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

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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 5 μ 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 5-30 μg/ml for relationship coefficient about 0.9997. LOD Also LOQ were found will make 0.076 μg/ml Furthermore 0.23 μg/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 ±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.

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 burst 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-oxopyrrolidin-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 Levipil tablet 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 | C18, 250 X 4.6 mm, 5µ |
|-----------------------------------|------------------------|
| Column                            |                        |
| 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 phenomenon 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 clear 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 diluant, sonicate to melt for 10 proceedings and diluted to capacity by diluant. 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.

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,
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                   | 99.78±0.704  | 0.705                           |
| 100                   | 20                   | 100.45±0.676 | 0.666                           |
| 150                   | 30                   | 99.65±0.567  | 0.568                           |

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.

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  |

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.

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 replica- tion 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 investiga- tions 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

\[ \text{LOD} = 3.3 \left( \frac{\text{SD}}{S} \right) \]

\[ \text{LOQ} = 10 \left( \frac{\text{SD}}{S} \right) \]

**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.

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**Conflict of Interest**

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

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