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Comparative Evaluation of different Marketed Brands of Levetiracetam Tablet

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ABSTRACT: Epilepsy is one of the utmost prevalent neurological conditions; its primary treatment is the administration of antiepileptic drugs (AEDs). An antiepileptic medication with excellent pharmacologic properties is levetiracetam (LEV) which shows initiative in improving seizure control. For the treatment of focal onset, myoclonic, and primary generalized seizures in both adults and children, levetiracetam has been recommended. It shows a significant affinity for a synaptic vesicle protein (SV2A). The study was assessed to find out the parameters of different brands of LEVETIRACETAM tablets I.P. in Mandvi region, Kutch (Gujarat) to match them typically with the standard parameters of I.P. specifications. The tablets available in the market of several brands were taken for investigation and tablets were evaluated for different quality control tests like weight variation, hardness, friability, disintegration time, and dissolution rate. The recorded weight variation was<10%, and hardness results were less than 4-10 kg-ft. and the friability results were also not more than 1 %. As per the *in-vitro* dissolution of each brand, the results observed more than 70% release.

Keywords: Levetiracetam, Anti-epilepsy, physicochemical Parameters, Immediate release, Tablet.

INTRODUCTION

A *seizure* is a transient variation of activitybecause of the imbalanced, synchronous, and rhythmic firing of a population of brain neurons. Epilepsy relates to a disease of brain function marked by the recurrent and unexpected appearance of seizures (Brunton *et al.,* 2008). Epilepsy is amongstthe most usual neurological disorder and its primary treatment is the administration of antiepileptic drugs (AEDs). These are split into the First, Second, and latest drugs AEDs. The frequentlyused first-generation AEDs are Phenytoin (PHT), Phenobarbital (PB), Carbamazepine (CBZ), Valproic acid (VPA), primidone, and Ethosuximide. Post-second-generation AEDs are frequentlyrecognized as new AEDs. Gabapentin (GBP), Topiramate (TPM), Lamotrigine (LTG), Levetiracetam (LEV), Felbamate, Tigabine, Oxcarbazepine, Zonisamide and Pregabalin are the second generation (AEDs).The latest drug encompasses Lacosamide (LCM), Eslicarbazepine, Rufinamide, Stiripentol, Retigabine, and Perampanel (Verma, 2021; Bickel, 2000).

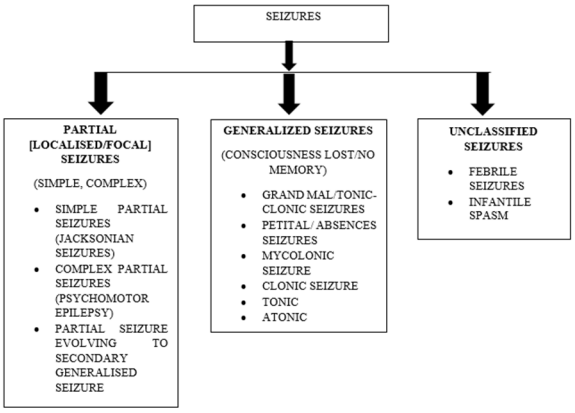

Fig. 1. Classification of Seizures (Noyer *et al.,* 1995).

Focal Seizures (Paliwal *et al.,* 2016; Noyer *et al.*, 1995)

Focal seizures involvesimply some of thehemispheres of the brain. These are the most common seizure types occurring in approximately 80% of epileptic patients. These are 3 types: 1) Simple partial seizure, 2) Complex partial seizure, and 3) Partial seizure evolving to secondary generalized.

1. **Simple Partial Seizure (Jacksonian Seizures):** These are characterized by the unilateral clonic movement that begins in one group of muscles and spread gradually to adjacent groups reflecting the march of epileptic activity (e.g. mouth, thumb, great toe) such type of Jacksonian motor seizures.
2. **Complex Partial Seizure (Psychmotor Epilepsy):** These usually originate in the temporal or frontal lobe and are accompanied by partial loss of consciousness. The attack is usually associated with auditory, visual, or olfactory aura.
3. **Partial Seizures Evolving to Secondary Generalised Seizures:** The partial seizure occurs first and evolves into generalized tonic-clonic seizures with loss of consciousness. Patients usually report aura beforehand.

Generalized Seizures (Paliwal *et al.*, 2016; Pugsley *et al.,* 2008; Noyer *et al.,* 1995).

