

NOTE

Spectrophotometric Determination of Dapsone from Pharmaceutical Preparations

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A simple spectrophotometric method for determination of dapsone was developed by diazotization of drug followed by addition of ammonia solution. The absorbance of the yellow colour solution developed was measured at 445 nm on Spectronic-1001 spectrophotometer. Beer's law is obeyed in the concentration range of 0.2-0.6 mg/mL at the wavelength of maximum absorption. Results of analysis were validated statistically and by recovery studies. The method is successfully employed for the determination of dapsone in various pharmaceutical preparations.

Key Words: Spectrophotometric determination, Dapsone.

Dapsone [bis(4-amino phenyl)sulphone] is used in the treatment of leprosy caused by *Mycobacterium leprae*. Few methods for the determination of dapsone have been reported. These includes spectrophotometry¹⁻⁴ and colorimetry^{5, 6}. The aim of the present work was to develop a simple spectrophotometric method with greater precision, accuracy and sensitivity for the determination of dapsone in bulk and tablets. In this method, the drug was reacted with sodium nitrite in acidic medium at 0-5°C for diazotization. After diazotization, the diazotized drug was treated with 1 : 10 ammonia-water solution. The yellow colour formed was measured at 445 nm against reagent blank prepared in similar manner omitting drug solution.

Milton Roy Spectronic-1001 spectrophotometer with 10 mm matched quartz cells was used in the present investigation for electronic spectral measurements.

All analytical grade chemicals were used. Solution of 0.1 N sodium nitrite was prepared by dissolving 0.66 g of sodium nitrite in 100 mL of distilled water and 0.1 N solution of hydrochloric acid was standardized with standard procedure. 1 : 10 Ammonia- water solution was prepared by usual way. Distilled water was used to prepare all solutions.

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Preparation of standard dapsone solution

Dapsone (100 mg) was weighed accurately and transferred to 100 mL volumetric flask. It was dissolved in 100 mL of 0.1 N hydrochloric acid solution and adjusted to the mark with 0.1 N hydrochloric acid solution. It was further diluted with distilled water to obtain the final concentration 200 $\mu\text{g}/\text{mL}$ of dapsone.

Preparation of Calibration Curve

The following procedure was adopted for obtaining the standard curve. In a series of 10 mL volumetric flasks, aliquots of dapsone solution (1.0, 1.5, 2.0, 2.5 and 3.0 mL) were placed. The volume in each flask was brought to 3 mL with distilled water. To these solutions, 1 mL of 0.1 N hydrochloric acid solution and 1 mL of cold solution of 0.1 N sodium nitrite were added with swirling. The resultant solution in each flask was allowed to stand for 5 min at 0-5°C temperature for diazotization. The solutions were swirled and allowed to stand for 5 min. Then 1 mL of 1 : 10 ammonia-water solution was added to each flask. The solutions was made up to the mark with water, mixed thoroughly and after 5 min the absorbance of the yellow-coloured solution was measured at 445 nm against the corresponding reagent blank and calibration graph was constructed. The calibration curve was found to be linear over the concentration range of 0.2 to 0.6 mg/mL of dapsone. The amount of dapsone was computed from the corresponding calibration graph.

Determination of Dapsone in Formulations

The method was then applied to the determination of the drug from the market tablet 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, 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 $\mu\text{g}/\text{mL}$. In a series of 10 mL volumetric flasks, aliquots of dapsone solution (1.0, 1.5, 2.0, 2.5 and 3.0 mL) were placed. The volume in each flask was brought to 3 mL with distilled water. To these solutions, 1 mL of 0.1 N hydrochloric acid solution and 1 mL of cold solution of 0.1 N sodium nitrite were added with swirling. The resultant solution in each flask was allowed to stand for 5 min at 0-5°C temperature for diazotization. The solutions were swirled and allowed to stand for 5 min. Then 1 mL of 1 : 10 ammonia-water solution was added to each flask. The solution was made upto the mark with water and analyzed under procedure as described for pure dapsone.

Recovery Experiment

In order to study the accuracy and suitability of the proposed method, known quantity of dapsone was added to the previously analysed samples and the same mixture were reanalyzed by the proposed method. The results are tabulated in Table-1.

The present study was carried out to develop a simple, sensitive, precise and

reproducible spectrophotometric method for the analysis of dapsone in pharmaceutical tablet dosage forms. Few commercial tablets were analysed by proposed and official methods. The data is presented in Table-1. The results obtained by the proposed method and the official method are in good agreement, indicating that the proposed method can be successfully applied to the analysis of various pharmaceutical formulations of dapsone. Statistical analysis was carried out and the results are presented in Table-2. Statistical data of standard deviation and coefficient of variation clearly indicate the high accuracy and reproducibility of the method. The method is simple and sensitive and can be applied for routine quantitative estimation of dapsone in its formulations.

TABLE-1
ASSAY OF DIFFERENT BATCHES OF DAPSONE TABLET DOSAGE FORMS

Batches	Labelled amount (mg/tablet)	Amount found in mg		% Recovery*
		Proposed method*	Official method*	
1	100	99.13	99.00	99.80
2	100	100.20	99.80	99.60
3	100	99.76	99.40	100.40

*Average of five determinations based on label claim.

TABLE-2
STATISTICAL ANALYSIS OF ESTIMATION OF DAPSONE

Batches	Labelled amount	Standard deviation*	Coefficient of variation*
1	100	0.8055	0.8125
2	100	0.9848	0.9980
3	100	0.5131	0.5143

*Average of five determinations based on label claim.

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