ORIGINAL ARTICLE

INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACEUTICAL SCIENCES

Published by JK Welfare & Pharmascope Foundation Journal Home Page: www.ijrps.com

Analysis on Bulk Pharmaceutical Formulation, Validation and Estimation Using Levetiracetam Methods

Smitha M*[1], Kal Satyavathi Devi[1], Virendra Kumar[2], Jaffar Hussain[2]

[1]Department of OBG, Konaseema Institute of Medical Sciences Research Foundation, Amalapuram, Andhra Pradesh- 533201, India
[2]Department of Forensic Medicine, Meenakshi Academy of Higher Education and Research, Chennai - 600078, Tamilnadu, India

Article History:

Received on: 11 Nov 2020
Revised on: 16 Dec 2020
Accepted on: 19 Dec 2020

Keywords:

Levetiracetam,
RP- HPLC,
Authentication,
Pharmaceutical
Formulations

ABSTRACT

A new sensitive, specific, direct, exact and correct RP-HPLC technique is established and authenticated to estimate Levetiracetam in Majority and Pharmaceutical Tablet Formulations. An isocratic, turned around period HPLC system might have been created should differentiate the pill starting with the corruption products, Phenomenex Gemini 5μ C18 (2) 100A (250 x 4.60mm, 5 μ) section. Hamilton syringe (705 NR, 50 μL) might have been utilized to injecting example Furthermore standard result. The versatile stage comprises about mixture of Methanol: Acetonitrile in the proportion (90:10 v/v) toward A stream rate about 1.0 ml /min. UV identification might have been performed toward 210 nm. The linearity might have been made for Levetiracetam in the extent from claiming 5- 30μg/ml for relationship coefficient about 0.9997. LOD Also LOQ were found will make 0.076μg/ml Furthermore 0.23μg/ml individually. Maintenance duration of the time of Levetiracetam were found with make 2.281min and 2.274min. % recuperation might have been discovered on be 99.78-100.45 What's more %RSD might have been found for over $\pm$2. Those system needs been approved as stated by ICH rules to linearity, precision, accuracy, robustness, ruggedness, LOD furthermore LOQ. Those produced approved system might have been effectively connected to dependable quantification about Levetiracetam to mass and pharmaceutical measurement type.

*Corresponding Author

Name: Smitha M
Phone: 8106141143
Email: smitha43@gmail.com

ISSN: 0975-7538

DOI: https://doi.org/10.26452/ijrps.v11iSPL4.3787

Production and Hosted by

IJRPS | www.ijrps.com

INTRODUCTION

Levetiracetam is an anticonvulsant drug used treat epilepsy (Abou-Khalil, 2008). Levetiracetam is a drug within the pyrrolidine session is utilized to delicacy numerous types of appropriations (Madhu *et al.*, 2015). Chemically it is known as pyrrolidinone and acetamide derivatives. Levetiracetam may selectively prevent synchronization of epileptic form bust firing and propagation of seizure activity. It is correspondingly utilized to treat neuropathic pain (Ravisankar *et al.*, 2015a). The chemical term of Levetiracetam is (S)-2-(2-oxopyrollidin-1- yl) butanamide with molecular weight of 170.20g/ml Figure 1. Fiction survey exposed that there were limited investigational approaches to be described

for the purpose of the Levetiracetam in pure drug and pharmaceutical dosage form by using UV spectrophotometric, HPLC, (Ganapathy *et al.*, 2010; Nagaraju *et al.*, 2014). The purpose of the current work is to progress and validate a novel, fast, exact and specific area under curve UV spectrophotometric technique for approximation of Levetiracetam in bulk and tablet dosage form.

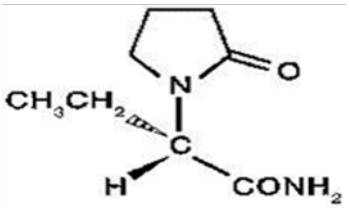

Figure 1: Chemical structure of levetiracetam.

MATERIALS AND METHODS

Material and reagents

The Levetiracetam was obtained as a gift sample from the pharmaceutical industry and Levipiltablet obtained from Pharmacy store. Methanol and distilled water were obtained Bharathi College of pharmacy, Bharathi nagara, KM Doddi, Maddur Taluk, Mandya District, India. All chemicals used are of HPLC grade. Distilled water is utilized during the research (Ravisankar *et al.*, 2015b).

Table 1: HPLC method development parameter.

