

Table 5: Recovery Studies for Method B

Level of recovery	Sample Conc. (µg/mL)	Standard conc. added (µg/mL)	Total Conc. (µg/mL)	Amount Recovered (µg/mL)	% Recovery	Mean % Recovery±%RSD
80%	6	4.8	10.8	4.77	99.5	99.9±0.76
	6	4.8	10.8	4.8	100	
	6	4.8	10.8	4.81	100.4	
100%	6	6	12	5.94	99	100.1±0.43
	6	6	12	6.01	100.3	
	6	6	12	6.06	101	
120%	6	7.2	13.2	7.15	99.4	100.4±0.21
	6	7.2	13.2	7.31	101.6	
	6	7.2	13.2	7.21	100.2	

Table 6: Estimation of Orlistat in Pharmaceutical Formulation

Formulation	Labeled amount	Amount found		% Recovery	
		Method A	Method B	Method A	Method B
Capsule 1	60 mg	59.98 mg	59.76 mg	99.96	99.60
Capsule 2	120 mg	119.92 mg	119.89 mg	99.93	99.90

Precision

The precision of analytical procedure expresses the closeness of agreement between a series of measurement obtained from multiple sampling of the same homogenous sample under the prescribed condition. The system precision was analysed by six different solutions of same concentration and absorbances were noted. The result was indicated by % RSD. The results are shown in **Table 1**. Repeatability or Intra-day precision was investigated on six replicate sample solutions on the same day. Inter-day precision was assessed by analyzing newly prepared sample solutions in triplicate over three consecutive days. Both inter day and intraday precision was expressed as % RSD. The % RSD values for intraday precision for Method A was 0.78-0.96 and for Method B 0.86-0.96. The % RSD for inter day precision for Method A and Method B are 0.88-1.01 and 0.91-1.2. The results were summarized in **Table 2 & 3**. The low value of % RSD for both methods indicates the high precision of the both methods.

Accuracy

Accuracy of the method was determined by preparing solutions of different concentrations that is 80%, 100% and 120% in which the amount of marketed formulation was kept constant and the amount of pure drug was varied. Solutions were prepared in triplicates and accuracy was indicated by % recovery. The results for both Method A and Method B were a shown in **Table 4 & Table 5** respectively.

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

LOD and LOQ were determined based on statistical calculation from the calibration curves, where $LOD = (3.3 \times \sigma)/m$; $LOQ = (10.0 \times \sigma)/m$ (σ is the standard deviation of the y-intercepts of the three regression lines and m is mean of the slopes of the three calibration curves). The LOD and LOQ values of the developed methods were summarized in **Table 1**.

Application of proposed method to formulation

The proposed methods are applied to pharmaceutical formulation and results are shown in **Table 6**.

CONCLUSION

The two visible spectrophotometric methods proposed for the determination of Orlistat, which are fairly sensitive, simple and economical with reasonable precision and accuracy. Parameters and statistical comparison justify this method for application in estimation of Orlistat in pure and dosage form. Moreover the methods are free from interference by common additives and excipients for the assay and evaluation of Orlistat in pharmaceutical dosage form.

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