April 2007 Volume 5 Issue 1-6

Trade Science Inc.

Analytical CHEMISTRY

An Indian Journal

Note

ACAIJ, 5(1-6), 2007 [134-136]

# Spectrophotometric Method For Estimation Of Itopride Hydrochloride In Bulk And Tablet Dosage Form

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*Received: 6th February, 2007*
*Accepted: 11th February, 2007*

*Web Publication Date : 15th April, 2007*

## ABSTRACT

A simple, accurate and precise spectrophotometric method for estimation of itopride hydrochloride in bulk and tablet formulation was developed. Beer's law obeyed in the concentration range of 5-50 g/ml at the detection wavelength of 257.6. Correlation coefficient, LOD, LOQ and % COV found to be 0.9996, 0.424, 1.125 and 0.875 respectively. Results of analysis validated statistically with mean percent recovery of 99.366±0.225. 

## KEYWORDS

Itopride hydrochloride;
UV-Vis spectrophotometry.

## INTRODUCTION

Itopride hydrochloride is a gastrokinetic agent, which increases the release of acetylcholine(Ach) through dopamine D2 receptor antagonistic action and inhibits decomposition of Ach through its acetyl cholinesterase inhibitory action, resulting in enhancement of gastrointestinal motility. Itopride hydrochloride chemically is N-[4-[2-(dimethylamino)ethoxy]-benzyl]-3,4-dimethoxybenzamide hydrochloride. The empirical formula for itopride hydrochloride is $C_{20}H_{26}N_2O_4.HCl$[1,2].

Literature survey revealed analytical and stability indicating HPLC methods for estimation of itopride hydrochloride in tablet dosage form and bulk drug[3,4]. Two bioanalytical HPLC methods for detection of itopride in blood serum and urine also have been reported[5,6]. Extensive survey revealed that there is no spectrophotometric method reported for estimation of itopride hydrochloride. In the present investigation an economical, precise and accurate spectrophotometric method has been developed for quantitative determination of itopride hydrochloride in the bulk drug and tablet dosage form.

## MATERIALS AND METHODS

### Equipment

The instrument used in the present study was JASCO double beam UV/visible spectrophotometer

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(Model UV-530) with fixed slit width of 2nm connected to a computer with spectra manager software. All weighing were done on electronic balance(Model Shimdzu AY-120).

### Chemicals and reagents

Itopride hydrochloride was obtained from Burgeon Pharmaceuticals Pvt.Ltd., Pondicherry and used as such without further purification. All chemicals used in spectrophotometric analysis were analytical grade.

### Procedure

A stock solution of drug(100 µg/ml) was prepared by dissolving 10mg of drug in 5ml of 0.1N NaOH and the volume of the solution was made up to 100 ml with 0.1N NaOH. The aliquots of stock solution of drug were transferred to 10ml volumetric flasks and volume was made up to 10 ml with 0.1N NaOH to get working standard solutions of itopride hydrochloride in concentration range of 5-50 µg/ml. Absorbance of the solutions were measured at 257.6nm against reagent blank. Calibration curve was prepared.

For analysis of dosage form tablet powder (Itoprid 50 mg, Cipla Ltd.) equivalent to 10 mg of itopride hydrochloride was accurately weighed and dissolved in 5 ml of 0.1N NaOH and the volume of the solution was made up to 100ml with 0.1N NaOH. The solution was filtered and diluted with 0.1N NaOH to get final concentration of 10 µg/ml of itopride hydrochloride. Absorbance of the solution was measured at 257.6 nm against reagent blank and concentration of drug in sample solution was determined from calibration curve.

## RESULTS AND DISCUSSION

The optical characteristics of the proposed method have been calculated and presented in TABLE 1. To evaluate the accuracy and precision of the proposed method, recovery studies were carried out by addition of standard drug solution to preanalysed sample and determination was repeated at three concentration levels[7]. The percent recovery data of the drug by this method is given in TABLE 2. Overlain zero order spectrums of itopride hydrochloride are shown in figure 1. The accuracy and reproducibility is evident from the data as results are close to 100% and low standard deviation. The proposed method is simple, sensitive, precise and accurate. Hence it can be used for routine analysis of itopride hydrochloride in bulk as well as tablet formulation.

**TABLE 1: Optical characteristics of the proposed method**

| Parameters | Values |
|---|---|
| λ max(nm) | 257.6 |
| Beer's law limit µg/ml | 5 -50 µg/ml |
| Molar absorptivity l $Mol^{-1}cm^{-1}$ | $1.1785\times10^4$ |
| Regression equation | |
| Slope (m) | 0.0317 |
| Intercept(c) | 0.0067 |
| Correlation coefficient | 0.9996 |
| % COV(n=5) | 0.875 |
| Limit of detection(µg/ml) | 0.424 |
| Limit of quantitation(µg/ml) | 1.125 |

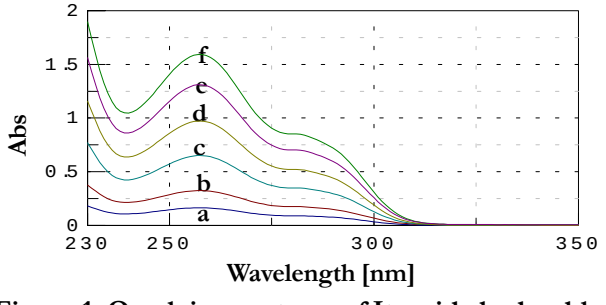


**Figure 1: Overlain spectrum of Itopride hydrochloride (a) 5.0; (b) 10.0; (c) 20.0; (d) 30.0; (e) 40.0, (f) 50.0 µg/ml**

**TABLE 2: Recovery study**

| Drug name | Amount present (µg/ml) | Amount of standard drug added (µg/ml) | Total amount Recovered* | % Recovery* | Mean % recovery (± SD) |
|---|---|---|---|---|---|
| Itopride Hydrochloride | 10 | 5 | 14.90 | 99.35 | 99.366 ± 0.225 |
| | 10 | 10 | 19.92 | 99.60 | |
| | 10 | 15 | 24.79 | 99.15 | |

*Avg. of three determinations

Note

## ACKNOWLEDGMENT

The authors thank to Burgeon Pharmaceutical Pvt.Ltd., Pondicherry for providing gift sample of itopride hydrochloride.

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