

Application of Orange G Dye for Quantitation of Citalopram Hydrobromide, Donepezil Hydrochloride and Rabeprazole Sodium from Tablet Formulation

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Three simple, rapid and accurate visible spectrophotometric methods have been developed using Orange G dye for the quantitative estimation of citalopram hydrobromide, donepezil hydrochloride and rabeprazole sodium from respective tablet formulations. These developed methods are based on formation of chloroform-extractable coloured complex of drug and dye. The extracted coloured complex shows absorption maxima at 476 nm and linearity in the concentration range of 10-50 µg/ml for citalopram hydrobromide (method I); at 482 nm and linearity in the concentration range of 5-35 µg/ml for donepezil hydrochloride (method II) and at 477.4 nm with linearity in the concentration range of 10-70 µg/ml for rabeprazole sodium (method III). The results of analysis for all three developed methods were validated statistically and by recovery studies.

Citalopram hydrobromide, chemically 1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-5-iso-benzofuran-carbonitrile hydrobromide, is a recently developed antidepressant drug¹. Few analytical methods

for estimation of citalopram hydrobromide from biological fluid, including GC², GLC³, HPLC⁴⁻⁵ and capillary liquid chromatography⁶, are reported. Donepezil hydrochloride, chemically 2,3-dihydro-5,6-dimethoxy-2-[[1(phenylmethyl)-4-piperidinyl]methyl]-1-H-inden-1-one hydrochloride, is a recently developed anti-Alzheimer drug⁷. Few analytical methods for estimation of donepezil hydrochloride from

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biological fluid, including LC⁸ and HPLC⁹⁻¹¹, are reported.

Rabeprazole sodium, chemically 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole sodium, is the latest proton pump inhibitor¹² and is used in the management of acid-related disorders. Few analytical methods for estimation of rabeprazole sodium, including HPLC¹³, LC-MS¹⁴ and capillary electrophoresis¹⁵, are reported.

In the present work, simple and sensitive visible spectrophotometric methods have been developed using Orange G dye for the estimation of citalopram hydrobromide, donepezil hydrochloride and rabeprazole sodium in the respective tablet dosage forms.

A Systronics UV/Vis double beam spectrophotometer (model 2101) with 1 cm matched quartz cells was used for spectral analysis. All the chemicals used were of analytical grade. Orange G dye (Thomas Baker) solution (0.3% w/v) was prepared in potassium chloride-hydrochloric acid buffer pH 1.2 and extracted several times with chloroform (Qualigens) so as to remove chloroform-soluble impurities. Double-distilled water was used for the preparation of buffer and standard stock solution for all the three drugs.

The tablet samples of citalopram hydrobromide (Celica 10, Ranbaxy Laboratories; Citalop 20, RPG Life Sciences), donepezil hydrochloride (Donecept 5, Protec; Dopezil 10, Ranbaxy Laboratories) and rabeprazole sodium (Rabeloc 10, Cadila; Veloz 20, Torrent) were procured from the local pharmacy.

For method I, in a series of 10 ml volumetric flasks, aliquots of standard drug solution of citalopram hydrobromide (100 µg/ml) in distilled water were transferred and diluted with the same so as to give several dilutions in the concentration range of 10-50 µg/ml of drug. To each dilution (5 ml) taken in a separating funnel, 5 ml of Orange G solution was added, shaken and allowed to stand for 10 min for the formation of coloured complex. The coloured complex was extracted with 5, 3, 2 ml portions of chloroform, the volume of combined chloroform layer was made up to 10 ml and absorbance was measured at 476 nm against a reagent blank. A calibration curve was prepared by plotting concentration versus absorbance.

For method II, in a series of 10 ml volumetric flasks, aliquots of standard drug solution of donepezil

hydrochloride (100 µg/ml) in distilled water were transferred and diluted with the same so as to give several dilutions in the concentration range of 5-35 µg/ml of drug. To each dilution (5 ml) taken in a separating funnel, 5 ml of Orange G solution was added, shaken and allowed to stand for 10 min for the formation of coloured complex. The coloured complex was extracted with 5, 3, 2 ml portions of chloroform, the volume of combined chloroform layer was made up to 10 ml and absorbance was measured at 482 nm against a reagent blank. A calibration curve was prepared by plotting concentration versus absorbance.

For method III, in a series of 10 ml volumetric flasks, aliquots of standard drug solution of rabeprazole sodium (100 µg/ml) in distilled water were transferred and diluted with the same so as to give several dilutions in the concentration range of 10-70 µg/ml of drug. To each dilution (5 ml) taken in a separating funnel, 5 ml of Orange G solution was added, shaken and allowed to stand for 10 min for the formation of coloured complex. The coloured complex was extracted with 5, 3, 2 ml portions of chloroform, the volume of combined chloroform layer was made up to 10 ml and absorbance was measured at 477.4 nm against a reagent blank. A calibration curve was prepared by plotting concentration versus absorbance.

