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High performance liquid chromatographic of Itopride hydrochloride in tablet dosage form

B. CHOUDHARY*, A. GOYAL[1] and S.K. KHOKRA

Institute of Pharmaceutical Sciences, Kurukshetra University, Kurukshetra - 136 119 (India).
[1]Bhupal Nobels College of Pharmacy, Udaipur - 313 002 (India).

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ABSTRACT

A simple, economical, precise and fast High Performance Liquid Chromatograhic method has been developed for the determination of itopride hidrochloride in tablet dosage form. A phenomenex C18 (Luna) column of length 250 × 7.5 mm with particle size of the stationary phase 5 µm and mobile phase potassium dihydrogen phosphate buffer (pH adjusted to 7.5 with 1M Sodium hydroxide) and acetonitrile in the ratio 60:40 were used in this study. The flow rate was adjusted to 2ml /min and effluent was monitored at 258.0 nm. The proposed method describes the determination of itopride hydrochloride by HPLC, which is a simple, precise and selective.

Key words: HPLC, Itopride hydrochloride, Domperidone.

It is a hydrochloride salt of N-{[4-2-dimethylamino ethoxy) phenyl] methyl]}-3,4-dimethoxy-benzamide. It is used as anti emetic drug. It is not official in I.P. and Merck Index and has been launched in the market recently. Different[2-5] types of HPTLC and spectrophotometry methods have been reported for its estimation from tablet formulation but nobody has reported its estimation with HPLC method. So, a successful attempt has been made to estimate itopride hydrohcloride by high performance liquid chromatography.

A high performance liquid chromatograph {Shimadzu HPLC class VP series) with two LC-10 ADVP double reciprocating plunger pump, LC-10 ADVP UV-visible spectrophotometric detector and Shimadzu 1700 spectrophotometer was used. The chemicals used were of HPLC grade. Commercially available tablets of itopride hydrochloride procured from local market. Gift sample of standard itopride hydrochloride drug was procured from Abbott India Ltd.

Preparation of standard solutions and its analysis

The mobile phase used in this study was potassium dihydrogen phosphate buffer (pH adjusted to 7.5 with 1M sodium hydroxide) and acetonitrile in the ratio 60:4. Standard stock drug solutions of itopride hydrochloride and domepridone in concentrtions of 100 µg/ml each were prepared separately in mobile phase. To record the calibration curbe, Itopride hydrochloride standard stock drug solution in volume ranging from 1.0 to 6.0 ml was transferred to a series of 10 ml volumetric flasks. Then, in each flask 1.0ml of domperidone standard stock solution was added and volume make up to the mark with mobile phase. Each solution was injected after filtraiton through 0.2 µ membrance filter and chromatogram was recorded. The calibraiton curve was plotted between concentration of drug and ratio of peak area of itopride hydrochloride and domperidone (as internal standards). The flow rate was maintained at 2ml/min. Temperature of column was kept at ambient and the effluent was monitored at 258.0 nm. A mixed standard dilution of pure drugs containing 30µg/m of itopride hydrochloride and domperidone 10µg/ml respectively was prepared in mobile phase, filtered through 0.2µ membrane filter and loaded in injection port of instrument fitted with 20µl fixed volume loop. The solution was injected three times and chromatogram recorded.

Linearity study was carried out at different concentrations, and it was found to be linear in concentration range of 10-60 µg/ml. On the basis of above, it was clear that calibration curves could be represented by the following.

$$Y=0.9565x \{r^2 = 0.9996\}$$

Estimation from tablets

Twenty tablets were accurately weighted

Table 1: Recovery studies

S.No	Formulation (µg/ml)	Amount added (µg/ml)	Amont recovered	% Recovery
1.	40	05	44.60	99.11
2.	40	10	50.35	100.70
3.	40	15	54.92	99.85

Table 2: Analysis of commercial formulations of Itopride hydrochloride

Formulation (Tablet)	Label Claim (mg)	Label claim estimated Mg	%	Standard deviation	Relative Standard deviation	Coefficient of variance
A	50	50.04	100.08	0.3035	0.00307	0.3070
B	50	49.89	99.78	0.5317	0.00539	0.5394

and average weight per tablet determined. Powdered the tablets and power equivalent to 10mg of itopride hydrochloride was accurately weighted and tranferred to 100 ml volumetric flask containing 75ml of mobile phase. To the same volumetric flask 2.5mg accurately weighted pure sample of domperiodone was added. The powder mixture was dissoved in mobile phase with the aid of sonicator. The solution was filtered through Whatman filter paper no. 41 into anotehr 100ml volumetric flask and make up the volume to the mark with mobile phase. The solution was then again filtered through 0.2µ membrance filter. Eight miillimeters of this solution was further diluted to 10 ml with mobile phase and chromatogram was recorded.

To study the acccuracy, reproducibility and precision of proposed method, recovery studies were also carred out. On teh basis of values of coefficient of variance (0.3070-0.5394), standard deviation (0.3035-0.5317) and relative standard deviation (0.003007-0.00539) for itopride hydrochloride the method was found to be highly precised. A fixed amount of preanalysed sample was taken and stadard drug was added at three different levels. Each level was repeated at least three times. The summaries of recovery studies and reported in table 1.

The present study comprises a high performance liquid chromatographic method to determine itopride hydrochloride from tabet dosage forms. The mobile phase bearing potassium dihydrogen phosphate buffer and acetonitrile (60:40) was found to be ideal. The elution was observed (Mean Retention Time = 6.61min) as shown in figure 1. The values of percentage recovery and standard deviation indicate that the method is accurate, precise and reproducible. The summaries of the results of marketed formulatoin are illusrated in table 2.

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