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UV SPECTROSCOPIC METHOD FOR ESTIMATION OF TOPIRAMATE BULK AND PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

The Current Study estimation of Drug Topiramate is Simple, Precise, Spectroscopic Techniques in Pharmaceutical Dosage Forms. The Standard Stock Solution Was Prepared For Topiramate by Weighing the Drug topiramate 100mg Topiramate in 100 ml methanol and make up volume of Volumetric Flask with methanol. The Stock was produce 1000µg/ml with methanol. The prepared Dilution were scanned at 235nm. The Specificity, Linearity, was in Range of 1-5µg/ml. The Correlation Coeifficient was found to be 0.999. That it will be said that equivalent. The Regession Equation are Found to be in Range of Y= 0.998X + 0.0259. The Spectroscopic Method are Should be Validated for Range, Linearity, Accuracy, LOD, LOQ, and Ruggedness, robustness,. The Limt of Detection and Limit of Quantitation of Topiramate was Found to be 0.015 (µg/ml) and 0.028 (µg/ml). The Recovery study involve that are said to be % recovery Topiramate was found to be an in range of 100.60 ±0.065 -100.40 ± 0.080. Discovered method can be greatly applied in Detemination of Topiramate in Pharmaceutical Dosage Forms.

KEYWORDS: Topiramate, Method Validation, UV-Spectroscopy, ICH guidelines.

INTRODUCTION

Topiramate, having Chemically is β-D- Fructopyranose 2,3,4,5. bis-o-(1-methylethylidene)-1-Sulphamate sold under the brand name **Topamax** among others, is a medication used to

treat epilepsy and prevent migraines. It has also been used in alcohol dependence. For epilepsy this includes with generalized or focal seizures. It is taken by mouth.[1]

Common side effects include tingling, loss of appetite, feeling tired, abdominal pain, hair loss, and trouble concentrating. Serious side effects may include suicide, increased ammonia levels resulting in encephalopathy, and kidney stones. Use in pregnancy may result in harm to the baby and use during breastfeeding is not recommended. How it works is unclear. Effects on specific GABA-A receptor isoforms could also contribute to the antiseizure activity of the drug. Topiramate selectively inhibits cytosolic (type II) and membrane associated (type IV) forms of carbonic anhydrase. The action on carbonic anhydrase isoenzymes may contribute to the drug's side-effects, including its propensity to cause metabolic acidosis and calcium phosphate kidney stones. Topiramate inhibits maximal electroshock and pentylenetetrazol-induced seizures as well as partial and secondarily generalized tonic-clonic seizures in the kindling model, findings predictive of a broad spectrum of activities clinically. Its action on mitochondrial permeability transition pores has been proposed as a mechanism.[3,4]

While many anticonvulsants have been associated with apoptosis in young animals, animal experiments have found that topiramate is one of the very few anticonvulsants [see: levetiracetam, carbamazepine, lamotrigine] that do not induce apoptosis in young animals at doses needed to produce an anticonvulsant effect.

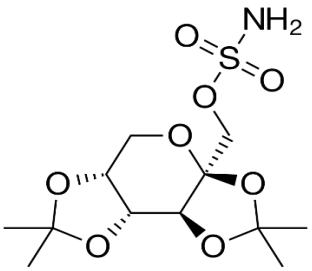

Fig. 1: Structure of Topiramate.

MATERIALS AND METHODS

1. Material

Tab No.: Material used in present research work.

SR.NO	Material	Source
1	Topiramate	Glenmark Pharma, Goa.
2	Methanol	Lupin Chemicals, Mumbai.
3	Water	Lupin, Mumbai

2. Equipments

Tab. No.:- Equipment used in present research work.

SR.No	Equipment	Source
1	UV Spetrophotometer	Shimadzu
2	Sonicator	Lupin

METHOD

UV Spectrophotometry

Experimental: Jasco single beam spectrophotometer are are used for spectral measurement. the drug sample of Topiramate is gift sample by Glenmark Pharmaceutical, Goa. tablet of Topiramate were getting from local market.[5]

Method Development

Solvent Selection: Choice solvent of Topiramate, by Differnt suitability studies Which found Topiramate are freely soluble in Methanol, Ethanol….etc. methanol selected as solvent.

Using methanol

The UV spectrometric determination Topiramate in Bulk and Pharmaceutical Dosage Form has absorption maximum at 235nm in methanol.

Standard Solution: 100mg of Topiramate was dissolve in methanol in 100ml Volumetric Flask and volume made up by methanol.

Procedure: The Topiramate Solution For Absorption was diluted with methanol to which was containing 1,2,3,4,5µg of Topiramate in1 ml solution The absorbance was measured in Jasco. uv spectrophotometerat 235 nm when putting methanol as blank. Conc Range of Topiramate and related absorbance are given in table no.1. The all absorbance ranges were ploted against concentration of Topiramate in show in fig 1. The unknown sample determine from caliberation graph. The Equation and correlation coeifficient were show in table no; 4.[8,9]

Sample preparation of Topiramate: 10 tablet of Topiramate weighed and powdered in mortar and pestle equivalent to 10 mg of Topiramate in 100ml methanol. the content were completely dissolve and ultrasonicated for few min. This solution was filterd and get 10µg/ml.

Validation of Spectrophotometric method

1 Accuracy: This Method Are show true Value. Accuracy study, 10 tablet Topiramate are taken and powder for analysis The drug solution are carried (10,15,20µg/ml) and result were present in table no:5.

2. Precision: The method Degree of agreement shows repeated and alternate sampling of homogeneous sample.

Intra and Inter –day precision: That this will be analyzed and shown in table no. 6 they can be analysed Topiramate Two to Three time in same day at 235nm that daily once for two days at 235nm.