HPLC method development parameters	
Column	C18, 250 X 4.6 mm, 5μ
Flow rate	1.0 mL / min
Wavelength	210 nm
Column temperature	30°C
Injection volume	50 μL
Run time	7 minutes
Diluents	Mobile phase
Elution	Isocratic

Instrumentation

Chromatographic separation might have been performed once a Shimadzu LC-20AT HPLC framework including a variable wavelength programmable UV/VIS identifier SPD-20A (VP series), Shimadzu LC-20AT (VP series) pump furthermore phenomenex gemini 5μ C18 (2) 100A (250 x 4. 60mm, 5 μ) section Table 1. Hamilton syringe (705 NR, 50 μL) might have been utilized for injecting test also standard result. Information might have been aggregated utilizing Spinchrom programming. Research of solutions mobile stage preparation. The mobile stage contained a combination of methanol (90%), acetonitrile (10%) in the ratio of v/v, that is clean concluded a film and vented earlier use. pH adjusted to 3.5 with 0.1% Ortho-phosphoric acid.

Preparation of sample Standard Solution

The formulation tablets of Levetiracetam (Levipil-500mg) were crushed to give finely powdered material. From the powder prepared a 100 mg of Levetiracetam was accurately weighed, transferred in a 100 ml volumetric flask, add 30 ml of diluents and sonicate to dissolve and dilute to volume with diluent.

Transfer 10 ml of the standard stock solution into 100 ml volumetric flask and dilute to volume with diluent (Rao and Jahnavi, 2010). And an appropriate concentration of sample was prepared at the time of analysis. 50μl of these solutions were injected in triplicate into HPLC system and the peak areas are verified.

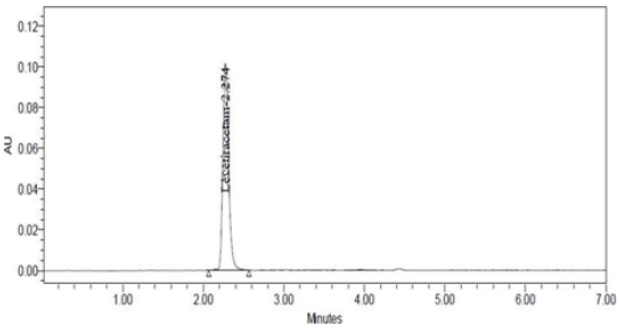

Figure 2: Chromatogram of standard solution of Levetiracetam.

Table 2: Specificity of Levetiracetam.

Name of the solution	Retention time in min
Blank	0
Levetiracetam(Standard)	2.274
Levetiracetam(Sample)	2.281

Preparation of Standard solution

Levetiracetam weigh and transmission the tablet powder equal to 100 mg of Levetiracetam into 100 ml volumetric flask add 30 ml of dilutant, sonicate to melt for 10 proceedings and diluted to capacity by dilutant. Additional strainer the resolution finished 0.45μ filter and an appropriate concentration of sample is equipped at the period of examination. 50μl of these solutions were injected in triplicate into HPLC system and preceded as said for the standard respectively.

Table 3: Linearity of Levetiracetam.

Concentration (μg/ml)	Retention time (min)	Peak area* (mv)
5	2.281	25912
10	2.283	52996
15	2.279	78486
20	2.281	103841
25	2.280	128401
30	2.279	157356

Table 4: Results of recovery of Levetiracetam.

Level of Addition/%	Amount added (μg/ml)	Amount found	%Recovery ± Standard deviation*	%RSD
50	10	30.10 29.91 29.70	99.78±0.704	0.705
100	20	39.89 40.42 40.24	100.45±0.676	0.666
150	30	49.97 50.05 49.5	99.65±0.567	0.568

RESULTS AND DISCUSSION

Authentication of the projected technique

The projected techniques authenticated as per ICH strategies (Shah *et al.*, 2012). The strictures concentrated on to acceptance were specificity, linearity, precision, accuracy, robustness, framework suitability, breaking point of detection, cutoff of quantification and also result solidness in Figure 2.

Specificity

Toward thinking about those chromatograms from claiming blank, standard also example (Prepared from Formulation). It might have been found that there is no obstruction because of excipients in the tablet detailing. Furthermore, additionally discovered beneficial correspondence the middle of those maintenance times of standard What's more example (Devanaboyina *et al.*, 2011). The specificity effects are indicated in Table 2.

Linearity

The linearity of the reaction of the medication regardless might have been checked during six focus levels, extending starting with 5-30μg/ ml about Levetiracetam Previously, every linearity level were arranged. 50μl from claiming each centralization might have been injected in copy under those HPLC framework. This reaction might have been perused during 210 nm and the comparing chromatograms were recorded (Bhavani and Aruna, 2015). Starting with these chromatograms, the mean crest ranges were presented in Table 3.

Table 5: Ruggedness of Levetiracetam.

