

New visible spectrophotometric method for estimation of Itopride hydrochloride from tablets using mordant blue 3 reagent

B. CHOUDHARY^{1*}, A. GOYAL¹, S.L. KHOKRA² and D. KAUSHIK²

¹B.N.P.G College of Pharmacy, Udaipur - 313 001 (India).

²Institute of Pharmaceutical Sciences, Kurukshetra University, Kurukshetra - 136 119 (India).

(Received: April 06, 2009; Accepted: May 11, 2009)

ABSTRACT

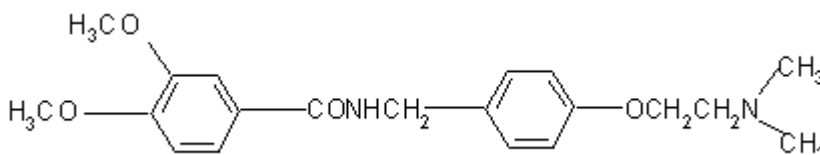
A simple, precise economical and fast visible spectrophotometric method has been developed for the determination of Itopride hydrochloride in tablet dosage form. Developed is based on formation of extractable colored complex of drug with coloring agent mordant blue 3. A wavelength maximum was found to 471.0 nm. Linearity was observed 30-70 mg /mL. The proposed method describes the determination of Itopride hydrochloride by visible spectrophotometric method which is a precise and selective. The result of analysis have been validated statistically and also by recovery studies.

Key words: Visible spectrophotometry, itopride hydrochloride, mordant blue 3.

INTRODUCTION

Itopride hydrochloride is chemically hydrochloride salt of N-[[4-(2-dimethylamino ethoxy) phenyl] methyl]-3, 4-dimethoxy-benzamide and used as antiemetic agent used in the management of gastrointestinal symptoms like nausea, vomiting, non-ulcer dyspepsia, emesis and chronic gastritis¹.

Literature survey reveals spectrophotometric², HPLC³⁻⁵ and HPTLC⁶ methods for the estimation of Itopride hydrochloride from pharmaceutical formulation has been developed. Visible Spectrophotometric estimation of drug is based on the formation of coloured complex of drug with mordant blue 3. In present research work a colorimetric method has been developed for estimation of Itopride hydrochloride from its tablet formulations.



MATERIAL AND METHODS

Shimadzu 1700 spectrophotometer was used for the present work. The chemicals used were of analytical grade. Mordant blue 3 solution of

concentration 0.8% w/v was prepared in 0.1 N HCl. Commercially available tablets of itopride hydrochloride were procured from local market. Gift sample of standard itopride hydrochloride drug was procured from Abbott India Ltd.

Procedure for calibration curve

Standard drug solution (100 µg /mL) was prepared in double distilled water and was diluted with same, so as to give several dilutions in concentration range 30-70mg/mL of drug. To 10 mL of each dilution taken in separating funnel, 10 mL of mordant blue 3 solution was added and shaken gently, then 5 mL of chloroform was added and reaction mixture was shaken gently and allowed to stand so as to separate aqueous and chloroform layer. The chloroform layer was separated out and transferred to 10 mL of volumetric flask. Reaction mixture extracted further with 3 mL and 2 mL of fresh chloroform and combined it with previously extracted chloroform containing complex. Absorbance of this final extracted chloroform layer was measured at wavelength maxima 471.0 nm against blank. Calibration curve (Fig. 1) was plotted between concentration of drug and measured absorbance.

Analysis of tablet formulations

Twenty tablets were accurately weighed and average weight per tablet was determined. Tablets were crushed to fine powder and tablet powder equivalent to 10 mg of itopride hydrochloride was accurately weighed and extracted four times with 20 ml portion of water and filtered through

whatman filter paper no. 41 into 100 ml volumetric flask, filter paper was washed with water. Washings were added to the filtrate and volume was made up to 100 ml with water. From this solution 4 ml was taken in another 10 ml volumetric flask and volume was made with so as to give concentration of 40 mg/ml and treated as per the procedure for calibration curve. The absorbance of extracted complex was measured at wavelength maxima 471.0 nm. Concentration of drug in sample was calculated from respective calibration curve. The analysis procedure was repeated five times for both marketed formulations. Results are reported in table 1.

RESULTS AND DISCUSSION

In present research work a colorimetric method has been developed for determination of Itopride hydrochloride from its tablet formulations. The developed method was based on formation of chloroform extractable complex of drug with mordant blue 3 in 0.1N HCl. Wavelength maxima of Itopride hydrochloride was found to be at 471.0 nm and linearity was observed in concentration range of 30-70 µg/mL. Percentage label claim estimated for tablet formulation was found to be in the range of 99-101 % as shown in table in 1.

Table 1: Analysis of commercial formulations

Method	Formulation (Tablet)	Label Claim (mg)	Label claim estimated*	
			Mg	%
M B	A	50	49.52	99.04
	B	50	50.29	100.58

* Average of five determinations

MB = mordant blue3

Table 2: Recovery studies

Method	Formulations	% Recovery **	Standard Deviation	Relative Standard Deviation	Coefficient of variance
M B	A	98.8	0.5758	0.00572	0.5725
	B	101.9	0.7810	0.00772	0.7727

** Average of recovery studies at three different concentration levels

Respective values of standard deviation were found in the range of 0.5758-0.7810 for two different batches of tablet formulations of Itopride hydrochloride as shown in table 2.

ACKNOWLEDGEMENTS

Authors thanks to abbott India ltd for providing the gift sample of itopride hydrochloride

REFERENCES

1. Tripathi, K.D., *Essential of Medical Pharmacology*, 5th edn. Jaypee Brothers medical publishers Pvt. Ltd. New Delhi. 13 (2003).
2. Hussaniny, S. Smitha, G. Swamy, P.V. and Raju, S. "Spectrophotometric determination of Itopride hydrochloride". *Int J. Chem. Sci.*, **4**(3): 713 (2006).
3. Singh, S.S. Jain, M. Sharma, K. Shah, B. Vyas, M. Thakpar, P. Shah, R. Singh, S and Lohray, B. "Quantitation of Itopride in human serum by high performance liquid chromatography with fluorescence detection and its application to a bioequivalence study". *J. Charatogr. B. Analyst. Technol. Biomed. Life. Sci.*, **2**: 818 (2005).
4. Kaul, N. Agrawal, H. Maske, P. Rao, J. Ramchandra, M. Kakashaeb, R. and Kadam, S.S. "Chromatographic determination of Itopride hydrochloride in the presence of its degradation products". *J. Sepr. Sci.*, **28**: 1556 (2005).
5. Choudhary, B. Goyal, A. and Khokra, S.L. "High Performance Liquid Chromatographic determination of Itopride hydrochloride in tablet dosage form". *Oriental. J. Chem.*, **25**: 235 (2009).
6. Suganthi, A. Karthikeyan, R. and Ravi, T.K. "HPTLC methods for estimation of Itopride hydrochloride from its tablet formulations". *Indian Drugs.*, **43**: 827 (2006).