SHORT COMMUNICATIONS

Spectrophotometric Determination of Lamotrigine

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A new simple, sensitive spectrophotometric method in ultraviolet region has been developed for the determination of lamotrigine in bulk and in dosage form. Lamotrigine shows maximum absorbance at 305 nm. Beer's law was obeyed in the concentration range of 2-50 mcg/ml. Results of the analysis were validated statistically and by recovery studies.

Lamotrigine is one of newer antiepiletic drugs, with less side effects which is marketed in UK since 1992 and introduced in India recently¹. Chemically it is 6 (2, 3-dichlorophenyl)-1, 2, 4-triazine-3, 5 - diamine or 3, 5-diamino, -6 (2, 3-dichlorophenyl)-1, 2, 4-triazine². It is official in Martindale Extra Pharmacopoeia³. A survey of the literature revealed a HPLC method^{4.5} and radioimmunoassay⁶ for its analysis. In the present investigation an attempt has been made to develop a simple spectrophotometric method for the analysis of this drug from tablet formulations.

A Shimadzu model 2501 UV/Vis spectrophotometer with 1 cm matched quartz cells was used. Methanol of analytical grade was obtained from Ranbaxy Chemicals Ltd., S.A.S. Nagar. Lamotrigine in bulk and in tablet formulation was obtained as a gift sample from Cipla (Protec) Ltd. Mumbai. Lamotrigine (10 mg) was accurately weighed and dissolved in 10 ml methanol to give stock solution of concentration 1000 mcg/ml. Aliquots of 100 mcg/ml solution were transferred into six 10 ml volumetric flasks and volume was adjusted with methanol to give final concentrations of 5, 10, 20, 30, 40 and 50 mcg/ml. The solutions were scanned in the UV range. The absorbance was measured at 305 nm against methanol as a blank.

For analysis of lamotrigine from formulation, 20 tablets were weighed and triturated. The tablet powder equivalent to 25 mg of lamotrigine was transferred into a stoppered conical flask. It was extracted with 15 ml methanol three times and the filtrate was transferred in a 50 ml volumetric flask and final volume was made with methanol. This solution was further diluted to give final concentration of about 10 mcg/ml and absorbance was measured at 305 nm against methanol as a blank. The assay was carried out for six samples from different batches.

Recovery studies were carried out by adding 10, 15 and 20 mg of pure drug to different samples of tablet powder containing the equivalent of 25 mg of drug. From the amount drug found, percentage recovery was calculated. The proposed method of determination of lamotrigine shows molar absorptivity - 8.317 x 10³ lit mole¹ cm¹ and Sandell's sensitivity - 0.03078 mcg/cm²/ 0.001 absorbance unit. Linear regression of absorbance on concentration gave the equation - Y = 0.0319 x -0.042 with a correlation coefficient of r - 0.998.

Relative standard deviation of 0.097 was observed for analysis of six replicate samples. Lamotrigine exhibits maximum absorption at 305 nm and obeyed Beer's law in the concentration range of 2-50 mcg/ml. The results of analysis and recovery studies are presented in Table 1. The percentage recovery value 99.17% indicates that there is no interference of the excipients present in the formulation.

The developed method was found to be sensitive, accurate, precise and reproducible and can be used for the routine determination of lamotrigine in bulk and in dosage forms.

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TABLE 1: RESULTS OF ASSAY AND RECOVERY EXPERIMENTS

Pharmaceutical	Labelled	Amount found		% Recovery
formulation	amount	(mg)	<u>%</u>	
Α	25	25.180	100.72	99.50
B	25	24.997	99.91	99.25
C	25	24.930	99.72	98.35
D	25	24.680	99.44	99.48
E	25	25.075	100.30	99.30
Mean	,	24.97	100.018	99.17
±S.D.		±0.134	±0.490	

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