For analysis of formulation, 20 tablets each of citalopram hydrobromide (method I), donepezil hydrochloride (method II) and rabeprazole sodium (method III) were accurately weighed and average weight per tablet was determined. The tablets were powdered separately and powder equivalent to 20 mg for each drug was accurately weighed and was extracted four times with 20 ml portions of distilled water. The combined extract was filtered through Whatman filter paper no. 41 into 100 ml volumetric flask. The residue was washed with distilled water and the washings were added to the filtrate. Final volume of filtrate was made up to the mark with distilled water.

For method I and II, 1 ml of filtrate was diluted to 10 ml with distilled water. This was treated as per the respective procedure for the calibration curve, and amount of drug present in the sample was computed from respective calibration curve. For method III, 2 ml of filtrate was diluted to 10 ml with distilled water. This was treated as per the respective procedure for the calibration curve, and amount of drug present in the sample was computed from respective calibration curve.

TABLE 1: ANALYSIS OF TABLET FORMULATION

Method	Drug	Formulation	Label claim mg/tab	% of label claim estimated*	Standard deviation	% recovery**	Standard deviation
I	Citalopram	Tablet 1	10	99.56	0.421	100.2	0.557
	Hydrobromide	Tablet 2	20	99.73	0.411	99.86	0.532
II	Donepezil	Tablet 1	5	98.90	0.598	99.96	0.601
	Hydrochloride	Tablet 2	10	99.23	0.569	100.1	0.582
III	Rabeprazole	Tablet 1	10	99.56	0.568	99.22	0.521
	Sodium	Tablet 2	20	99.66	0.549	99.24	0.505

*Average of five determinations. **Average of determinations at three different concentration levels.

All the three developed methods were repeated five times for two different strengths of tablet formulations. Results of analysis are reported in Table 1. Recovery studies were carried out for all the three developed methods by addition of known quantity of pure drug sample to preanalyzed tablet sample solution at three different concentration levels. The result of recovery studies is reported in Table 1.

The proposed spectrophotometric methods for determination of citalopram hydrobromide, donepezil hydrochloride and rabeprazole sodium from tablet formulation are based on formation of chloroform-extractable coloured complex of drug with Orange G dye. The pH required for visible spectrophotometric methods was optimized at pH 1.2. The results of analysis for all three developed methods were close to 100% and standard deviation was satisfactorily low, indicating accuracy and reproducibility of the methods. Recovery studies were satisfactory, which shows that there is no interference from excipients. The developed methods were found to be simple, rapid, accurate and can be used for routine analysis of drug from tablet formulations.

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REFERENCES

- Budvari, S., Eds., In: The Merck Index, 12th Edn., Merck and Co., Inc., Whitehouse Station, NJ, 1996, 391.
- Eap, C.B., Bouchoux, G., Amey, M. and Cochard, N., *J. Chromatogr. Sci.*, 1998,36, 365.
- Martinez, M.A., Sanchez, C., Tarrae, C. and Almarza, E., *J. Anal. Toxicol.*, 2004, 28, 174.
- Macek, J., Ptecek, P. and Klima, J., *J. Chromatogr. B. Biomed. Sci. Appl.*, 2001, 755, 79.
- Olesen, O.V. and Linnet, K., *J. Chromatogr. B. Biomed. Sci. Appl.*, 1996, 675, 83.
- Molander, P., Thomassen, A., Kristoffersen, L. and Greibrokk, T., *J. Chromatogr. B. Anal. Technol. Biomed. Life Sci.*, 2002, 766, 77.
- Gilman, A.G., In: The Pharmacological Basis Of Therapeutics, 10th Edn., 179.
- Matsui, K., Oda, Y., Nakata, H. and Yoshimura, T., *J. Chromatogr. B. Biomed. Sci. Appl.*, 1999, 72, 147.
- Pappa, H., Farru, R., Vilanova, P.O., Palacios, M. and Pizzorno, M.T., *J. Pharm. Biomed. Anal.*, 2002, 27, 177.
- KrishnaReddy, K.V.S.R., MosesBabu, J., Kumar, P.A., Chandrshakar, E.R.R. and Reddy, M.S., *J. Pharm Biomed. Anal.*, 2004, 72, 214.
- Christa, F.N., Kumar, D., Carlos, A. and Suman Wason., *Brit. J. Clin. Pharmacol.*, 2004, 47, 241.
- Budvari, S., Eds., In: The Merck Index, 12th Edn., Merck and Co., Inc., White house Station, NJ, 1996, 1392.
- El-Gindy, A., El- Yazby, F. and Maher, M.M., *J. Pharm. Biomed. Anal.*, 2003, 31, 229.
- Chung, E.W., Ho, E.N.M., Leung, D.K.K., Tang, F.P.W., Yiu, K.C.H. and Wan, T.S.M., *Chromatographia.*, 2004, 59, 29.
- Tivesten, A., Folestad, S., Schonbacher, V. and Svensson, K., *Chromatographia.*, 1999, 49, 7.

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