Generalized seizures arise using both cerebral hemispheres and diencephalon concurrently, implicating the complete body, and have a characteristic bilateral pattern in EFG recording. Primary generalized seizures may be convulsive or non-convulsive and the patient commonly has an onset of losing consciousness.

These are of 6 Types: -

1. Grand Mal/Tonic-Clonic Seizures
   - Commonest lasts 1-2 min.
   - The common sequence is aura- cry-consciousness-tonic spasm coveringthe entire body muscle-clonic jerking accompanied by delayed sleep and depression of every CNS function.
2. Absence Seizures
   - Commonly occurs in children, the last 1/2min.
   - In momentary losing consciousness, the patient freezes and stares in one direction, with no muscular component or little bilateral jerking. ECG shows characteristic 3 cycles per second spike and wave pattern.
3. Myoclonic Seizures
   - A shock-like momentary contraction of muscles of a limb or the whole body may recur for several minutes.
   - ECG shows 2 Hz spikes and wave pattern per second.
4. Clonic Seizures
   - These seizures comprised brief episodes of muscle contraction and may nearlyrepresent myoclonic seizures.
   - Consciousness is extranegatively affectedby clonic seizures as matched to myoclonic.
   - ECG shows fast activity(10 Hz or more) and slow waves.
5. Tonic Seizures
   - These seizures involve increased tone in the extension muscles and are generally less than 60sec.
   -
   - ECG shows low-voltage fast activity waves.
6. Atonic Seizures
   - These seizures are similarly named drop attacks and are best described by a sudden loss of muscle tone.
   - ECG shows short over simplified spike and wave discharge accompanied by diffused slow waves that directly relatetothe reduction of muscle tone.

Unclassified Seizures (Pugsley *et al.*, 2008; Noyer *et al*., 1995)

It covers undetermined epilepsies and epileptic syndromes such as:

1. Febrile Seizures
   - Young children frequently develop seizures with an illness accompanied by hyperpyrexia.
2. Infantile Spasm
   - With progressive mental retardation.

These are generalized tonic-clonic convulsions of short duration which may appear frightening but are usually benign.

Etiology of Seizures. Epilepsy can result from underlying genetic, structural, or metabolic causesthat are known or unknown cause. The neuronal release in epilepsy results from the firing of a small population of neurons in a particular area of the brain called the "primary focus".

Focal areas that are functionally anomalous may be prompted into action by alteration in physiologic factors, such as a change in blood gases, pH, electrolytes, and blood glucose, and varies in environmental factors, such as sleep deprivation, alcohol intake, and stress (Reddy and Kalpana 2020).

A variety of factors, like illicit drug use, tumor, head injury, hypoglycemia, meningeal infection, and the quickremoval of alcohol from an alcoholic, can cause rapid seizures (Paliwal *et al.*, 2016).

Epilepsy has several causes which are presented below

- Genetic or heredity: - juvenile myoclonic epilepsy disorder, childhood absence epilepsy diseases, juvenile absence epilepsy disorder, and progressive myoclonic epilepsy syndrome. The majority of themarise from the totalimpact of greater than one mutant gene (polygenic).
- Brain lesions, mainly because of birth trauma.
- Infections are the same as cerebral meningitis and brain abscess.
- Metabolic syndromes such as lack of oxygen, alkalosis, hypoglycemia, hypocalcemia, hyperpyrexia, and vitamin B6 insufficiency.
- Rapid withdrawal of several drugs such as barbiturates and alcohol.

• Watching television, disco flashes, and listening full blast Pop music (Musicogenic temporal lobe seizures)

Sr. No.	Molecular target and activity	Newer antiepileptic drug
1.	Na+ channel modulators that enhance fast inactivation	Lamotrigine, felbamate, oxcarbazepine, topiramate
2.	Na+ channel modulators that enhance slow inactivation	Lacosamide
3.	Ca2+ channel blockers	Lamotrigine
4.	α2 δ ligands	Gabapentin, pregabalin
5	GABAA receptor allosteric modulators	Felbamate, topiramate, oxcarbazepine
6	GABA uptake inhibitors/ GABA-transaminase inhibitors	Tiagabine, vigabatrin
7	NMDA receptor antagonists	Felbamate
8	AMPA/kainate receptor antagonists	Topiramate
9	Enhancers of HCN channel activity	Lamotrigine
10	SV2A protein ligand	Levetiracetam
11	Inhibitors of brain carbonic anhydrase	Topiramate,zonisamide

Fig. 2. Classification & Molecular Targets of Newer Antiepileptic Drug (Pugsley *et al.,* 2008).

