Spectrophotometric Determination of Terbutaline Sulphate in Bulk and Dosage Forms

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Terbutaline sulphate on oxidation with sodium periodate in alkaline medium followed by treatment with acetylacetone produces yellow coloured chromogen with maximum absorbance and 412 nm. The Beer's-Lambert range observed is 20-160 µcg/ml of the reaction mixture. The calculated % RSD is ±1.61. The proposed method is applicable to the drug is pure powder form and to pharmaceutical dosage forms.

Terbutaline sulphate, (RS)-2-(tert-butylamino)-1-(3,5-dihydroxyphenyl) ethanol sulphate, is a beta$_2$ selective bronchodialator. It is official in Indian Pharmacopoeia 1996[1]. Various methods are reported for estimation of terbutaline sulphate in single and combined dosage forms. They include, colourimetric methods[2-7]. Reverse phase HPLC[8], gas-liquid chromatographic estimations[9] and fluorimetric estimation[10].

The present work deals with treatment of terbutaline sulphate with sodium periodate in alkaline medium followed by acetylacetone reagent to produce yellow coloured chromogen with maximum absorbance at 412 nm.

A UV/vis spectrometer with matched quartz cells of 1cm light path was used. All analytical reagent grade (AR) chemicals and reagents were used. Solution of 0.1 M sodium hydroxide and 0.01 M sodium periodate were prepared. Acetylacetone reagent solutions was prepared by dissolving 30 g of ammonium acetate in 50 ml water and to it 1 ml of freshly distilled acetylacetone was added. The final volume was adjusted to 100 ml with water. standard terbutaline sulphate of 1000 µcg/ml strength was prepared. For sample preparation of tablets, 20 tablets were weighed and powdered. Powder equivalent to 10 mg terbutaline sulphate was weighed and mixed with absolute ethanol (50 ml) and shaken throughly. The solution was filtered through a Whatman No. 40 filter paper. The residue was washed with absolute ethanol. The filtrate and washings were combined together in a 100 ml volumetric flask and diluted to the mark with the same solvent. The resulting solution (2.0) was analysed by recommended method. For ampoules, content of ten 1.0 ml ampoules, each containing 0.5 mg terbutaline sulphate was collected in a clean 50 ml beaker. The solution (2.0 ml) was analysed by the recommended method.

Standard drug solution containing 500-4000 µcg of terbutaline sulphate or 2.0 ml of the sample solution prepared from tablets or injection was pipetted into a series of volumetric flasks, each containing 1 ml of sodium hydroxide solution. Sodium periodate solution (2.0 ml) was added to each flask and reaction mixture was kept in a water bath maintained 50° for 10 min. The acetylacetone reagent solution (5.0 ml) was added to each flask and this mixture was immersed in a boiling water bath for 10 min. The flasks were cooled to room temperature and diluted to the mark with water. The absorbance of the yellow coloured solution was measured at 412 against blank. A graph of absorbance of the reaction mixture against concentration of the drug was plotted.

The proposed method is based on the oxidation of terbutaline sulphate with sodium periodate in alkaline

Table 1 - Optical Characteristics

1.	Beer's Law Limits	20-160 mcg ml^{-1}
2.	Molar absorptivity	1.290 x 103 Mole^{-1} cm^{-1}
3.	Regression equation,	
	Slope (b)	0.0037.
	Intercept	0.01
4.	Correlation coefficient	0.999

*For correspondence

Table 2 - Assay of Formulations

	Formulation	Labeled amount (mg)	Recovery (%) By Proposed Method.	Recovery (%) By Pharmacopoeial Method.
1.	Powder	—	99.8	99.6
2.	Table 1.	2.5	98.8	99.0
3.	Tablet 2.	2.5	97.9	97.5
4.	Injection	0.5	97.3	97.5

medium followed by reaction with acetylacetone reagent to give yellow coloured product having maximum absorbance at 412 nm. Various parameters involved in colour development such as concentration of sodium hydroxide, sodium periodate, acetylacetone temperature and time involved at various stages of reactions were optimized. Maximum colour intensity was obtained in boiling water bath after addition of acetylacetone reagent. They yellow coloured chromogen is stable for more than five hours.

The linear concentration range, molar absorptivity, the slope, intercept and correlation coefficient are shown in Table-1. The method was checked for precision by repeating the experiment nine times with the same quantity of drug. The percent relative standard deviation was found to be ±1.61.

The method has been applied for the analysis of terbutaline sulphate in bulk powder and in marketed formulations. The results are in good agreement with those obtained by the pharmacopoeial methods and match favourably with the labeled amount of the drug (Table-2). None of the usual excipients employed in the formulation of dosage forms interfere in the proposed method. The method is simple, rapid, precise and accurate. It is less time consuming and can be used for on line routine laboratory analysis.

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