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NOTE

UV Spectrophotometric Determination of Clopidogrel and Repaglinide

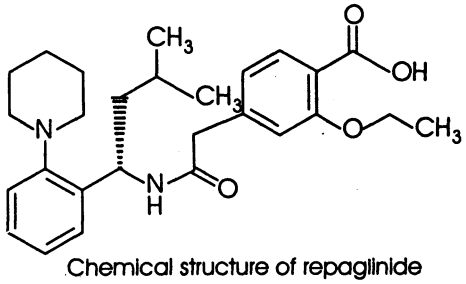
D. GOWRI SANKAR*, S. KALYAN SUMANTH, A.K.M. PAWAR and P.V. MADHAVI LATHA

Department of Pharmaceutical Sciences
Andhra University, Visakhapatnam-530 003, India

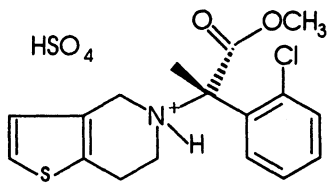
Simple and sensitive UV spectrophometric methods have been developed for the determination of clopidogrel and repaglinide in pure and pharmaceutical formulations. These methods obey Beer's law in the concentration ranges 10–60 and 5–25 μg/mL exhibiting maximum absorption at 225 and 220 nm respectively. The methods were extended to pharmaceutical formulations and there was no interference from common pharmaceutical additives and excepients.

Key Words: UV spectrophotometric estimation, Clopidogrel, Repaglinide.

Chopidogrel (CPD) is an antiplatelet agent and chemically is alpha-(4,5,6,7-tetrahydrothieno [3,2-c]pyrid-5-yl) (2-chlorophenyl)methyl acetate hydrogen sulphate. The chemical formula is $C_{16}H_{16}ClNO_2S{\cdot}HSO_4$. Repaglinide (RPG) is an anti-diabetic agent. Chemically RPG is, 2-ethoxy-4-[2-[[3-methyl-1-[2-(1-piperidinyl)phenyl]butyl]amino]-2-oxoethyl] benzoic acid. An LC-ionisation electrospray method[1] is reported for clopidogrel. A few HPLC methods[2, 3] have been reported for repaglinide. Literature survey reveals that no visible and UV methods are reported for the estimation of CPD and RPG. An attempt has been made to develope the two simple, accurate and reliable UV spectrophotometric methods for the estimation of CPD and RPG in pure as well as in pharmaceutical dosage forms.



Chemical structure of repaglinide



Chemical structure of clopidogrel bisulphate

All the chemicals used were of analytical grade. Spectral and absorbance measurements were made on Systronics UV-Visible spectrophotometer-117 with 10 mm matched quartz cells.

Preparation of standard and sample solutions: Accurately weighed 100 mg of CPD was dissolved in 100 mL of distilled water. The stock solution was further diluted with distilled water to obtain a working standard of 200 μg/mL.

An accurately weighed tablet powder of CPD equivalent to 100 mg of drug was dissolved in 100 mL of distilled water and filtered. This solution was further diluted with distilled water to obtain a concentration of 200 μg/mL.

Accurately weighed 100 mg of RPG was dissolved in 5 mL of methanol and made up to 100 mL with distilled water. This stock solution was further diluted with distilled water to obtain a working standard solution of 100 μg/mL.

An accurately weighed tablet powder of RPG equivalent to 100 mg of drug was dissolved in 5 mL of methanol, made up to 100 mL with distilled water and filtered. This solution was further diluted with distilled water to obtain a concentration of 100 μg/mL.

Assay procedure for CPD and RPG: Aliquots of solution 0.5 to 3.0 mL (200 μg/mL for CPD or 100 μg/mL for RPG) were transferred into a series of 10 mL volumetric flasks and the volume was made up to 10 mL with distilled water. The absorbance was measured at 225 or 220 nm against a reagent blank. The amount of CPD or RPG present in the sample solution was computed from its calibration curve.

The Beer's law limits, Sandell's sensitivity, molar extinction coefficient, per cent relative standard deviation, regression equation, correlation coefficients, % range of error (0.05 and 0.01 confidence limits) are calculated and shown in Table-1.

Pharmaceutical formulations of clopidogrel and repaglinide were successfully analyzed by the proposed methods. The results obtained by the proposed methods are presented in Table-2. To evaluate the validity and reproducibility of the methods, known amounts of pure drug were added to previously reported pharmaceutical preparations and the mixtures were analyzed by the proposed methods and the results are presented in Table-2. Interference studies revealed that the common excepients and other additives usually present in the dosage form did not interfere in the proposed methods.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF THE PROPOSED METHODS

Parameter	CPD	RPG
λ_{max} (nm)	225	220
Beers law limit (μg/mL)	10–60	5–25
Sandell's sensitivity (μg cm^{-2}/0.001 absorbance unit)	0.083	0.025
Molar absorptivity (L mol^{-1} cm^{-1})	5.038×10^3	3.0173×10^4
Regression equation (Y = a + bC)		
Slope (b)	0.011	0.04
Intercept (a)	0.005	–0.005
Correlation coefficient (r)	0.9998	0.9999
Relative standard deviation (%)*	0.305	0.263
%Range of error (Confidence limits)*		
0.05 level	0.255	0.220
0.01 level	0.377	0.325

*Average of eight determinations

TABLE-2
ESTIMATION OF CPD AND RPG IN PHARMACEUTICAL FORMULATIONS

Sample	Labeled amount (mg)	Amount found (mg) in proposed method	Recovery (%)
Clopidogrel			
Tablet I	75.0	75.15	100.2
Tablet II	75.0	75.00	100.0
Repaglinide			
Tablet I	2.0	2.01	100.5
Tablet II	2.0	1.99	99.5

In conclusion, the proposed methods are most economic, simple, sensitive and accurate and can be used for the determination of CPD and RPG in bulk as well as in pharmaceutical preparations.

ACKNOWLEDGMENTS

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