Levetiracetam: Levetiracetam (LEV) is belonging to 2nd-a generation of antiepileptic or Anticonvulsant agents (Sudar Codi, 2018; Ulloa *et al.,* 2009). Chemically it is (αS)-α-ethyl-2-oxo-1-pyrrolidine acetamide including a molecular formula of C8H14N2O2 and a molecular weight of 170.20 g/mol. This is structurally similar to the nootropic compound piracetam, which binds to a synaptic vesicle protein SV2A and prevents pre-synaptic calcium channels andlowers neurotransmitter release, and acts asa neuromodulator (Gandhi *et al.,* 2014; Raju *et al*., 2008) Levetiracetam is a white to off-white crystalline powder with a faint odor and bitter taste (Mruk *et al*., 2015). Levetiracetam appears to be secure and has sound effects inthe treatment of migraine together with aura (Gandhi *et al.*, 2014). Levetiracetam may selectively block hyper synchronization of epileptiform burst firing and propagation of seizure activity (Raju *et al.,* 2008).

It is showing activity in patients with Lennox-Gastuat syndrome, as a complementary therapy for principal generalized tonic-clonic seizures, myoclonic seizures of juvenile myoclonic epilepsy, and partial onset seizures with or without secondary generalization. Currently, it is also widely used in the prophylaxis of postoperative seizures in neurosurgery (Swaroop *et al.,* 2013).

opposite to conventional therapy, LEV has a broad safety ratioalong with any need for serum drug monitoring, and no associations with remaining antiepileptics. This preferable pharmacological profile makes LEV an appealing primary or adjunctive therapy for epileptic seizures (Swaroop *et al.,* 2013).

Immediate-Release Drug Delivery System: The set of action-release tablets is formulated to disintegrate and release the drug without the presence of any controlling factorslike coating or other formulation methods. The phrase "immediate release" of pharmaceutical formulation comprises every formulation where, the rate of release of drug from the formulation and/or the absorption of the drug, is neither appreciably, nor purposefully, delayed by galenic ploys. Besides a startling risein interest in controlled-release drug administration mechanisms, by far frequent tablets are those aimed to be ingested whole, disintegrating, and releasing medicaments fastly in the gastrointestinal tract. A disintegrant is aningredient in a tablet formulation thatallows the tablet to break up into narrower fragments upon contact with gastrointestinal liquid. This quick puncture of the tablet matrix enhances the surface area of the tablet particles, thus raising the rate of absorption of the active ingredient and generating the required the rapeutic action (Mohan and Sangeetha 2019; Hazarika and Deb 2017).

Finalized Product Quality Control [FPQC] of Levetiracetam-IP: A pharmaceutical tablet needs to comply with specific specifications to assert it to be aneffective drug. The main criteria for the quality of any drug in the dosage form are its safety, potency, efficacy, stability, patient acceptability, and regulatory compliance. The quality of a pharmaceutical tablet needs to be intended from the product development phase (Bickel, 2000). Pre- requisite of drug products and should be chemically and pharmaceutically comparable must be confirmed in strength, reliability, purity, active substance release model, and likewise in the identical dosage form, for the identical route of administration (Boozer *et al.,* 2015).

Quality control evaluation is accomplished for Levetiracetam commercialized products to make suresafety; efficiency; approved quality; rationality in use for the protectionof public health. The aim of the work was consequently to investigate the pharmaceutical quality of seven distinct brands of Levetiracetam tablets dispensed in Kutch and to select

the ideal brand by comparing the quality outcomes (Sahab Uddin *et al.,* 2015).

MATERIALS AND METHODS

Collection of Sample: Seven different famous products were retrieved from the local retail markets (Mandvi, Kutch). For the analysis, about 20 tablets of each brand were gathered. All brands of Levetiracetam contain 500 mg per tablet (SahabUddin *et al.,* 2015).

The samples were appropriately inspected for their batch number, date of manufacturing, date of expiration, and manufacturing license number at the time of purchase.Similarly, the level inforegarding the sample of the several pharmaceutical brands is provided in Table 1.

Table 1: Different Brands of Sample taken from the Market.

