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SPECTROPHOTOMETRIC ESTIMATION OF XANTHINOL NICOTINATE IN BULK AND SUSTAINED RELEASE TABLET DOSAGE FORMS

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ABSTRACT

A simple, fast and precise method has been developed for determination of Xanthinol nicotinate in bulk and sustained release tablet dosage forms. The selected wavelength for the drug is 268.5nm using 0.1N HCl as solvent. The linearity for the drug at the selected wavelength lies in the range of 2.5-40µg/ml. The concentration of the drug was evaluated in laboratory mixture and marketed formulation. Accuracy was determined by recovery studies from SR tablet dosages forms and ranges from 99.41-100.86%. Precision of method was found out as both intra-day and inter-day precision shows the values within acceptable limit (R.S.D. <2 %).

Keywords: Xanthinol nicotinate, sustained release tablet, UV-spectroscopy.

INTRODUCTION

Xanthinol nicotinate is a peripheral vasodilator[1].Chemically it is 7-[2-hydroxy-3-(N-methyl-β-hydroxythylamino)-propyl]theophylline nicotinate[2].Extensive literature review reveals that a Spectrophotometric method using Charge Transfer Reaction[3],a LC-MS method for estimation of Xanthinol nicotinate in biological fuilds[4],a capillary isotachophoresis method[5] have been reported. Some HPLC methods including a stability indicating HPLC method has been reported[6,7]..But no UV-Spectrophotometric method has been reported so far for the estimation of Xanthinol nicotinate in Sustained Release Tablet Dosage Form using 0.1N HCl as the solvent. There is a lack of fast, simple, accurate, precise and cost effective UV-Spectrophotometric method for determination of Xanthinol nicotinate.In view of these points an attempt was made to develop a simple, accurate and validated UV-Spectrophotometric method for estimation of Xanthinol nicotinate in bulk and sustained release tablet dosage form.

MATERIALS AND METHODS

Instruments Used

An ELICO SL-159 UV Visible Spectrophotometer with 1cm matched quartz cells was used for scanning the sample solutions. Spectra Treats software was used for interpreting the scan results. Afcoset electronic balance was used to weigh the samples.Enertech ultrasonicatior was used to facilitate dissolution of marketed formulation.

Chemicals and Reagents

Xanthinol nicotinate pure drug(purity>99%) was procured as gift samples from Zydus Healthcare,Sikkim,India.Hydrochloric acid AR grade was purchased from Merck Ltd., Mumbai. Double distilled water was prepared using a double distillation unit. Marketed formulations of Xanthinol nicotinate was purchased from the local market.

Preparation of Standard Stock Solution

A quantity of 25 mg of the drug was taken in a 25ml volumetric flask and dissolved in 10ml of 0.1N HCl. Finally the volume was made up to the mark with 0.1N HCl to obtain a final concentration of 1000µg/ml.

Determination of λ_{max}

From the standard stock solution two dilutions of 10µg/ml and 25µg/ml were prepared and scanned against the reagent blank (0.1N HCl).The drug shows a λ_{max} values at 268.5nm.The overlain spectrum of Xanthinol nicotinte at concentrations of 10µg/ml and 25µg/ml is shown in Fig 1.

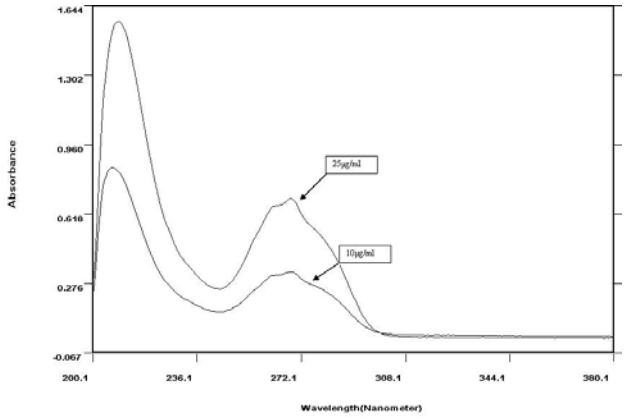

Fig. 1: It shows overlain spectra of Xanthinol nicotinate in 0.1n hcl

Preparation of Calibration Curve

From the Standard Stock Solution suitable aliquots were taken and diluted to 10ml with 0.1N HCl to obtain solutions in concentration range 2.5, 5.0,10,15, 20, 25, 30, 40 µg /ml.The absorbances of each solution were

measured at λ_{max} 268.5nm against 0.1N HCl as blank reference. The calibration curve for Xanthinol nicotinate was plotted by taking concentration of drug on X-axis and absorbance on Y-axis and is given in Fig 2.

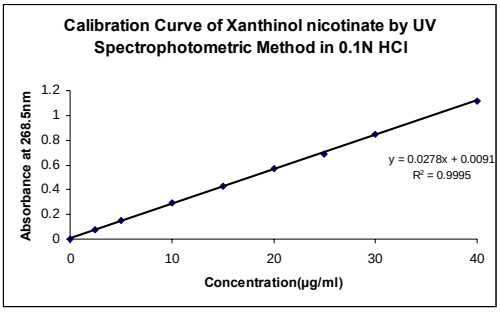

Fig. 2: It shows calibration curve of xanthinol nicotinate

Procedure for Analysis of Sustained Release Tablet Dosage Form

For analysis of commercial formulation, twenty tablets of Complamina Retard SR containing Xanthinol nicotinate were taken and powdered. The powder equivalent to 25mg of Xanthinol nicotinate was taken in a 250ml volumetric flask, containing 170ml of 0.1N HCl and ultrasonicated for 30 minutes. The volume was made up to 250ml with 0.1N HCl and filtered.

