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Spectrophotometric Methods for the Determination of Sibutramine Hydrochloride from Capsules

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A new simple, sensitive spectrophtometric method in ultraviolet region has been developed for the determination of sibutramine hydrochloride in bulk and in capsule dosage form. Sibutramine hydrochloride shows maximum absorbance at 220 nm. Beer's law was obeyed in the concentration range 10–50 μg/ml. Results of the analysis were validated statistically and by recovery studies.

Sibutramine hydrochloride is chemically 1-(4-chlorophenyl)-N-N-dimethyl-α(2-methyl propyl)-hydrochloride monohydrate. It is a relatively new antiobesity drug[1-3]. It is not yet official in any pharmacopoeia. Survey of literature reveals that sibutramine hydrochloride is estimated in pharmaceuticals and in biological fluids by spectrophotometry[4-8], GC[9-10], HPLC[11-15] and polarography[16]. In the present work a simple and sensitive spectrophotometric method was developed for the determination of sibutramine hydrochloride in bulk as well as from solid dosage forms using methanol as a solvent.

An Elico UV/Vis spectrophotometer model SL-150 with 1 cm matched quartz cells was used for all absorbance measurements. All the chemicals used were of AR grade. Pure sibutramine hydrochloride was obtained as a gift sample from Cipla, Pune. Sibutramine hydrochloride (100 mg) was accurately weighed and dissolved in 100 ml of methanol to give a stock solution (1000 μg/ml). From this stock, aliquots of solution were transferred into six 10-ml volumetric flasks and the final Volume was adjusted with methanol to give concentration of 10, 20, 30, 40, 50 and 60 μg/ml. The solution was scanned in the UV range. The absorbance was measured at 220 nm against a methanol blank.

For analysis of sibutramine hydrochloride from formulation, 10 capsules (1. Sibutrim-10, Sun Pharma, 2. Sibutrex-10, Glenmark and 3. Slenfig-10, Torrent) were weighed. The capsule powder equivalent to 10 mg of sibutramine hydrochloride was transferred into a 100-ml standard flask. A small quantity of methanol was added and it was shaken well to dissolve the drug and then volume was made up to mark with methanol and filtered. The absorbance of this solution was measured at 220 nm against methanol as blank.

Recovery studies were performed by adding a known amount of the drug to previously analyzed capsules. From the amount of drug found, percentage recovery was calculated. The proposed method of determination of sibutramine hydrochloride shows molar absorptivity 17.88×10^{3}/mol.cm. Linear regression of absorbance with concentration gave a correlation co-efficient of 0.9996. Sibutramine hydrochloride

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TABLE 1: ESTIMATION OF SIBUTRAMINE HYDROCHLORIDE IN PHARMACEUTICAL PREPARATIONS.

Sample	Labelled Amount (mg)	Amount Found (mg)	Percentage	% Recovery*	Standard deviation	Co-efficient of variation
Capsule 1 (Sibutrim-10)	10	9.94	99.9	99.3	0.111	1.100
Capsule 2 (Sibutrex-10)	10	10.21	101.0	100.2	0.071	0.708
Capsule 3 (Slenfig-10)	10	9.91	99.8	99.2	0.064	0.637

*Mean ± S.D of 6 observations. Capsule 1 represents Sibutrim-10 (10mg) of Sun Pharma, capsule 2 refers to Sibutrex-10 (10mg) of Glenmark and capsule 3 is Slenfig-10 (10mg) of Torrent.

exhibited λ_{max} at 220 nm. The Beer's law in the concentration range of 10–50 μg/ml. The results of analysis and recovery studies are presented in Table 1. The percentage recovery obtained indicated that there is no interference of excipients present in the formulation. The proposed method is simple, accurate and precise. It can be used for the routine quality control analysis of sibutramine hydrochloride in bulk and in pharmaceutical formulation.

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