Brand No.	Batch No.	Mfg. Date	Exp. Date	Mfg. Lic. No.
B1	ZD2098	09/2020	08/2022	97/UA/2007
B2	LZ5T-027	04/2020	03/2022	MNB/09/763
B3	EMV1901461	11/2019	10/2021	G/25/2011
B4	EX2369	09/2020	08/2022	M/645/2014
B5	LMT200202	03/2020	03/2022	21/UA/2015
B6	4510004	09/2020	08/2022	L/17/2023/MNB& L/17/2024/MNB
B7	BA01967	07/2020	06/2022	MNB/05/109

Reagents, Instruments, and Equipment's used: Water, Tablet Hardness tester (Monsanto Tablet Hardness Tester), test tubes, basket rack, Friabilator, IP dissolution apparatus Type-1, filter paper, Pipette, Volumetric flask, UV-visible spectrophotometer, constant temperature bath (37±0.5°C), volumetric flask, analytical precision balance, dissolution beaker, etc Sahab Uddin *et al.*, 2015; Palanisamy *et al*., 2013).

Estimation of Weight Variation of Tablets: Ten tablets of every company of Levetiracetam were picked.Individual weight variations were recorded utilizing an analytical balance. The median weight and the percent difference of the tablets for each label were recorded. Consequently,% of weight variation is recordedby applying the given formula:

Percentage weight variation= (average weight – individual weight)/ individual weight × 100 %. The method indicates variation in weight within limits (Raut and Dubey 2019; Peltola *et al*., 2009).

Hardness and Friability Test: Tablet hardness has been outlined as the force needed to break a tablet in a diametric compression test. Tablet hardness or tablet crushing strength is usually expressed as the load required to crush a tablet kept on its edge. Hardness signifies the capacity of a tablet to sustain mechanical shocks throughout processing in manufacturing and inhibit the damage of tablets from packaging and transportation. To undertake this test, a tablet is keptamong two anvils, force is implemented to the anvils and the crushing force that just causes the tablet to break is recorded (Lachman 2007). The hardness evaluation was conducted using Monsanto Tablet Hardness Tester. (Gunda *et al.,* 2019).

The majority of cases of friction and shock forces induce tablets to chip cap or break. The friability evaluation has likewisean endreferencefor tablet hardness and is required to test the capacity of the tablet to resist abrasion in packaging, handling, and shipping. The friability of the tablets was evaluatedutilizing Roche Friabilator. The device tests tablets for the merged effect of abrasion and shock by using the plastic chamber that revolves at 25 rpm and going to drop the tablets at 6 inches besideevery revolution. Upon four minutes of the procedure or 100 revolutions, the tablets weighed, and the masswas evaluated by comparingit with the preliminary weight. During the friability test, a weight loss of no more than 1% of the tablets' original weight is regarded as generally acceptable. then the following formula was used to get the % reduction in weight of the tablets (Karna *et al*., 2014; Ibezim *et al.,* 2008).

% Friability = W0 - - W / W0 × 100

Determination of Disintegration Time of Tablets: Upon oral intake, the solid form of the compressed tablet has to be in solution for the activity of an active substance in the human body. Thus, the disintegration test is one moresignificant qualitycheckmethod to assess the quality, bioavailability, and performance of tablets. Usually, disintegration is the Physical break-up task of tablets into less granular particles additionally the amount of time that is needed to evaluate for disintegrating is named disintegration time.

The disintegration time influences the drug's absorption rate and therapeutic efficacy. We can readily verify that a drug's efficacy is good if the disintegration time is ideal and meets the criteria. Six tablets were put in a basket, which was then soaked in 900 ml of water at 37 + or - 0.5 °C. The tablet's total disintegration time was calculated in minutes. The above-noted approach was used to measure the disintegration time, whereas Table 3 displays the findings(Mean values ± SD) (Brunton *et al.,* 2008).

Method Development for Absolute Drug Content: Levetiracetam 500 mg tablet was crushed, and 123 mg of the resulting weight was precisely measured in an analytical balance and poured into a 100 ml volumetric

flask.In the beginning, 50 to 60 ml of water was added and mixed. Utilizing the same solvent, the volume was increased to 100 ml and filtered. Using an appropriate UV-VIS spectrophotometer, the absorbance of the standard was determined.

