High Performance Liquid Chromatographic Estimation of Ciprofloxacin Hydrochloride and Tinidazole from Tablets

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A new precise, selective and accurate reverse phase high performance liquid chromatographic method for simultaneous estimation of tinidazole and ciprofloxacin hydrochloride from their tablets has been developed. This chromatographic method utilises a 12.5 cm Nucleosil 100-5C_{18} bonded phase column with a mobile phase consisting of acetonitrile:methanol:0.002 M phosphoric acid (20:30:50) at a flow rate of 1.2 ml/min. Caffeine was used as the internal standard. Results of analysis gave standard deviation values below 1.5 and recovery study values between 98 to 103 per cent. Thus the method is suitable for routine analysis of multicomponent formulations of these two drugs.

Tinidazole (TZ) is an antiprotozoal and antibacterial drug. Ciprofloxacin hydrochloride (CH) is a fluroquinolone antimicrobial agent with potent activity against a broad spectrum of bacteria. The formulations containing these two drugs are used for treatment of diarrhoea and dysentery of amoebic, bacterial or mixed origin. The IP and the USP describe high performance liquid chromatographic (HPLC) methods[1,2] for the estimation of CH from its formulations while IP describes a ultraviolet spectrophotometric method[3] for the estimation of TZ. Few colorimetric[4-6] and HPLC[7,8] methods for the analysis of CH in formulations have been cited. Three colorimetric methods[9-11] have been reported in literature for analysis of bulk drug as well as dosage forms containing TZ. A difference spectrophotometric method[12] for estimation of TZ and diloxanide furoate, a polarographic method[13] for estimation of TZ and furazolidone and a HPLC method[14] for estimation of TZ and norfloxacin from their multicomponent formulations have also been reported.

However, there is no method reported for simultaneous analysis of TZ and CH from combined dosage forms. Therefore, it was thought worthwhile to develop a HPLC method for rapid and accurate estimation of TZ and CH from their combined tablets.

An isocratic Spectra Physics HPLC with a 5µ Nucleosil 100-C_{18} (125x4 mm) column was used for this work. A mobile phase consisting of acetonitrile: methanol:0.002 M phosphoric acid (20:30:50) was employed at a flow rate of 1.2 ml/min to achieve resolution of TZ and CH along with the internal standard caffeine (CF). The ultraviolet detector was monitored at 278 nm. Using a flow rate of 1.2 ml/min, CF, CH and TZ were eluted at 2.18, 5.33 and 6.45 min respectively. Resolution factor for CF and CH was 4.26 while that for CH and TZ was 1.69. Standard curves for TZ and CH in the range of 100 to 500 µg/ml were generated by plotting the peak area ration (area of drug peak/area of internal standard peak) against the concentration of the respective drugs in their standard solutions.

Twenty tablets of each formulations were crushed and ground to a fine powder. Power equivalent to 25 mg of CH was transferred to a 100-ml volumetric flask containing about 75 ml of the mobile phase. To this volumetric flask, 25 mg of pure standard caffeine was added. The powder mixture was dissolved that the volume was made upto the mark with the mobile phase. This solution was first filtered through whatman filter paper no. 41 and then through a 0.4 micron membrane filter.

After setting the chromatographic conditions and stabilizing the instrument to obtain a steady baseline, 10 µl of the sample solution was injected and a chromatogram was recorded. The concentrations of the two drugs were obtained from the standard curves using the peak area

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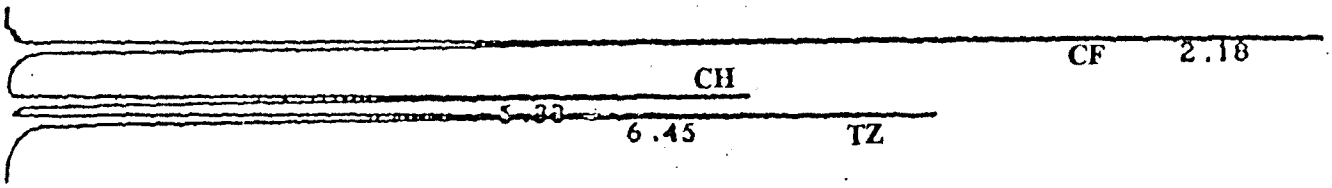

Fig. 1 : Chromatogram of commercial Formulation

The peak with retention time of 2.18 min is caffeine (CF) and the peaks at 5.33 and 6.45 min represent ciprofloxacin hydrochloride (CH) and tinidazole (TZ), respectively.

Table 1 - Results of Analysis of Commercial formulations

Analyte	Label Claim mg/tab		% Estimated±Standard Deviation		Standard Error	
	TZ	CH	TZ	CH	TZ	CH
Tablet-A	600	500	100.22±1.164	100.18±1.474	0.520	0.659
Tablet-B	600	500	100.27±1.415	100.26±0.905	0.632	0.404

*Average of five estimations

TZ and CH represent tinidazole and ciprofloxacin hydrochloride, respectively.

ratio of each drug to the internal standard. A resolved chromatogram of the sample solution is given as Figure 1.

Results of analysis of the formulations are tabulated in table-1. To a preanalysed tablet sample solution different volumes of a mixed standard solution containing 250 µg/ml each of CF, TZ and CH were added and these solutions were chromatographed for carrying out recovery studies. Recovery studies gave results between 98.3 and 102.4 per cent.

The standard deviation and standard error values presented in table-1 along with the results of recovery studies conform that the proposed method is accurate and reproducible in addition to being simple and rapid. Thus the method can be easily and conveniently adopted for the routine quality control analysis of formulations containing TZ and CH.

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REFERENCES

1. Indian Pharmacopoeia, Vol I, The Controller of Publications, New Delhi, 1996, 190.
2. United States Pharmacopoeia, United States Pharmacopoeial Convention, 1995, 379.
3. Indian Pharmacopoeia, Vol I The Controller of Publications, New Delhi, 1996, 764.
4. Shanbag, S.G. Thampi, P.P. and Thampi, C.S., **Indian Drugs**, 1991, 28, 279.
5. Ramanarao, G., Avadhanulu, A.B. and Vatsa, D.K., **Indian Drugs**, 1990, 27, 532.
6. El Walily, A.F.M. Belal, S.F. and Bakry, R.S., **J. Pharm. Biomed. Anal.**, 1996, 14, 561.
7. Parasrampuria, J. and Das Gupta, V., **Drug Dev. Ind. Pharm.**, 1990, 16, 1597.
8. Lacroix, P.M., Curran, N.M. and Sears, R.W., **J. Pharm. Biomed. Anal.**, 1996, 14, 641.
9. Sanghavi, N.M., Joshi, N.G., and Saoji, D.G., **Indian J. Pharm Sci.**, 1979, 41, 226.
10. Devani, M.B., Shishoo, C.J., Doshi, K. and Shah, A.K., **Indian J. Pharm. Sci.**, 1981, 43, 151.
11. Kamalapurker, O.S. and Menezes, C., **Indian Drugs**, 1984, 22, 164.
12. Parimoo, P. and Umapathi, P., **Drug Dev. Ind. Pharm.**, 1994, 20, 2143.
13. Joshi, D.M. and Joshi, A.P., **Indian Drugs**, 1996, 33, 338.
14. Ghosh, S.K. and Banerjee, M., **Indian Drugs**, 1996, 33, 127.