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METHOD DEVELOPMENT FOR THE ESTIMATION OF SOLASOLIDINE IN ITS GEL FORMULATION

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ABSTRACT

Solasodine has diuretic, anticancer, antifungal, cardiotonic, antispermatogenetic, antiandrogenic, immunomodulatory, antipyretic and various effects on central nervous system. The new, simple, reliable, rapid, precise ultraviolet spectrophotometric method has to validate and been developed to analyses Solasolidine in bulk & poly-herbal formulation. Statistical tests are conducted on validation data. It can be concluded that the proposed method is simple, rapid, accurate, precise, economic and reproducible for UV spectro-photometric estimation of solasolidine from pharmaceutical formulation. This method can be successfully applied for routine estimation of solasolidine in bulk and pharmaceutical dosage form.

Keywords: Solasolidine, Gels, Estimation.

INTRODUCTION

In order to determine the drug in biological fluid or in pharmaceutical preparations, there are no. of methods available, that is HPTLC, HPLC, and spectrophotometery. Solasodine is a poisonous alkaloid chemical compound that occurs in plants of the family Solanaceae such as potatoes and bitter tomatoes. Solasonine and solamargineare glycoalkaloid derivatives of Solasodine. Solasodine is teratogenic to hamster fetuses in a dose of 1200 to 1600 mg/kg. Literature survey reveals that Solasodine has diuretic, anticancer, antifungal, cardiotonic, antispermatogenetic, antiandrogenic, immunomodulatory, antipyretic and various effects on central nervous system.The new, simple, reliable, rapid, precise ultraviolet spectrophotometric method has to validate and been developed to analyses Solasolidine in bulk & poly-herbal formulation. Statistical tests are conducted on validation data.

MATERIALS AND METHODS

UV-Vis spectrophotometer 1700, Make: Shimadzu, Kyoto, Japan, Scan speed: 40nm/min, Bath Sonicator**.** All the reagents used in this assay were of analytical grade. Poly herbal gels of Solasolidine were prepared for estimation.

EXPERIMENTAL

Determination of λ_{max}

Weighed amount of Solasolidine was dissolved in 0.1N NaOH to obtain a 100µg/ml solution. Later, scan the solution between 200-400nm to determine maximum absorption. Study the dilution effect in maximum absorption by the solution of stock 20ug/ml and has been scanned from 200-400nm.

Preparation of Standard Stock Solution

10mg of Solasolidine was dissolved in 100ml 0.1N NaoH to obtain 100**µg/ml** conc. Of stock solutiin. Therefore, standard drug solution of Solasolidine was prepared.

Preparation of Calibration Curve

Calibration curve was prepared in 0.1N NaOH at λ_{max} 276nm by using UV-Vis spectrophotometer Model 1700. 100 µg/ml is prepared for this stock solution. Serial dilution of 10, 15, 20, 25, 30µg/ml were prepared and absorbance was taken at λ_{max} 278nm. Averages of such 6 sets of values were taken for calibration curve, and solution were scanned in the range of 200-400 nm against blank.

Assay

500mg of gel containing of 5 mg of Solasolidine was weighed. Gel equivalent to 100 mg of Solasolidine was transferred into 100 ml volumetric flask dissolved in 0.1N NaOH. The solution is filtered with Whatmann filter paper No. 40 i.e.,0.45 micron. Aliquots of the sample were removed and diluted to 10 ml of 0.1N NaOH to obtain strengths of 20µg/ml determined at the respective absorbance of 278nm against 0.1N NaOH as a blank.

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Limit of Detection (LOD) and Limit of Quantification (LOQ)

Determine the limit of detection and limit of qualification of GLP by using standard deviation of response & slope approaches defined in ICH guidelines. The LOD & LOQ are seen in table1. These are calculated by the equation, LOD= 3.3δ/*s* and LOQ = 10 δ/*s* respectively, where δ is the standard deviation of blank and '*s'* is slope.

Recovery studies

Recovery studies were conducted to judge the accuracy of the method. Recovery studies were performed by addition of pure drug of known quantity to the pre-analyzed formulation and the proposed method was followed. % recovery was determined by the amount of drug present. Recovery study was performed by adding standard drug to the sample at 3 different concentration levels.

RESULTS & DISCUSSION

The UV scan of standard solution between 200 – 400 nm showed the absorption maxima at 278nm. The overlay spectra of different concentration range of standard solasolidine was recorded. The Beer's law was verified from the calibration curve by plotting a graph of concentration vs. absorbance. The linearity range was observed between 15-39µg/ml. The plot clearly showed a straight line passing through origin with equation Y= 0.0624X - 0.0672 with correlation coefficient of 0.997. The coefficient of correlation was highly significant. The optical characteristics and other validation parameters are thus summarized in table 1. The assay method was validated by low values of standard deviation and standard error, indicating accuracy and precision in table 2 of the methods. Excellent recovery studies further prove the accuracy of the method table3.The assay result was repeated for three times which was found to be 103.42-104.13% of labelled claim in table 4.

Table 1: Optical Parameters for Solasolidine

S. No.	Parameters	values
1	max(nm)	278
2	linearity range	15-39µg/ml
3	regression equation	Y=0.0624X-0.0672
4	correlation coefficient	0.997
5	slope	0.0721
6	intercept	0.0589
7	Limit of detection(µg/ml)	0.9417
8	Limit of quantification(µg/ml)	4.9240

Table 2: Precision Data for Solasolidine

S. No.	Conc. ug/ml	intraday	cv	Interday	cv
1	15	0.7912±0.00823	2.1465	0.7812±0.0084	5.673
2	20	0.9135±0.0452	34.5327	0.9478±0.0125	6.472
3	25	0.9996±0.0078	1.7984	1.156±0.0089	2.725

Table 3: Recovery Study Data for Solasolidine

S. No.	Amount of sample (ug/ml)	Added drug (ug/ml)	Drug recovered (ug/ml) ±sd	%recovery
1	20	0	20.8562±0.6869	101.9365
2	20	10	30.9453±0.5612	101.4126
3	20	20	40.6830±0.7943	100.8654
4	20	30	50.7986±0.8345	100.7357

Table 4: Assay Results for Solasolidine

S. No.	Actual conc. (µg/ml)	Amount obtained (µg/ml)	%drug
1	20	19.87	99.12
2	20	19.86	99.13
3	20	19.98	99.84

CONCLUSION

It can be concluded that the proposed method is simple, rapid, accurate, precise, economic and reproducible for UV spectro-photometric estimation of solasolidine from pharmaceutical formulation. This method can be successfully applied for routine estimation of solasolidine in bulk and pharmaceutical dosage form.

CONFLICT OF INTEREST

Authors declare no conflict of interest

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