Asian Journal of Chemistry Vol. 14, No. 2 (2003), 1146–1148

NOTE

A Simple and Rapid Spectrophotometric Determination of Dapsone and its Dosage forms

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A new spectrophotometric method was developed for estimation of dapsone. The method was based on the bromination of dapsone with a solution of excess brominating mixture. After bromination, the excess brominating mixture was treated with potassium iodide to obtain a yellow coloured solution. The absorbance of the yellow coloured solution was measured at 350 nm on Spectronic 1001 spectrophotometer against distilled water as blank. The method obeys Beer's law ranging from 40–200 μg/mL.

Key Words: Spectrophotometric, Dapsone, Dosage forms.

Dapsone bis(4-aminophenyl) sulphone, is used in the treatment of leprosy caused by *Mycobacterium leprae*. The survey of literature for the estimation of dapsone includes spectrophotometric[1–4] and calorimetric methods[5, 6].

The method was based on bromination of the respective drug with brominating mixture. At this stage, bromine was liberated from the brominating mixture. The liberated bromine undergoes bromination with a drug. The excess brominating mixture was treated with potassium iodide solution. The yellow coloured solution formed was measured at 350 nm against distilled water as blank.

Instrument: A Milton Roy 1001 Plus spectrophotometer with 10 mm matched quartz cells was used for absorbance values of dapsone.

Reagents: All chemicals used were of analytical grade and all of the solutions were freshly prepared with double distilled water. 4N hydrochloric acid was prepared and standardized with standard procedure. Potassium iodide (0.1 N) was prepared by dissolving 0.166 g in 100 mL distilled water.

Brominating mixture solution (0:1 N): 0.695 g of potassium bromate and 1.75 g of potassium bromide were dissolved in distilled water and diluted to 100 mL. Further dilution is done to obtain the working concentration of 0.02 N brominating mixture solution.

Stock solution: 100 mg of pure dapsone was dissolved in 0.1 N hydrochloric acid and diluted to 100 mL with 0.1 N hydrochloric acid. This stock solution was further diluted to get desirable working concentration of 200 μg/mL.

Procedure: Aliquots of 0.2, 0.4, 0.6, 0.8 and 1.0 mL of the drug solution were transferred into a series of 25 mL standard flasks. To each flask, 1 mL of 4 N hydrochloric acid and 1 mL of 0.02 N brominating mixture were added. The flasks were shaken well and kept aside for 5 min for complete bromination. Then 0.1 N potassium iodide was added to each flask and diluted to 25 mL with distilled water. The yellow coloured solution formed was measured at 350 nm against distilled

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water as blank. The amount of drug present in the sample was read from the calibration curve. The calibration curve was found to be linear over a concentration range of 40–200 μg/mL. The results are presented in Table-1.

TABLE-1
DETERMINATION OF DIFFERENT BATCHES OF DAPSONE IN PHARMACEUTICAL FORMULATIONS

S. No.	Batches	Labelled amount (mg)	Amount found in mg		Per cent recovery
			Proposed method	Official method	
1	I	100	99.86	99.70	99.8
2	II	100	99.74	99.65	99.7
3	III	100	100.03	99.80	100.0
4	IV	100	99.96	100.2	100.2

The method was then applied to the determination of the drug from the marketed formulations. Tablets were weighed and contents well mixed and the powder equivalent to 50 mg of dapsone was dissolved in 0.1 N hydrochloric acid, filtered, the residue was washed with distilled water and the volume was adjusted to 50 mL with 0.1 N hydrochloric acid solution. This solution was further diluted stepwise with distilled water to get working concentration of 200 μg/mL and analyzed under procedure described in above recommended procedure.

Recovery: In order to study the accuracy and suitability of the proposed method, known quantities of dapsone were added to the previously analyzed samples and the same mixtures were reanalyzed by the proposed method. The percentage recovery was calculated and the results are given in Table-1.

The present study was carried out to develop a simple, rapid, precise and reproducible spectrophotometric method for the estimation of dapsone in pharmaceutical formulations. Dapsone in slightly acidic conditions undergoes bromination with brominating mixture. After bromination was completed, the excess brominating mixture was treated with potassium iodide to form yellow coloured complex of potassium iodate having maximum colour sensitivity and stability. The experimental conditions were optimized by studying the effect of brominating mixture, hydrochloric acid, potassium iodide and sequence of addition. The recovery stndies conducted by addition of different amounts of pure drugs to a reanalyzed tablet sample solution and data are tabulated in Table-1. The recovery values were close to 100 per cent indicating the accuracy of the method. The statistical analysis of various parameters was studied and the results are summarized in Table-2. The values of standard deviation and coefficient of variation were satisfactorily low, indicating the reproducibility of the method. The data of assay values of commercial formulations is subjected to statistical evaluation for Student's 't' test to study the proposed method. The 't' values are less than 't' theoretical with 4 degrees of freedom at 5 per cent level of significance indicating that there is no significant difference between proposed method and reference method.

TABLE-2
STATISTICAL ANALYSIS OF ESTIMATION OF DAPSONE

S. No.	Sample	Labelled amount (mg)	Standard deviation	Coefficient of variation	t_{cal}	t_{tab}
1	I	100	0.2495	0.2498	0.9723	2.132
2	II	100	0.4496	0.4506	1.0019	
3	III	100	0.1699	0.1686	0.3062	
4	IV	100	0.2494	0.2495	0.2779	

Average of three determinaations based on the label claim.
t_{tab} = tabulated value or theoretical value.

The proposed spectrophotometric method was found to be simple, precise, highly accurate and less time consuming. Hence it is a preferred method for routine analysis of estimation of dapsone in tablet dosage forms.

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(*Received*: 22 December 2002; *Accepted*: 22 January 2003) AJC-2996