

Spectrophotometric Method for Estimation of Mosapride Citrate in Tablets

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Simple colourimetric method for the estimation of mosapride citrate in solid dosage forms is described. Estimation of mosapride citrate is based on diazotization of mosapride and coupling of the diazonium salt with N-(1-naphthyl) ethylene diamine dihydrochloride to form a stable purple colored chromogen. With absorbance maxima at 540 nm the chromogen obeyed linearity over 20 to 160 $\mu\text{g/ml}$.

Chemically mosapride is (\pm)-4-amino-5-chloro-2-ethoxy-N-[[4-(p-fluorobenzyl)-2-morpholinyl]methyl]benzamide, which is clinically used as the citrate, for its prokinetic action¹. It is recommended in reflux esophagitis and also enhances the gastric motility². It is not official in any pharmacopoeia and available in tablet form. Literature survey reveals that the drug has been analyzed by HPLC method³. The present work describes simple colourimetric method for estimating mosapride citrate.

A Systronics spectrophotometer 106 with 1 cm matched cuvettes was used for spectrophotometric estimation. Standard drug solution of mosapride (100 $\mu\text{g/ml}$ in methanol) was prepared. 5% Hydrochloric acid, sodium nitrite solution (0.1% in distilled water), ammonium sulfamate (0.5% in distilled water), N-(1-naphthyl) ethylene diamine dihydrochloride [NED] (0.1% in distilled water) were freshly prepared.

Twenty tablets each containing 5 mg mosapride citrate were weighed and the average weight was determined. The tablets were powdered in a glass mortar and amount equivalent to 5 mg of mosapride citrate was transferred to 50 ml of volumetric flask, dissolved in distilled water and final volume was made upto the mark with the same solvent.

Aliquots of 0.2 to 1.6 ml of standard solution were transferred to a series of 10 ml corning test tubes. To each test tube, 1 ml of hydrochloric acid and 0.5 ml sodium nitrite were

added, mixed and cooled in ice-bath for 3 min, then 0.5 ml of ammonium sulphamate was added and the test tubes were kept at room temperature for 2 min for complete neutralization of the HNO_2 formed in the reaction. One ml of NED solution was added and mixed well. Immediately purple colour was developed⁴. The volume was made upto 10 ml of each test tube with distilled water. The purple colour was measured at 540 nm against the reagent blank. The calibration curve was constructed. The absorbance of sample solution was similarly measured and the amount of mosapride citrate was determined by computing from the calibration curve.

Estimation of mosapride citrate is based on its diazotization using HCl and sodium nitrite and then coupling of the

TABLE 1: OPTICAL CHARACTERISTICS AND PRECISION.

Characteristics	Observation
Absorption maxima (nm)	540
Beer's law limit ($\mu\text{g/ml}$)	20 – 160
Correlation coefficient	0.9972
Molar absorptivity ($\text{l.mole}^{-1} \text{cm}^{-1}$)	2.2274×10^4
Sandell's sensitivity ($\mu\text{g/cm}^2/0.001$)	0.0186
Regression equation ($y = mx + c$)	
Slope (m)	0.0539
Intercept (c)	0.0038
% Range of error (95% confidence limit)	0.0009

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TABLE 2: ANALYSIS DATA OF TABLET FORMULATION.

Formulation (Tablet)	Label Claim (mg/tab)	Amount found (mg/tab)	% of Label claim * \pm S.D.	% COV	S.E. of Mean	% Recovery
Brand 1	5	4.97	98.72 \pm 0.99	1.0028	0.6877	101.5395
Brand 2	5	4.96	98.66 \pm 1.02	1.0338	0.6897	100.3246

*Mean of five determinations.

diazonium salt with NED in presence of ammonium sulphamate producing purple chromogen^{4,5}. Stability of the chromogen was determined by measuring the absorbance values of chromogen at 540 nm at time interval of 30 min and was found to be stable for 5 h.

The optical characteristics such as absorption maxima, Beer's law limits, correlation coefficient (r), slope (m), y -intercept (c), molar absorptivity, Sandell's sensitivity and percent range of error have been calculated from measurements containing 3/4th of upper Beer's law limit and are summarized in Table 1. The molar absorptivity and Sandell's sensitivity show that the method is sensitive. Percent COV (coefficient of variance) and percent range of error reveal the precision of the method.

To test the accuracy and reproducibility of the proposed method, recovery experiments were performed by adding known amount of drug to the preanalyzed formulations and reanalyzing the mixture by proposed method. The results of analysis of marketed formulation are shown in Table 2. The reproducibility and accuracy of the method was found to be good which is evidenced by low standard deviation.

The percent recovery values indicate non-interference from the excipients used in formulation. In conclusion, the method developed in the present investigation is simple, sensitive, precise and accurate. Hence it can be successfully applied in estimation of mosapride citrate in pharmaceutical solid dosage forms such as tablets.

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Spectrophotometric Determination of Isoniazid in Pure and Pharmaceutical Formulations

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A simple, sensitive and accurate spectrophotometric method has been proposed for the determination of Isoniazid in pharmaceutical formulations. The method is based on the oxidation of tiron

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