3. Linearity: That linearity are shows the concentration range 1-5µg/ml are prepared from standard solution. the curve will present in fig.3.

4. Ruggedness: The solvent prepare analyzing at different analyst at different condition in table no.7.

5. Robustness: The length condition will be shows in table no. 8

Sr.No	Concentration µg/ml	Absorbanceat 235nm
1	5ppm	0.1243
2	10ppm	0.2283
3	15ppm	0.3245
4	20ppm	0.4244
5	25ppm	0.5255

RESULT AND DISCUSSIONS

UVSPECTROSCOPY

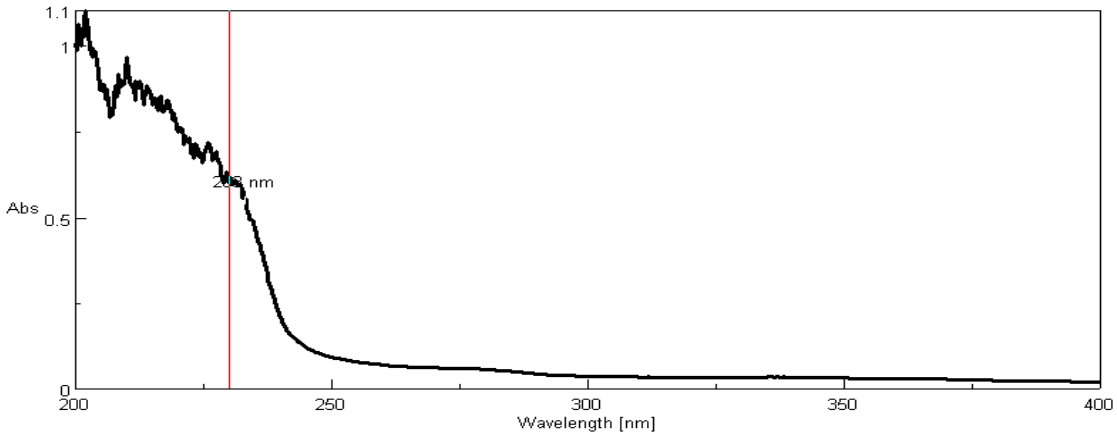

Table No. 4: Optimum condition, Optical characteristic and Statistical data of the Regression equation.

Parameter	UV Spctroscopic Method
Λmax(nm)	235
Regression Equation(Y*)	Y= 0.998X + 0.0259
Slope(b)	0.259
Intercept(a)	-0.028
Correlation coefficient r^2	0.998
Limit of Detection(µg/ml)	0.015
Limit of Quantitation	0.028
Beer law limit	1-5

Table No. 5: Accuracy result for Topiramateat 235nm by UV spectroscopy.

Brand Used	Amount of sample (µg/ml)	Amount of drug added (µg/ml)	Amount Recovered	%Recovered±SD*
QuadexyXR	10	10	15.2	100.60±0.0035
QuadexyXR	10	20	18.10	100.65±0.048
Quadexy XR	10	30	25.06	100.40±0.080

****Average of five determination**

Table No. 6: Precision result for Topiramate at 235 nm by Spectroscopy.

Conc µg/ml	Inter-day AbsorbanceMean±SD**	%CV	Intra-Day Absorbance±SD**	%CV
1	0.309±0.00165	0.30	0.309±	0.35
2	0.863±0.0025	0.30	0.863±	0.25
3	0.895±0.0010	0.08	0.895±	0.15
4	1.288±0.00225	0.15	1.288±	0.14
5	1.588±0.00145	0.08	1.588±	0.06

Table No. 7: Ruggedness Result for Topiramate at 235nm by Spectroscopy.

Brand Name	Label claim(mg)	Analyst1		Analyst2	
		Amtfound	%Recovery±SD	Amt.Found(mg)	%Recovery±SD
Quadexy XR	25	20.95	98.77±0.08	20.98	98.88±0.08

Table No. 8: Robustness result for Topiramate at 235nm by Spectroscopy.

S.no	Condition	Modification	Mean Abs±SD	%RSD
1	λ nm	230(nm)	0.306±0.001634	0.306
		235(nm)	0.398±0.002	0.398

Table No. 9.

S.no	Slope	S.D	LOD
1	0.325	0.0013	0.015

Table No. 10: Limit of quantitation result for Topiramate at 235 nm by Spectroscopy.

Sn.no	Slope	S.D	LOQ
1	0.325	0.013	0.025

CONCLUSION

The proposed method are AUC method are used for an simultaneous estimation of Topiramate and in bulk and Pharmaceutical Dosage Forms. The value of %RSD was satisfactorally, indicating an the reproducibility and accuracy of the proposed methods.

This spectrometric method are validated in terms of Precision, Repeatability, ruggedness and should be determine Topiramate in Bulk Drug and Pharmaceutical formulations.

This analytical method introduceappliocable to estimation of Topiramate in bulk drug as well as Pharmaceutical Dosage Forms.

Analytical method validation and method transfer data playing a fundamental role in pharmaceutical industry for releasing the commercial batch and long term stability data therefore, the data must be produced to acceptable scientific standards. For this reason and the need to satisfy regulatory authority requirements, all analytical methods should be properly validated and documented. The aim of this article is to provide simple to use approaches with a correct scientific background to improve the quality of the analytical method development and validation process. This article gives an idea about number of sample preparation, procedure and acceptance criteria for all analytical method validation parameters in wider range. Applications of analytical method and method transfer are also taken into consideration in this article. These various essential development and validation characteristics for analytical methodology have been discussed with a view to improving the standard and acceptance in this area of research.[4,5]

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