Selection of wavelength: When using a UV spectrophotometer in spectrum mode and using water as a blank, the wavelength of analysis (max), 234 nm, and absorbance 0.928 were obtained and were taken into consideration as standards for the following calculations because the pure API sample was degraded due to a few factors (Gandhi *et al.,* 2014).

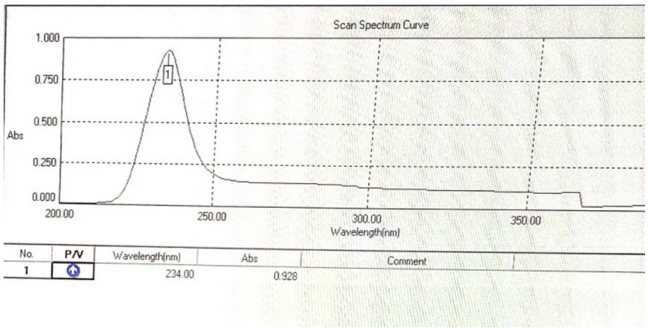

Fig. 3. UV scanning of Levetiracetam (standard solution).

Dissolution Rate Test of Tablets: Generally speaking, the process of a solid medicine being dissolved into a liquid influences the rate of drug absorption under standard parameters of temperature, solvent content, and the liquid or solid interface. For a medicine to work perfectly in an internal organ of a human body at a certain moment, a quality control type drug release pattern over a specific length of time is needed. A dissolution test for every brand of Levetiracetam tablet was conducted by IP. Dissolutiont ype apparatus no. 1. 900 ml of water was employed in this equipment as the dissolving medium. A fixed temperature bath was used to keep the process at 37 0.5°C for 30 minutes at a specified speed of 50 rpm.

Typically, one tablet of each brand is placed in the flask, and samples were taken,10 ml from the medium was replaced immediately with an identical volume of new dissolving medium (water). UV Scanners set to 234 nm were used to assess diluted, filtered samples appropriately. A percentage (%) of drug release after 15 minutes for different brands was estimated by measuring the absorbance. The gathered information was indicated in Table 4 and (Fig. 2) [(Govt of India, 2019), (Abdullah *et al.,* 2018).

RESULTS

Weight Variation: Using an electronic balance, the weight of seven different brands of levetiracetam tablets was calculated. The findings are shown in the table below:

Table 2: Average weight of different brands of LEVETIRACETAM tablets.

Brand No.	Average Weight (gms)	Weight Variation Limit (%)
B1	0.904 ± 0.003	0.4
B2	0.718 ± 0.005	0.27
B3	0.663 ± 0.007	0.45
B4	0.617 ± 0.003	0.64
B5	0.664 ± 0.005	0.602
B6	0.768 ± 0.006	0.20
B7	0.646 ± 0.004	0.30

As per IP, for the average weight of tablets (mg) to be 80 or less the maximum percentage variations permitted is ±10 and for the limit of 80-250 mg, the percentage deviationneeds to be ±7.5, and more than 250mg this needs to be ±5. The weight variation of B6- 0.20 & B2-0.24 revealsthe least weight variation and B4-0.64 & B5-0.60 resulted in maximum weight variation (Vossel *et al.,* 2021). The experiment's results (Table 2) made it clear that no abnormalities had occurred, and the weight variation limit values of all brands of pills were all within the maximum allowable variances.

Hardness and Friability of Tablets: One of the most crucial physical characteristics for assessing tablets is hardness. It canimpact tablet friability, disintegration time, and bioavailability. A reduction in the drug's release might be caused by tablets that are too hard. Ten different brands' harnesses were measured using a digital hardness tester (Mean values ± SD).

The Oral tablet has a hardness of 4-10kg-f. The obtained data demonstrate that the maximum hardness for all brands of tablets is 4 to 9 kg-f. (Table 3). The majority of the brands of levetiracetam tested positive for hardness and had acceptable crushing strengths

ranging from 4.9 kg-f to 7.1 kg-f, according to the study.

Also, the friability of the tablets, which was assessed using a Friabilator, was discovered to be within 0-1% (Table 2), which represents an outstanding and widely recognized outcome. There exists a B3 exception that displays a friability of 0.15%.

Table 3: Hardness and friability of different brands of Levetiracetam tablets.

