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NOTE

Spectrophotometric Determination of Itopride Hydrochloride in Pharmaceutical Formulations

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A simple, sensitive and reproducible spectrophotometric method is developed for the determination of itopride hydrochloride in pharmaceutical formulations. This method is based on the formation of coloured species on binding of itopride hydrochloride with potassium ferrocyanide followed by ferric chloride to produce a blue coloured solution (λ_{max} at 720 nm). Results of analysis were validated statistically and by recovery studies. This method is successfully employed for the determination of itopride hydrochloride in various pharmaceutical preparations.

Key Words: Itopride hydrochloride, Visible spectrophotometric determination, Beer's law.

Itopride hydrochloride (ITH) is N-[[4-(2-dimethylaminoethoxy)phenyl]methyl]-3,4-dimethoxybenzamide hydrochloride, is a gastro intestinal tract stimulant and one of the most recent drugs in this category. It increases acetylcholine concentration by inhibiting dopamine D2 receptor and acetylcholine esterase. Higher acetylcholine increases gastro intestinal peristalsis, increases the lower esophageal sphincter pressure, stimulates gastric motility, accelerates gastric emptying and improves gastro-duodenal coordination.

Only a few HPLC[1-7] methods and three spectrophotometric[8-10] methods appeared in the literature for the determination of itopride hydrochloride in bulk and pharmaceutical formulations.

Spectral and absorbance measurements are made with Systronics UV-visible double beam spectrophotometer model 2201. All the chemicals used were of analytical grade. All the solutions were freshly prepared with double distilled water. Freshly prepared solutions were always used. Aqueous solutions of potassium ferrocyanide (0.1 %) and ferric chloride (0.1 %) were used.

Standard and sample solution of itopride hydrochloride: About 100 mg of itopride hydrochloride (bulk or formulation) was accurately weighed and dissolved in 100 mL of water in a volumetric flask to make a solution of 1 mg/mL standard solution and further dilution is made with the same solvent (100 µg/mL) for this method.

Assay procedure: Aliquots 1-5 mL of standard itopride hydrochloride solution (100 µg/mL) were transferred to a series of 10 mL graduated tubes. To each tube 1 mL of potassium ferrocyanide solution was added followed by 1 mL of ferric chloride solution and the absorbance of the blue coloured chromogen was measured at 720 nm against the reagent blank. The amount of itopride hydrochloride was computed form the calibration curve.

The proposed method is based on reaction of itopride hydrochloride with potassium ferrocyanide and ferric chloride and resulting in the formation of a blue coloured chromogen. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and sandell's Sensitivity for this method is presented in Table-1. The regression analysis using the method of least squares was made for the slope (a), intercept (b) and correlation coefficient (r) obtained from different concentrations was summarized in Table-1. The precision and accuracy were found by analyzing 6 replicate samples containing known amounts of the drug and the results are summarized in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS, PRECISION AND ACCURACY OF ITOPRIDE HYDROCHLORIDE

Parameters	
λ_{max} (nm)	720
Beer's law limit (µg/mL)	1-5
Sandell's sensitivity (µg/cm^2/0.001 abs. unit)	0.06211
Molar absorptivity (L mol^{-1} cm^{-1})	0.635789×10^4
Correlation coefficient (r)	0.9953
Regression equation (Y)*	
Slope (a)	0.0108
Intercept (b)	0.0017
% RSD**	0.47
% Range of errors (95 % confidence limits)	
0.05 Significance level	± 0.392
0.01 Significance level	± 0.581

*Y = a + bx, where Y is the absorbance and x is the concentration of cefpirome sulfate in µg/mL; ** For 6 replicates.

The accuracy of this method was ascertained by comparing the results obtained with the proposed and reference method in the case of formulations and are presented in Table-2. An additional check on the accuracy of this method, was analyzed by adding known amounts of pure drug to pre-analyzed formulations. Performed recovery experiments and percent recovery values obtained are listed in Table-2. Recovery experiments indicated the absence of interferences from the commonly encountered pharmaceutical additives and excipients.

Thus, the proposed method is simple and sensitive with reasonable precision and accuracy and can be used for the routine determination of itopride hydrochloride in quality control analysis.

TABLE-2
ESTIMATION OF ITOPRIDE IN PHARMACEUTICAL FORMULATIONS

Formulations	Labeled amount (mg/vial)	Recovery by Proposed method (%)
Tablet 1	50	99.53
Tablet 2	50	99.43
Tablet 3	50	99.69
Tablet 4	50	100.3

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REFERENCES

1. N. Kaul, H. Agarwal, P. Maske, J.R. Rao, K.R. Mahadik and S.S. Kadam, *J. Separ. Sci.*, **28**, 1566 (2005).
2. S.S. Singh, M. Jain, K. Sharma, B. Shah, M. Vyas, P. Thakkar, R. Shah, S. Singh and B. Lohray, *J. Chromatogr. B*, **818**, 213 (2005).
3. R.-S. Zhao, Y. Li and X.Y. Bao, *Chin. Pharm. J.*, **13**, 1012 (2005).
4. C.-C. Li and S.F. Wu, *Chin. Pharm. Therap. J.*, **8**, 647 (2005).
5. C.-C. Li and S.F. Chun, *Chin. Pharmacologist*, **3**, 112 (2005),
6. C.-C. Li, C. Fanq, L. Cui, L. Hai and S.F. Chen, *J. Binzhou Medical College*, **5**, (2004).
7. D.-M. Zhang, B.X. Liu and Y.L.-L. Li, *Qilu Pharmaceutical Affairs*, **24**, 147 (2005).
8. L.-W. Ling, *Chin. J. Hospital Pharm.*, **20**, 22 (2000).
9. D. Aizheng and L. Wanzhong, *Chin. J. Hospital Pharm.*, **20**, 22 (2000).
10. H. Ying and H-T. Feng, *J. Anal. Sci.*, **16**, 297 (2000).

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