Analysts	Mean area ± Standard deviation*	%RSD
Analyst 1	103932±1001.01	0.96
Analyst 2	103895.3±987.67	0.9

Precision

Precision of the system might have been performed Similarly as intraday precision, bury vivos trust day precision. With investigation the intraday precision, six replication standard results (20μg/ml) for Levetiracetam were injected. % RSD might have been ascertained Furthermore it might have been found should a chance to be 1.029. Furthermore interday precision completed same as intraday, six replication standard results (20μg/ml) from claiming Levetiracetam were injected. % RSD might have been computed and it might have been discovered on be 0. 969 which would great inside the satisfactory criteria from claiming not more than 2.0. Effects about framework precision investigations (Gandhi *et al.*, 2014).

Accuracy

Exactness of the strategy might have been examined by recuperation trials. Those recuperation investigations were performed by including referred to sums of the medications in the placebo. This recuperation might have been performed toward three levels, 50, 100 and 150% of the name case of the tablet (500 mg from claiming Levetiracetam). The recuperation qualities for Levetiracetam went starting with 98.0 should 102.0%. Those normal recoveries of three levels about Levetiracetam were found should be 99.7–100.45%. The outcomes are indicated in Table 4.

Limit of identification and limit of quantification

Those farthest point from claiming identification may be an explanatory technique will be those littlest measure about analyte done an example which could be dependable distinguished Toward the explanatory strategy (ICH Harmonized Tripartite Guideline, 2005). The breaking point from claiming quantitation is a distinctive explanatory methodology will be those littlest measure of the analyte Previously, test which might make quantitatively dead set. LOD and LOQ were ascertained utilizing equation

$\mathrm{LOD} = 3.3\,(\mathrm{SD})\,/\mathrm{S}$ What's more $\mathrm{LOQ} = 10\,(\mathrm{SD})\,/\mathrm{S}$

Toughness

The toughness for test technique might have been showed by doing precision consider over six arrangements about example once an absolute clump test by separate analysts, those come about of the precision ponder are tabulated Similarly as underneath Table 5. The % RSD values are less than 2.

CONCLUSIONS

The current investigative technique is authenticated by ICH guidelines and met the acceptance criteria. It was concluded that the industrialized analytical technique is modest, precise, economical, and sensitive, and can be used for routine investigation of Levetiracetam in bulk drug and pharmaceutical dosage forms.

Funding Support

The authors declare that they have no funding support for this study.

Conflict of Interest

The authors declare that they have no conflict of interest for this study.

REFERENCES

Abou-Khalil, B. 2008. Levetiracetam in the treatment of epilepsy. *Neuropsychiatric Disease and Treatment*, 4(3):507–523.

Bhavani, L. R. D., Aruna, R. D. 2015. Method development and validation of HPLC for determination of Levetiracetam and Valsartan in their formulations. *Journal of Pharmaceutical Analysis*, 4(2):42–56.

Devanaboyina, N., *et al.* 2011. A novel RP-HPLC method for the analysis of levetiracetam in formulations. *Der Pharma Chemica*, 3(6):112–117.

Ganapathy, S., *et al.* 2010. New UV-Visible Spectrophotometric Methods for the Determination of Levetiracetam in Bulk and Pharmaceutical Formulation. *Asian Journal of Research in Chemistry*, 3(3):724–727.

Gandhi, S. V., *et al.* 2014. Development and Validation of Stability-Indicating Rp Hplc Method for Determination of Indapamide and Amlodipine Besylate. *Indian Journal of Pharmaceutical Education and Research*, 48(2):48–54.

ICH Harmonized Tripartite Guideline 2005. Q2 (R1) Validation of Analytical Procedures: Text and Methodology. Pages: 1-13.

Madhu, M., *et al.* 2015. Development and validation estimation of levetiracetam. *Journal of Global Trends in Pharmaceutical Sciences*, 6(4):2956–2962.

Nagaraju, P., *et al.* 2014. Development and validation of novel HPLC method for estimation of levetiracetam in pharmaceutical formulations. *International Journal of Pharmaceutical and Chemical Sciences*, 3(2):522–527.

Rao, A. L., Jahnavi, V. N. 2010. A Validated RP-HPLC Method for the Estimation of Levetiracetam in Bulk and Pharmaceutical Formulations. *E-Journal of Chemistry*, 7(2):600–604.

Ravisankar, P., *et al.* 2015a. A simple validated UV spectrophotometric method for quantitative analysis of Levetiracetam in pharmaceutical dosage form. *Indian Journal of Research in Pharmacy and Biotechnology*, 3(5):209–229.

Ravisankar, P., *et al.* 2015b. An improved RP-HPLC method for the quantitative determination and validation of levetiracetam in bulk and pharmaceutical formulation. *International Research Journal of Pharmacy*, 6(8):537–543.

Shah, J. S., *et al.* 2012. Stability indicating RP-HPLC method for estimation of levetiracetam in pharmaceutical formulation and application to pharmacokinetic study. *Der Pharmacia Sinica*, 3(5):576–589.