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Assay of tolperisone by extractive spectrophotometry

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ABSTRACT

Two simple and sensitive visible spectrophotometric methods have been developed for the estimation of Tolperisone in pure and pharmaceutical dosage forms. These methods are based on the formation of ion-pair complexes of the drug with acidic dyes Solochrome Black T(SBT : λ_{max} 430 nm) and Methyl Orange(MO : λ_{max} 510 nm).The absorbance of the chloroform extracts is measured against the corresponding reagent blanks. The methods have been statistically evaluated and found to be precise and accurate.

Keywords: tolperisone, assay, spectrophotmetry

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INTRODUCTION

Tolperisone which is chemically 2-methyl-1-(4-methylphenyl)-3-(1-piperidyl)-propan-1-one [1] is a centrally acting muscle relaxant which acts by inhibiting voltage-gated sodium and calcium channels [2]. It is used to treat acute muscle spasms in back pain and spasticity in neurological disorders**.** A number of methods such as HPLC [3,4] and visible spectrophotometry [5] were reported for the estimation of Tolperisone, in its pure form and pharmaceutical formulations. Literature survey reveals that visible spectrophotometric methods have not been reported for its quantitative determination its pure form and pharmaceutical formulations. In the present investigation, two simple and sensitive visible spectrophotometric methods have been developed for the determination of Tolperisone. The developed methods involve the formation of colored extractable complexes with SBT and MO. Extractable complexes showed absorption maximum at 510 and 430 nm respectively. Beers law is obeyed in the concentration ranges of 5-10µg/ml and 2-8µg/ml respectively. The results of analysis for the two methods have been validated statistically and by recovery studies [6].

EXPERIMENTAL

Preparation of Reagents

1. Solochrome Black T Solution: 0.5 g SBT dye was dissolved in 100 ml of distilled water.
2. Methyl Orange Solution: 0.1g of MO dye was dissolved in 100 ml of distilled water.
3. Acid Phthalate Buffer pH 2.2 [I.P.]
4. Standard drug solution: About 100mg of Tolperisone was accurately weighed and dissolved in 100ml water to obtain a stock solution of 1mg/ml. This solution was further diluted with distilled water to get working standard solution of 100µg/ml.

Assay procedures

Method A: Aliquots of working standard solution of Tolperisone ranging from 0.5-1.0ml were transferred in to a series of 125ml separating funnels. To these 1ml of buffer solution (pH 2.2) and 1ml SBT dye were added. The total volume of aqueous phase was adjusted to 10ml with distilled water and 10 ml chloroform was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the pink colored chromogen was measured at 510 nm against reagent blank and the amount of Tolperisone present in the sample was computed from its calibration curve.

Method B: Aliquots of working standard solution of Tolperisone ranging from 0.2-1.6ml were transferred in to a series of 125ml separating funnels. To these 1ml of MO dye were added. The total volume of aqueous phase was adjusted to 10ml with distilled water and 10 ml chloroform was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the yellow colored chromogen was measured at 430 nm against reagent blank and the amount of Tolperisone present in the sample was computed from its calibration curve.

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RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, percentage relative standard deviation, percentage range of error (0.05-0.01) were calculated for the method and results are summarized in table 1. The values obtained for the determination of Tolperisone in pharmaceutical formulation (tablets) by the proposed method is presented in table 2. Studies reveal that the common excipients and other additives usually present in the tablets did not interfere in the proposed methods

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CONCLUSION

The proposed methods are applicable for the assay of drug Tolperisone and have an advantage of wider range under Beer's law limits. The proposed methods are simple, selective and reproducible and can be used in routine determination of Tolperisone in pure form and formulation with reasonable precision and accuracy.

Table-1: Optical characteristics, precision and accuracy of the proposed method

PARAMETERS	Method A	Method B
λ_{max} (nm)	510	430
Beer's law limit (µg/ml)	5-10	2-8
Sandell's sensitivity (µg/cm^2/0.001 abs. unit)	0.0083	0.010
Molar absorptivity(litre.mole^{-1}.cm^{-1})	0.0000339	0.0000264
Regression equation(Y*)		
Slope(b)	0.0997	0.1236
Intercept(a)	0.3624	0.018
Correlation Coefficient(r)	0.9993	0.9995
%Relative standard deviation	0.88	0.906
% Range of error	0.00314	0.0017
0.05 Significance level	0.735	0.757
0.01 Significance level	1.088	1.120

Y* = a + bx, where Y is absorbance and x is concentration of Tolperisone in µg/ml

Table 2: Estimation of Tolperisone in Pharmaceutical Formulations

Formulations (tablets)	Labelled Amount (mg)	Amount found* by proposed method		% recovery** by proposed method	
		Method A	Method B	Method A	Method B
Tablets 1	150	149.6	149.3	99.73	99.53
Tablets 2	150	149.2	149.6	99.46	99.73
Tablets 3	150	148.9	149.7	99.26	99.8

*Average of determinations

**Recovery of amount added to the pharmaceutical formulation

(Average of three determinations)

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