision

Reproducibility Precision

Accuracy

Accuracy is the degree of agreement of test results with the true value, or the closeness of the results obtained by the procedure to the true value[12,13,15,17,18]. Prepare 20 µg/ml of Cilastazol solution in three sets from stock solution. Spike standard Cilastazol in concentration of 50, 100,150% respectively. Analysis were carried out using 3.0 ml were added with ethanol and volume adjusted to 10 ml with phosphate buffer, the absorbance of resulting solution was measured at 258nm against blank.

Trueness and Bias

Recovery studies was carried out by applying the method to drug sample to which known amount of Cilastazol corresponding to 80, 100, 120% (Table 50) of label claim has been added (standard addition method)

ANOVA Test for Accuracy

Result of F and P Value Accuracy

Robustness

The absorbance of Cilastazol sample solution at varying wavelength and temperature to check the sustainability at change in λ max, pH and temperature was measured. The temperature of the solution was raised to 25ºC, RT and 40ºC and absorbance was recorded. Later absorbance of freshly prepared sample solution was recorded at varying λ max 266nm, 258nm and 260 nm and given in table-1[11-14].

RESULTS AND DISCUSSION

In present study by using UV method is developed for the determination of the Cilastazol, which is a product of Cilastazol for the preparation of stable complex of Cilastazol and ethanol with phosphate buffer 6.8 showing stable readings among all other solvents. The developed spectrophotometric method was simple, sensitive and specific for the detection of amino group in bulk and pharmaceutical formulation. It could be precisely LOD was found to be 1.7894µg/ml and LOQ was found to be 5.4224µg/ml. The calibration curve shows linear relationship between the absorbance and concentration and the coefficient correlation was higher than 0.99. Precision

Table 16: ANOVA Test for Accuracy.

80%			100%			120%		
	% purity (X1)	(X1)2		% purity (X2)	(X2)2		% purity (X3)	(X3)2
	99.18	9837.03		104.58	10937.22		98.52	9706.81
	96.37	9287.41		100.36	10073.21		98.13	9631.44
	99.96	9992.50		100.85	10172.17		98.90	9782.48
∑	295.51	29116.95	SUM	305.80	31182.61	SUM	295.56	29120.74
∑(X1)2	87329.46		∑(X2)2	93515.96		∑(X3)2	87361.34	
∑(X1)2/N	29109.82		∑(X2)2/N	31171.98		∑(X3)2/N	29120.44	

Table 17: Result of F and P Value Accuracy.

Source of Variation	Sum of Square	Mean Square	F Value	P Value
Between	9.00235616	4.50117808	0.8321	$\geq$0.05
Within	32.45346596	5.408910993		

Table 18: Robustness study on different pH.

		at different pH						
Sr. No.	pH	Drug Conc. (ppm)	ABS	Drug conc. found (ppm)	% recovery	Avg. % recovery	Std Dev	RSD
1.	4.5	6	0.459	5.919	98.66	98.80	0.6819	0.6901
2.		6	0.456	5.892	98.21			
3.		6	0.465	5.973	99.55			
4.	5.6	6	0.458	5.910	98.51	98.41	0.3097	0.3147
5.		6	0.459	5.919	98.66			
6.		6	0.455	5.883	98.06			
7.	7.8	6	0.458	5.910	98.51	98.36	0.3937	0.4002
8.		6	0.459	5.919	98.66			
9.		6	0.454	5.875	97.91			

Table 19: Robustness study on different wavelength.

		at different wavelength						
Sr. No.	Wavelength (Nm)	Drug Conc. (PPM)	Abs	Drug Conc. Found (PPM)	% Recovery	Avg. % Recovery	STD DEV	RSD
1.	254	6	0.462	5.946	99.10	98.26	0.7340	0.7470
2.		6	0.454	5.875	97.91			
3.		6	0.453	5.866	97.76			
4.	256	6	0.449	5.830	97.17	98.01	0.73405	0.7489
5.		6	0.458	5.910	98.51			
6.		6	0.457	5.901	98.36			
7.	258	6	0.45	5.839	97.32	97.61	0.2976	0.3048
8.		6	0.452	5.857	97.61			
9.		6	0.454	5.875	97.91			

Table 20: Robustness study on different Temperature.

		at different Temperature						
Sr. No.	temp(◦c)	Drug Conc. (PPM)	ABS	Drug Conc. Found (PPM)	% Recovery	Avg. % Recovery	Std Dev	RSD
1.	8	6	0.46	5.928	98.80	99.00	0.1718	0.1735
2.		6	0.462	5.946	99.10			
3.		6	0.462	5.946	99.10			
4.	R.T.	6	0.459	5.919	98.66	98.51	0.1488	0.1510
5.		6	0.458	5.910	98.51			
6.		6	0.457	5.901	98.36			
7.	60	6	0.461	5.937	98.95	98.61	0.3097	0.3141
8.		6	0.457	5.901	98.36			
9.		6	0.458	5.910	98.51			

was found to be less than 2%. The % recovery was found to be 106.07-97.63% and sample solution stable for three days. Accuracy/recovery results were found to be within the range of 99.09-100.61% ensures an accurate method as well as indicates non-interference with the excipients of formulation. In trueness percent purity of reference API was found to be 99.73% and by accuracy percent purity of standard was found to be 99.72%. Bias/error was found to be 0.5383% which was within range/acceptable limit so there was no significant different between % recovery of reference sample and product**.** Robustness method was unaffected by changing parameter like Light, Analyst, Wavelength, pH because % recovery for all parameters was found to be around 98.52, 97.96 and 98.70% respectively system remain unaffected while changing the parameter. Hence the method is developed and validated for the detection of Cilastazol, product of Cilastazol and by using concept of UV method on Cilastazol drug from Cilastazol drug product is estimated.

CONCLUSION

The results and the statistical parameters demonstrate that the proposed UV spectrophotometric method is simple, rapid, specific, accurate and precise. Therefore, this method can be used for the determination of Cilostazol either in bulk or in the dosage formulations without interference with commonly used excipients and related substances.

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