High performance liquid chromatographic of Itopride hydrochloride in tablet dosage form

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(Received: January 02, 2009; Accepted: February 22, 2009)

ABSTRACT

A high performance liquid chromatographic method has been developed for the determination of itopride hydrochloride in tablet dosage form. A phenomenex C18 (Luna) column of length 250 x 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.

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 domperidone in concentrations of 100 µg/ml each were prepared separately in mobile phase. To record the calibration curve, 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 filtration through 0.2 µ membrane filter and chromatogram was recorded. The calibration 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/ml 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.

\[ Y = 0.9565x \quad \left( r^2 = 0.9996 \right) \]

Estimation from tablets

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

To study the accuracy, reproducibility and precision of proposed method, recovery studies were also carried out. On the 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 standard 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 tablet 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 formulation are illustrated in table 2.

ACKNOWLEDGEMENTS

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

REFERENCES