Brand No.	Average Hardness (Kg/cm^2)	Friability (%)
B1	6.5±0.3	0
B2	6.4±0.4	0
B3	7.1±0.3	0.15
B4	6.5±0.5	0
B5	5.3±0.6	0
B6	4.9±0.8	0
B7	5.2±0.3	0

Table 4: Disintegration time of different brands of Levetiracetam tablets.

Brand No.	Average DT (Min)
B1	1.41±0.003
B2	0.48±0.005
B3	4.19±0.006
B4	2.60±0.004
B5	4.40±0.005
B6	6.53±0.007
B7	4.57±0.003

Disintegration Time of Tablets: The above-noted approach was used to measure the disintegration time, and Table 4 displays the findings. B6 indicated the longest disintegration time of 6.53 ± 0.007 min whereas B2 indicated the shortest disintegration time of 0.48 ± 0.005.

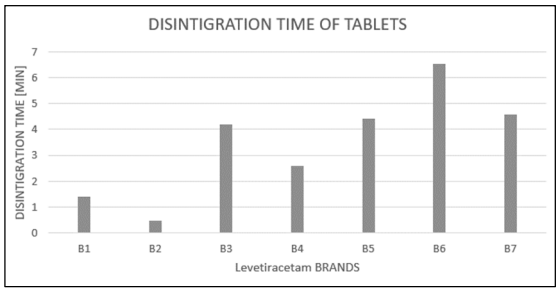

Fig. 4. Disintegration Time Chart of Different Brands of Levetiracetam Tablets.

Dissolution Rate Test of Tablets: Table 5 and Fig. 5 illustrate the results of the in-vitro release of branded tablets. The percentage of tablet release for many of the brands was greater than 70% at the end of the in-vitro release test (60 minutes), except for B3. The study's findings showed that most of the brands met the IP general standards (Sharma *et al.,* 2020).

Table 5: Dissolution Profile of Various Brands of Levetiracetam Tablet

TIME (Min)	B1	B2	B3	B4	B5	B6	B7
0	0	0	0	0	0	0	0
15	63.79±0.04	62.39±0.03	56.03±0.8	68.21±0.6	68.23±0.15	69.28±1.1	64.0±0.32
30	68.42±0.23	67.78±0.14	65.08±0.12	69.28±1.0	68.42±0.23	71.65±0.9	67.78±0.21
45	69.82±0.16	70.68±0.10	66.27±0.8	71.65±0.9	70.00±0.17	72.00±0.4	70.68±0.11
60	73.2±0.21	73.59±1.1	67.99±1.4	74.13±0.5	74.13±0.11	73.27±0.7	73.59±0.26

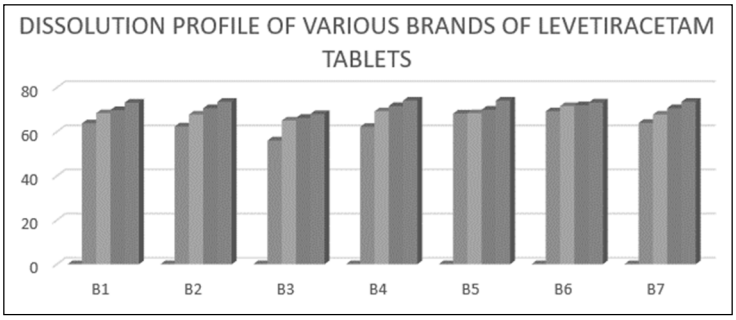

Fig. 5. Dissolution profile of various brands of LEVETIRACETAM.

CONCLUSIONS

The pharmaceutical sector relies on a variety of factors to maintain quality, including employee qualifications, the quality of active pharmaceutical components, validation of the production process, location, etc. All the brands of tablets utilized in the study's weight variation, hardness, friability, disintegration time, and dissolving test were within IP-specified limits. Acceptable hardness, friability, disintegration time, and dissolving profiles were displayed by most of the brands. Nonetheless, when compared to the other brands, B4 and B5 exhibited good dissolving profiles. This work can be a usefulsuggestion in the case of seeking compatibilities of the sample formulations along with the standardsmentioned in the official Pharmacopoeia.

This study supports the necessity for ongoing, thorough monitoring of Levetiracetam tablets that are sold in the nation to assure their quality and that their maintenance is directly related to public health.

FUTURE SCOPE

This study is anticipated to serve as a reference point for creating awareness among the general public and the prescribing community to have a higher excess of medications by selecting the right items from a variety of brands.

Conflict of Interest. None.

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