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NOTE

UV Spectrophotometric Determination of Temozolamide and Gemcitabine

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A new simple and sensitive UV spectrophotometric methods have been developed for the determination of temozolamide and gemcitabine in pureform and pharmaceutical formulations. These methods exhibit maximum absorption at 333 and 268 nm, respectively and both the methods obey Beer's law in the concentration range of 4-20 μg/mL. The methods are accurate and precise and are extended to pharmaceutical formulations and there was no interference from any common pharmaceutical additives and excepients. The results of the analysis have been validated statistically and by recovery studies.

Key Words: UV spectrophotometric determination, Gemcitabine, Temozolamide.

Temozolamide (TMZ) is an anticancer drug, chemically known as imidazo[5,1-d]-1,2,3,5-tetrazine-8-carbozamide,3,4-dihydro-3-methyl-4-oxo. Gemcitabine (GMC) is also an anticancer drug, chemically known as cytidine,2´-deoxy-2´,2´-difluoro. Literature survey reveals that no spectrophotometric method to determine the TMZ and GMC has been reported so far, however, several HPLC methods have been developed for the estimation of TMZ[1-3] and GMC[4,5]. The two simple, accurate and reliable UV spectrophotometric methods have been developed for the estimation of TMZ and BMC in pure as well as in pharmaceutical dosage forms.

All the chemical 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 solution: Accurately weighed 100 mg of TMZ or GMC was dissolved in 100 mL of distilled water. the stock soution was further diluted with distilled water to obtain a working standard of 80 μg/mL for TMZ or GMC.

Preparation of sample solution: An accurately weighed capsule powder of TMZ 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 concentration of 80 μg/mL for TMZ or GMC.

Measured quantity of GMC vial equivalent to 100 mg of drug solution was diluted to 100 mL with distilled water. This solution was further diluted with distilled water to obtain the required concentration of 80 μg/mL.

Proposed methods for TMZ and GMC: Aliquots of solution 0.5 to 2.5 mL (80 μg/mL of TMZ or GMC) were transferred into a series of 10 mL volumetric flasks and the volume was brought upto mark with distilled water. The absorbance was measured at 333 nm for TMZ and 268 nm for GMC against a reagent blank. The amount of TMZ or GMC present in the sample solution was computed from its calibration curve.

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, percent relative standard deviation, (calculated from the eight measurements containing 3/4th of the amount of the upper Beer's law limits), regression equation, correlation coefficient, % range of error (0.05 and 0.01 confidence limits) were calculated and the results and summarized in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF THE PROPOSED METHOD

Parameter		TMZ	GMC
λ_{max} (nm)		333	268
Beer's law limits		4-20	4-20
Sandell's sensitivity (μg cm^{-2}/0.001 absorbance unit)		0.026	0.027
Molar absorptivity (L mol^{-1} cm^{-1})		7.25×10^3	1.104×10^4
Regression equation (Y = a + bC)	Slope (b)	0.0382	0.0372
	Intercept (a)	-0.0006	-0.0006
Correlation coefficient (r)		0.9999	0.9999
Relative standard deviation (%)*		0.8835	0.9134
% Range of error (Confidence limits)*	0.05 level	0.7387	0.7637
	0.01 level	1.0929	1.1290

* Average of eight determinations

To evaluate validity and reproducibility of the methods, known amounts of pure drug were added to previously 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 did not interfere. Hence, the method is economic, simple, sensitive and accurate and can used for the routine determination of TMZ or GMC in bulk form as well as in pharmaceutical preparations.

TABLE-2
ESTIMATION OF TMZ AND GMC IN PHARMACEUTICAL FORMULATIONS

Sample	Labelled Amount (mg)	Amount Found (mg) Proposed method	Recovery (%)
Temozolamide			
Capsule I	20	20.1	100.5
Capsule II	20	19.9	99.7
Gemcitabine			
Vial I	200	199.4	99.7
Vial II	200	200.8	100.4

*Recovery amount was the average of five determinations.

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