This was further diluted with 0.1N HCl to get a concentration within the linearity range and the absorbances were measured against the blank at 268.5nm.The results are shown in Table 1.

Table 1: It shows analysis of the marketed formulation

Formulation	Labeled Amount (mg)	Observed Amount*(mg) ±S.D.	Recovery by proposed method (%)	R.S.D (%)
COMPLAMINA RETARD SR Tablet	500	489.25 ± 0.3464	97.85	0.07

* Average of six determination

Precision

The intra-day and inter-day precision of the method was ascertained by actual determination of eight replicates of fixed concentration of the drug within the Beer's range and finding out the absorbances by the method. The percent relative standard deviation was calculated. The results are shown in Table 2.

Table 2: It shows precision of the method

Precision	Concentration (µg/ml)	Absorbances* at 268.5nm	±Standard Deviation	RSD (%)
Intra-day	10	0.302	0.0021	0.69
Inter-day	10	0.300	0.0028	0.93

*Average of eight determinations

Recovery Studies

To check the accuracy of the proposed method, recovery studies were carried out at 80,100 and 120 % of the test concentration as per ICH guidelines[8].The recovery study was performed three times at each level. The results of recovery study are given in Table 3.

Table 3: It shows recovery study of the method

Type of Recovery in %	Amount Added Pure Drug (µg /ml)	Amount Present Formulation (µg /ml)	Recovery* (%)	Standard Deviation
80	4	5	99.41	0.76
100	5	5	100.86	0.11
120	6	5	99.77	0.38

*Average of three determinations at each level, † is the Relative Standard Deviation

Stability

Stability was observed by scanning the drug solutions in selected solvent system in time scan mode of UV-spectrophotometer for 6 hour.

RESULTS AND DISCUSSIONS

A simple UV spectrophotometric method has been developed to determine Xanthinol nicotinate present in sustained release tablet formulations. A critical evaluation of the method was performed. The Optical Characteristics are shown in Table 4.The drug was linear over a concentration range of 2.5-40µg/ml at the λ_{max}.The % recovery from commercial formulation was found to be 97.85%. The accuracy of the proposed method was evaluated by percentage recovery studies of the drug. The average recovery ranged from 99.41% to 100.86% for Xanthinol nicotinate, at 268.5nm. The %RSD was also less than 2%, for both intra-day and inter-day determinations showing high degree of precision of the proposed method. The results of the method lie within the prescribed limit, showing that method is free from interference from excipients.

Table 4. It shows optical characteristics for xanthinol nicotinate

Parameters	Obtained Values
λ_{max} (nm)	268.5
Beer's Law limit (μg/ml)	2.5-40
Sandell's sensitivity (μg/cm²/0.001 absorbance unit)	0.0344
Molar extinction coefficient (mole/l/cm)	1.295×10^4
*Regression equation (Y)**	0.0278x + 0.0091
% Range of error:	
0.05 confidence limits	±0.1455
0.01 confidence limits	±0.1915
Correlation co-efficient	0.9995

Y* = aX+b, where 'a' is slope,'b' is intercept,'X' is concentration in μg/ml and'Y' is absorbance unit.

CONCLUSION

The obtained results from the method for estimation of Xanthinol nicotinate indicates that the method is simple, accurate and precise hence can be used for routine analysis of commercially available drugs. Hence the developed method for Xanthinol nicotinte is quite simple, rapid, and economical with acceptance limits of accuracy and precision. Therefore this method may be useful for routine analysis of Xanthinol nicotinate as bulk drug, in sustained release tablet dosage forms and dissolution studies in pharmaceutical industries.

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REFERENCES

1. Sweetman SC, editor, cardiovascular drugs. In: Martindale-The complete drug reference. 36th ed. London. Chicago: Pharmaceutical Press; 2009.p.1433.
2. http://www.chemblink.com/products/437-74-1.htm Accessed on January 30, 2009
3. Zhao G, Kan H. Spectrophotometric Determination of Xanthinol Nicotinate Based on Charge Transfer Reaction. Chin. J Pharm. Anal.2002; 22.
4. Hua-qing L, Meng-xiang S, Bin D, Tai-jun H, Ying H, Xiao-qin T, et al. Development and validation of a liquid chromatography–tandem mass spectrometry method for the determination of xanthinol in human plasma and its application in a bioequivalence study of xanthinol nicotinate tablets. J Chromatogr. B 2008; 873: 20-26.
5. Pospísilová M, Jokl V, Dolejsová J.Determination of xanthinol nicotinate in drug preparations using capillary isotachophoresis. Ceska Slov. Farm.2000; 49:88-90.
6. Tsing H. Determination of Xanthinol nicotinate and it's related substances by RP-HPLC. Tianjin Pharmacy.2005
7. Hanchodeok, Han CD.High Performance Liquid Chromatographic Determination of Xanthinol Nicotinate. Pharmaceutical Bulletin. 1984; 28:321-325.
8. ICH harmonized Tripartite Guideline (Nov 2005) Validation of Analytical Procedures: Text and Methodology Q2 (R1).